ANALYSIS OF SCHEDULED VACCINES' BOX INFORMATION INSERT

By Ricardo Beas – July 4, 2015 (Rev. 7/10/2016)

Below is the list of the 12 recommended and now California mandatory children vaccines recommended by the Centers for Disease Control (CDC), who in turn follows the recommendation of the vaccines' manufacturers. This is an analysis of both the vaccines' box insert as well as the CDC's summary information statement sheets intended for parents of recipients of vaccines.

On July 6, 2015 I visited the Sharp Rees-Stealy Otay Ranch Medical Center, located at 1400 E Palomar Street, Chula Vista, CA 91913. I went to the pediatrics office and requested the inserts of all the vaccines noted below. Instead of the inserts, I was provided a CDC information sheet for each one. I again clarified what I was looking for so I was referred to a nurse who provided me all the inserts. I read all the documentation provided and then identified and located each document in the internet (links provided). The actual texts of the inserts were reviewed for statements pertaining to the safety of each vaccine. Those excerpts are reproduced below. All text is from the actual inserts, except for my personal comments and observations, which will be noted in RED letters. Highlights have also been added for emphasis. Basic comments statements will not be repeated where applicable in other part of this text.

CDC LIST OF RECOMMENDED/MANDATORY CHILDREN'S VACCINES

	VACCINE	VACCINE MANUFACTURER & BRAND NAME		Pg
1	Hepatitis B	Merck	**Recombivax HB**	2
2	Diphtheria, tetanus, acellular pertussis n (DTaP or Tdap)	(a) Sanofi Pasteur	**Pentacel**	6
		(b) Sanofi Pasteur	**DAPTACEL**	9
		(c) Sanofi Pasteur	**Adacel**	11
3	Diphtheria tetanus (DT or Td)	*See 2 above*	---	--
4	Haemophilus influenzae type b (Hib)	Sanofi Pasteur	**ActHIB**	13
5	Pneumococcal conjugate or polysaccharide	Pfizer	**Prevnar 13**	16
6	Inactivated poliovirus (IPV)	Sanofi Pasteur	**IPOL**	20
7	Measles-mumps-rubella (MMR)	Merck	**M-M-R II**	22
8	Varicella (chickenpox)	Merck	**Varivax**	25
9	Influenza (flu)	*Not available*	---	--
10	Meningococcal conjugate or polysaccharide	Sanofi Pasteur	**Menactra**	27
11	Hepatitis A	Merck	**VAQTA**	32
12	Rotavirus	Merk	**RotaTeq**	35
13	Human papillomavirus (HPV)	Merck	**Gardasil**	38
	Influenza Shot insert at: LINK	bioCSL Pty Ltd.	bioCSL	41

1. HEPATITIS B VACCINE - Recombivax HB

Insert webpage	https://www.merck.com/product/usa/pi_circulars/r/recombivax_hb/recombivax_pi.pdf
CDC webpage	http://www.cdc.gov/vaccines/hcp/vis/vis-statements/hep-b.html
CDC Info sheet excerpt	**Hepatitis B vaccine: Why get vaccinated?** Hepatitis B vaccine can prevent hepatitis B, and the serious consequences of hepatitis B infection, including liver cancer and cirrhosis. (From CDC website on Hepatitis B in general: "**Hepatitis B** is a liver infection caused by the Hepatitis B virus (HBV). Hepatitis B is transmitted when blood, semen, or another body fluid from a person infected with the Hepatitis B virus enters the body of someone who is not infected. **This can happen through sexual contact; sharing needles, syringes, or other drug-injection equipment; or from mother to baby at birth.**" This vaccine is given at the following ages: birth, 1-2 months, 6-18 months. **Question: what baby has sex or uses so called illicit drugs?)** **Who should not get hepatitis B vaccine?** Anyone with a life-threatening allergy to yeast, or to any other component of the vaccine, should not get hepatitis B vaccine. Tell your doctor if you have any severe allergies (How can you know if you have never used it before and considering that all ingredients, including trace amounts of chemicals and live/dead organisms, are not identified?) Anyone who has had a life-threatening allergic reaction to a previous dose of hepatitis B vaccine should not get another dose. (Admission that life-threatening allergic reactions due to this vaccine have occurred) **What are the risks from hepatitis B vaccine?** Hepatitis B is a very safe vaccine. Most people do not have any problems with it. (Contradiction: cannot be safe if life-threatening reaction can occur. "Most People" not having problems [their assumption] implies that for the others it may not be safe) Severe problems are extremely rare. **Severe allergic reactions are believed to occur about once in 1.1 million doses**. ("Believed" is no certainty. "Extremely rare" again admits they happen. **The vaccine's own study contradicts the "1 in 1.1 million" statement. There were a total of three clinical trials, giving 434 doses to 147 infants; a group study covered 3,258 doses administered to 1,252 healthy adults. Severe reactions were found in both group. Thus, even if there was only one severe reaction in these groups, the odds would be either 1 in 434, or 1 in 3,258)** A vaccine, like any medicine, could cause a serious reaction. But the risk of a vaccine causing serious harm, or **death**, is extremely small. (Adminsion that **death can and does happen** as a result of vaccination) **What if there is a serious reaction? What should I look for?** Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or **behavior changes**. (If it causes Autism, to what degree or how permanent? They have not done studies directly for an Autism/Vaccine link. It was avoided [see http://www.cafepeyote.com/files/Vaccines_-_No_On_SB_277_-_Exhibits_to_Letter_to_Gov_Brown.pdf, Exhibit 10]) Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would start a few minutes to a few hours after the vaccination. (No long-term studies are conducted by

	the manufacturer's or the CDC)
Live virus?	No
Insert's main hazards identified in Insert:	fatigue/weakness; headache; fever (≥100°F); malaise; nausea; diarrhea; Pharyngitis; upper respiratory infection; Vomiting; abdominal pains/cramps; dyspepsia; diminished appetite; Rhinitis; influenza; cough ; Vertigo/dizziness; paresthesia ; Arthralgia including monoarticular; myalgia; back pain; neck pain; shoulder pain; neck stiffness; Lymphadenopathy; Insomnia/disturbed sleep; **anaphylactic/anaphylactoid reactions (CAN KILL YOU)**; **systemic lupus erythematosus (SLE), lupus-like syndrome**, vasculitis, and polyarteritis nodosa. - Nervous System Disorders: **Guillain-Barré syndrome; multiple sclerosis; exacerbation of multiple sclerosis**; myelitis including transverse myelitis; **seizure; febrile seizure**; peripheral neuropathy including Bell's Palsy; radiculopathy; **herpes zoster**; migraine; muscle weakness; hypesthesia; **encephalitis** - Skin and Subcutaneous Disorders: Stevens-Johnson syndrome; alopecia; petechiae; eczema - Musculoskeletal and Connective Tissue Disorders: **Arthritis Pain in extremity** - Blood and Lymphatic System Disorders: Increased erythrocyte sedimentation rate; thrombocytopenia - Psychiatric Disorders: Irritability; agitation; somnolence - Eye Disorders: Optic neuritis; tinnitus; conjunctivitis; visual disturbances; uveitis - Cardiac Disorders: Syncope; **tachycardia**
Studies on Carcinogenicity	None
Studies on Fertility	None
Deaths reported	None. Clinical study covered only covered 434 doses in a total of 147 infants. Group study covered 3,258 doses administered to 1,252 healthy adults

EXCERPTS FROM VACCINE INSERT:

CONTRAINDICATIONS

Severe allergic or hypersensitivity reactions (e.g., anaphylaxis) after a previous dose of any hepatitis B-containing vaccine, or to any component of RECOMBIVAX HB, including yeast. (4, 11)

ADVERSE REACTIONS

In healthy infants and children (up to 10 years of age), the most frequently reported systemic adverse reactions (>1% injections), in decreasing order of frequency, were irritability, fever, diarrhea, fatigue/weakness, diminished appetite, and rhinitis. (6.1) In healthy adults, injection site reactions and systemic adverse reactions were reported following 17% and 15% of the injections, respectively. (6.1)

WARNINGS AND PRECAUTIONS

5.4 Prevention and Management of Allergic Vaccine Reactions Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration [see Contraindications (4)]. (Vaccines are allowed to be administered at such places as pharmacies and even job sites where such type of emergency equipment and medication may not be available. Also, reacciones are noted as being able to become present hours or days after injection, where the vaccine is outside of a medical facility)

5.5 Limitations of Vaccine Effectiveness

Additionally, **vaccination with RECOMBIVAX HB may not protect all individuals**. (Admissions that vaccines does not always prevent infection. In fact, in reported outbreaks children with the vaccine up to date where the most likely victims of any diseas outbreak. See http://www.cafepeyote.com/files/Vaccines_-_No_On_SB_277_-_Exhibits_to_Letter_to_Gov_Brown.pdf, Exhibits 1, 2 and 3).

6.1 Clinical Trials Experience

In three clinical studies, **434 doses of RECOMBIVAX HB, 5 mcg, were administered to 147 healthy infants** and children (up to 10 years of age) who were monitored for 5 days after each dose.

In a group of studies, **3258 doses of RECOMBIVAX HB, 10 mcg, were administered to 1252 healthy adults** who were monitored for 5 days after each dose. Injection site reactions and systemic adverse reactions were reported following 17% and 15% of the injections, respectively. The following adverse reactions were reported:

Incidence Equal To or Greater Than 1% of Injections (Admission that these reactions happen more than 1% of people vaccinated. That means that 1 out of every 100 [AT LEAST] will have one or several/many of these illnesses as a result of vaccination. Worse, there is no maximum % of incidents noted. Can it be 5%, 10%, 35%? Once these diseases manifest themselves, what will be the consequences to the body and immune system long-run?

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS

Injection site reactions consisting principally of soreness, and including pain, tenderness, pruritus, erythema, ecchymosis, swelling, warmth, nodule formation. The most frequent systemic complaints include fatigue/weakness; headache; fever (≥100°F); malaise.

GASTROINTESTINAL DISORDERS

Nausea; diarrhea

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS

Pharyngitis; upper respiratory infection Incidence Less Than 1% of Injections

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS

Sweating; achiness; sensation of warmth; lightheadedness; chills; flushing

GASTROINTESTINAL DISORDERS

Vomiting; abdominal pains/cramps; dyspepsia; diminished appetite

RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS
Rhinitis; influenza; cough
NERVOUS SYSTEM DISORDERS
Vertigo/dizziness; paresthesia
SKIN AND SUBCUTANEOUS TISSUE DISORDERS
Pruritus; rash (non-specified); angioedema; urticaria
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS
Arthralgia including monoarticular; myalgia; back pain; neck pain; shoulder pain; neck stiffness
BLOOD AND LYMPHATIC DISORDERS
Lymphadenopathy
PSYCHIATRIC DISORDERS
Insomnia/disturbed sleep
EAR AND LABYRINTH DISORDERS
Earache
RENAL AND URINARY DISORDERS
Dysuria
CARDIAC DISORDERS
Hypotension

6.2 Post-Marketing Experience
Because these reactions are reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency or establish a causal relationship to a vaccine exposure (Adminsts that many reactions may go unreported, while trying to deny such reactions as a result of vaccination)

Hypersensitivity reactions including anaphylactic/anaphylactoid reactions, bronchospasm, and urticaria have been reported within the first few hours after vaccination. An apparent hypersensitivity syndrome (serum-sickness-like) of delayed onset has been reported days to weeks after vaccination, including: arthralgia/arthritis (usually transient), fever, and dermatologic reactions such as urticaria, erythema multiforme, ecchymoses and erythema nodosum [see Warnings and Precautions (5.1)].

- Autoimmune diseases including **systemic lupus erythematosus (SLE), lupus-like syndrome**, vasculitis, and polyarteritis nodosa have also been reported.
- Gastrointestinal Disorders Elevation of liver enzymes; constipation
- Nervous System Disorders **Guillain-Barré syndrome; multiple sclerosis; exacerbation of multiple sclerosis**; myelitis including transverse myelitis; **seizure; febrile seizure**; peripheral neuropathy including Bell's Palsy; radiculopathy; **herpes zoster**; migraine; muscle weakness; hypesthesia; **encephalitis**
- Skin and Subcutaneous Disorders Stevens-Johnson syndrome; alopecia; petechiae; eczema
- Musculoskeletal and Connective Tissue Disorders Arthritis Pain in extremity
- Blood and Lymphatic System Disorders Increased erythrocyte sedimentation rate; thrombocytopenia
- Psychiatric Disorders Irritability; agitation; somnolence

- Eye Disorders Optic neuritis; tinnitus; conjunctivitis; visual disturbances; uveitis
- Cardiac Disorders Syncope; **tachycardia**

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

RECOMBIVAX HB **has not been evaluated for its carcinogenic or mutagenic potential, or its potential to impair fertility.**

2(a). DIPHTHERIA, TETANUS, ACELLULAR PERTUSSIS N (DTAP OR TDAP) - Pentacel

Insert webpage	https://www.vaccineshoppe.com/image.cfm?doc_id=11169&image_type=product_pdf
CDC webpage	http://www.cdc.gov/vaccines/hcp/vis/vis-statements/dtap.html
CDC Info sheet excerpt	Some children should not get DTaP vaccine or should wait (examples:) • had a seizure or collapsed after a dose of DTaP, • cried non-stop for 3 hours or more after a dose of DTaP, • had a fever over 105°F after a dose of DTaP. (Admits that these conditions can happen after using the vaccine) **What are the risks from DTaP vaccine?** A vaccine, like any medicine, is capable of **causing serious problems, such as severe allergic reactions**. The risk of DTaP vaccine causing serious harm, or death, is extremely small. Moderate Problems (Uncommon) • **Seizure (jerking or staring) (about 1 child out of 14,000)** • **Non-stop crying, for 3 hours or more (up to about 1 child out of 1,000)** • **High fever, over 105°F (about 1 child out of 16,000)** (Higher risk of bacterial infections. Notes over 105**°F**. Over 108°F Serious fever: The fever itself can (42°C) be harmful.) **Severe Problems (Very Rare)** • **Serious allergic reaction (less than 1 out of a million doses)** • **Several other severe problems have been reported after DTaP vaccine. These include:** ○ **Long-term seizures, coma, or lowered consciousness** ○ **Permanent brain damage.** These are so rare it is hard to tell if they are caused by the vaccine. (Hard to tell is not a scientific term, just admits that it can be related) **What if there is a serious reaction? What should I look for?** • **Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or behavior changes.** **Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness.** These would start a few minutes to a few hours after the vaccination.
Live virus?	No
Insert's main hazards identified in Insert:	**Encephalopathy (Can lead to death), coma, decreased level of consciousness, prolonged seizures: anaphylactic or acute hypersensitivity reaction; Guillain-Barré Syndrome and Brachial Neuritis ; DEATH.**
Studies on Carcinogenicity	None
Studies on Fertility	None

Deaths reported	**Yes. The study was evaluated based on four clinical studies** in which **a total of 5,980 participants**

EXCERPTS FROM VACCINE INSERT:

4. CONTRADICTIONS

4.2 Encephalopathy (Can lead to death)

Encephalopathy (eg, **coma**, **decreased level of consciousness, prolonged seizures**) within 7 days of a previous dose of a pertussis containing vaccine that is not attributable to another identifiable cause is a contraindication to administration of any pertussis-containing vaccine, including Pentacel vaccine.

5. WARNINGS AND PRECAUTIONS

5.1 **Management of Acute Allergic Reactions** Epinephrine hydrochloride solution (1:1,000) and other appropriate agents and equipment **must be available for immediate use in case an anaphylactic or acute hypersensitivity reaction occurs.** ("In Case" it happens means it happens)

5.2 Adverse Reactions Following Prior Pertussis Vaccination

If any of the following events occur within the specified period after administration of a pertussis vaccine, **the decision to administer Pentacel vaccine should be based on careful consideration of potential benefits and possible risks**.

- Temperature of ≥40.5°C (≥105°F) within 48 hours, not attributable to another identifiable cause.
- Collapse or shock-like state (hypotonic-hyporesponsive episode (HHE)) within 48 hours.
- Persistent, inconsolable crying lasting ≥3 hours within 48 hours.
- Seizures with or without fever within 3 days.

5.3 **Guillain-Barré Syndrome and Brachial Neuritis** (**Brachial neuritis** is a disease that is typically characterized by pain or loss of function in the nerves that carry signals to and from the brain and spinal cord [the central nervous system] to other parts of the body)

A review by the Institute of Medicine (IOM) found evidence for a causal relation between tetanus toxoid and both brachial neuritis and Guillain-Barré syndrome. (3) If Guillain-Barré syndrome occurred within 6 weeks of receipt of a prior vaccine containing tetanus toxoid, the risk for Guillain-Barré syndrome may be increased following Pentacel vaccine.

5.5 Limitations of Vaccine Effectiveness

Vaccination with Pentacel vaccine may not protect all individuals.

6. ADVERSE REACTIONS

6.1 Data from Clinical Studies

The safety of Pentacel vaccine was **evaluated in four clinical studies** in which **a total of 5,980 participants** received at least one dose of Pentacel vaccine.

Across Studies 494-01, 494-03, 5A9908 and P3T06, a total of **8 participants experienced a seizure within 7 days following either Pentacel vaccine.**

Across Studies 494-01, 494-03 and P3T06, within 30 days following any of Doses 1-3 of Pentacel or Control vaccines, overall, the **most frequently reported serious adverse events were bronchiolitis, dehydration, pneumonia and gastroenteritis**.

A total of 5 deaths occurred during Studies 494-01, 494-03, 5A9908 and P3T06.

(In perspective: The study was comprised of 5,980 participants, of which 5 died. Odds would be 1 in 1,192)

Causes of death among children who received Pentacel vaccine were asphyxia due to suffocation, head trauma, SUDDEN INFANT DEATH SYNDROME, and neuroblastoma (8, 23, 52 and 256 days post-vaccination, respectively). One participant with ependymoma died secondary to aspiration 222 days following DAPTACEL + IPOL + ActHIB vaccines.

6.2 Data from Post-Marketing Experience

The following adverse events were included based on one or more of the following factors: severity, frequency of reporting, or strength of evidence for a causal relationship to Pentacel vaccine.

- Cardiac disorders Cyanosis
- Gastrointestinal disorders Vomiting, diarrhea
- General disorders and administration site conditions Injection site reactions (including inflammation, mass, abscess and sterile abscess), extensive swelling of the injected limb (including swelling that involved adjacent joints), vaccination failure/therapeutic response decreased (invasive H influenzae type b disease)
- Immune system disorders Anaphylaxis/anaphylactic reaction, hypersensitivity (such as rash and urticaria)
- Infections and infestations Meningitis, rhinitis, viral infection
- Metabolism and nutrition disorders Decreased appetite
- Nervous system disorders Somnolence, HHE, depressed level of consciousness
- Psychiatric disorders Screaming
- Respiratory, thoracic and mediastinal disorders Apnea, cough
- Skin and subcutaneous tissue disorders Erythema, skin discoloration
- Vascular disorders Pallor

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Pentacel vaccine has not been evaluated for carcinogenic or mutagenic potential or impairment of fertility.

2(b). DIPHTHERIA, TETANUS, ACELLULAR PERTUSSIS N (DTAP OR TDAP) - DAPTACEL

Insert webpage	https://www.vaccineshoppe.com/image.cfm?doc_id=11179&image_type=product_pdf
CDC webpage	*Noted in 2(a) above*
CDC Info sheet excerpt	*Noted in 2(a) above*
Live virus?	No
Insert's main hazards identified in Insert:	**Encephalopathy, coma, decreased level of consciousness, prolonged seizures; Progressive neurologic disorder, including infantile spasms, uncontrolled epilepsy, or progressive encephalopathy; Temperature of ≥40.5°C (105°F**); **Collapse or shock-like state;** Persistent, inconsolable crying lasting ≥3 hours within 48 hours; **Guillain-Barré Syndrome and Brachial Neuritis** ; **Syncope (fainting); Convulsions: febrile convulsion, grand mal convulsion, partial seizures HHE, hypotonia, somnolence, syncope; screaming;** Lymphadenopathy. Immune system disorders: Hypersensitivity, allergic reaction, anaphylactic reaction (edema, face edema, swelling face, pruritus, rash generalized ; nausea, diarrhea cellulitis;
Studies on Carcinogenicity	No
Studies on Fertility	No
Deaths reported	None

EXCERPTS FROM VACCINE INSERT:

4. CONTRAINDICATIONS

4.2 **Encephalopathy**

Encephalopathy (eg, coma, decreased level of consciousness, prolonged seizures) within 7 days of a previous dose of a pertussis containing vaccine that is not attributable to another identifiable cause is a contraindication to administration of any pertussis-containing vaccine, including DAPTACEL vaccine.

4.3 **Progressive Neurologic Disorder Progressive neurologic disorder, including infantile spasms, uncontrolled epilepsy, or progressive encephalopathy** is a contraindication to administration of any pertussis-containing vaccine, including DAPTACEL vaccine. Pertussis vaccine should not be administered to individuals with such conditions until a treatment regimen has been established and the condition has stabilized.

5 WARNINGS AND PRECAUTIONS

5.1 Management of Acute Allergic Reactions Epinephrine hydrochloride solution (1:1,000) and other appropriate agents and equipment **must be available for immediate use in case an anaphylactic or acute hypersensitivity reaction occurs.**

5.2 Adverse Reactions Following Prior Pertussis Vaccination

If any of the following events occur within the specified period after administration of a whole-cell pertussis vaccine or a vaccine containing an acellular pertussis component, the decision to administer

DAPTACEL vaccine should be based on careful consideration of potential benefits and possible risks. [See Dosage and Administration (2.1).]

• **Temperature of ≥40.5°C (105°F**) within 48 hours, not attributable to another identifiable cause.

• **Collapse or shock-like state** (hypotonic-hyporesponsive episode (HHE)) within 48 hours.

• Persistent, inconsolable crying lasting ≥3 hours within 48 hours.

5.3 **Guillain-Barré Syndrome and Brachial Neuritis**

A review by the Institute of Medicine found evidence for a causal relation between tetanus toxoid and both brachial neuritis and Guillain-Barré syndrome. (1) If Guillain-Barré syndrome occurred within 6 weeks of receipt of a prior vaccine containing tetanus toxoid, the risk for Guillain-Barré syndrome may be increased following DAPTACEL vaccine.

5.5 Limitations of Vaccine

Effectiveness Vaccination with DAPTACEL vaccine **may not protect all individuals**.

5.8 Syncope

Syncope (fainting) has been reported following vaccination with DAPTACEL. Procedures should be in place to prevent falling injury and manage syncopal reactions. (Does not specify within what time frame such fainting may occur)

6 ADVERSE REACTIONS

6.1 Data from Clinical Studies

Approximately 18,000 doses of DAPTACEL vaccine have been administered to infants and children in 9 clinical studies. Of these, 3 doses of DAPTACEL vaccine were administered to 4,998 children, 4 doses of DAPTACEL vaccine were administered to 1,725 children, and 5 doses of DAPTACEL vaccine were administered to 485 children. A total of 989 children received 1 dose of DAPTACEL vaccine following 4 prior doses of Pentacel vaccine.

6.2 Data from Post-Marketing Experience

The following adverse events have been spontaneously reported during the post-marketing use of DAPTACEL vaccine in the US and other countries. Because these events are reported voluntarily from a population of uncertain size, it may not be possible to reliably estimate their frequency or establish a causal relationship to vaccine exposure.

The following adverse events were included based on one or more of the following factors: severity, frequency of reporting, or strength of evidence for a causal relationship to DAPTACEL vaccine.

• Blood and lymphatic disorders Lymphadenopathy

• Cardiac disorders Cyanosis (A bluish discoloration of the skin resulting from poor circulation or inadequate oxygenation of the blood)

• Gastro-intestinal disorders Nausea, diarrhea

• General disorders and administration site conditions Local reactions: injection site pain, injection site rash, injection site nodule, injection site mass, extensive swelling of injected limb (including swelling that involves adjacent joints).

• Infections and infestations Injection site cellulitis, cellulitis, injection site abscess

• Immune system disorders Hypersensitivity, allergic reaction, anaphylactic reaction (edema, face edema, swelling face, pruritus, rash generalized) and other types of rash (erythematous, macular, maculopapular) • Nervous system disorders Convulsions: febrile convulsion, grand mal convulsion, partial seizures HHE, hypotonia, somnolence, syncope • Psychiatric disorders Screaming.

13 NON-CLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

DAPTACEL vaccine has not been evaluated for carcinogenic or mutagenic potential or impairment of fertility.

2(c). DIPHTHERIA, TETANUS, ACELLULAR PERTUSSIS N (DTAP OR TDAP) - Adacel

Insert webpage	https://www.vaccineshoppe.com/image.cfm?pi=400-10&image_type=product_pdf
CDC webpage	*Noted in 2(a) above*
CDC Info sheet excerpt	*Noted in 2(a) above*
Live virus?	No
Insert's main hazards identified in Insert:	**Severe allergic reaction (eg, anaphylaxis); Encephalopathy, coma, prolonged seizures, or decreased level of consciousness; Guillain-Barré Syndrome and Brachial Neuritis; Progressive or Unstable Neurologic Disorders;** severe migraine with unilateral **facial paralysis;** nerve compression in neck and arm; anaphylactic reaction, hypersensitivity reaction (angioedema, edema, rash, hypotension; **Paraesthesia, hypoesthesia, facial palsy, convulsion, syncope, myelitis;**
Studies on Carcinogenicity	No
Studies on Fertility	No
Deaths reported	None

EXCERPTS FROM VACCINE INSERT:

4 CONTRAINDICATIONS

4.1 Hypersensitivity

A severe allergic reaction (eg, anaphylaxis) after a previous dose of any tetanus toxoid, diphtheria toxoid or pertussis containing vaccine or any other component of this vaccine is a contraindication to administration of Adacel vaccine. [See DESCRIPTION (11).] Because of uncertainty as to which component of the vaccine may be responsible, none of the components should be administered. Alternatively, such individuals may be referred to an allergist for evaluation if further immunizations are to be considered.

4.2 **Encephalopathy**

Encephalopathy (eg, **coma, prolonged seizures, or decreased level of consciousness**) within 7 days of a previous dose of a pertussis containing vaccine not attributable to another identifiable cause is a contraindication to administration of any pertussis containing vaccine, including Adacel vaccine.

5.1 Management of Acute Allergic Reactions

Epinephrine hydrochloride solution (1:1,000) and other appropriate agents and equipment must be available for immediate use in case an anaphylactic or acute hypersensitivity reaction occurs.

5.3 **Guillain-Barré Syndrome and Brachial Neuritis**

A review by the Institute of Medicine found evidence for acceptance of a causal relation between tetanus toxoid and both brachial neuritis and Guillain-Barré syndrome. (1) If Guillain-Barré syndrome occurred within 6 weeks of receipt of prior vaccine containing tetanus toxoid, the risk for Guillain-Barré syndrome may be increased following a dose of Adacel vaccine.

5.4 **Progressive or Unstable Neurologic Disorders**

Progressive or unstable neurologic conditions are reasons to defer Adacel. It is not known whether administration of Adacel to persons with an unstable or progressive neurologic disorder might hasten manifestations of the disorder or affect the prognosis.Administration ofAdacel to persons with an unstable or progressive neurologic disorder may result in diagnostic confusion between manifestations of the underlying illness and possible adverse effects of vaccination.

6. ADVERSE REACTIONS

6.1 Clinical Trials Experience

As with any vaccine, there is the possibility that broad use of Adacel vaccine could reveal adverse reactions not observed in clinical trials. (There can be other short-term or long-term effect related not only to the application of this vaccines, but the cumulative combination of all vaccines now required in California, a total of 35, to be given from birth until the age of 18 as of today)

Clinical study Td506 was a randomized, observer-blind, active controlled trial that enrolled adolescents 11 through 17 years of age (Adacel vaccine N = 1,184; Td vaccine N = 792) and adults 18 through 64 years of age (Adacel vaccine N = 1,752; Td vaccine N = 573). (Total participants in study where 4,301)

Serious Adverse Events in All Safety Studies

Throughout the 6-month follow-up period in study Td506, serious adverse events were reported in 1.5% of Adacel vaccine recipients and in 1.4% of Td vaccine recipients. Two serious adverse events in adults were neuropathic events that occurred within 28 days ofAdacel vaccine administration; one severe migraine with unilateral **facial paralysis** and one diagnosis of nerve compression in neck and left arm.

6.2 Postmarketing Experience

The following adverse events of Adacel have been spontaneously reported in the US and other countries. Because these events are reported voluntarily from a population of uncertain size, it may not be possible to reliably estimate their frequency or establish a causal relationship to vaccine exposure. The following adverse events were included based on one or more of the following factors: severity, frequency of reporting or strength of evidence for a causal relationship to Adacel vaccine.

• Immune system disorders Anaphylactic reaction, hypersensitivity reaction (angioedema, edema, rash, hypotension)

• Nervous system disorders **Paraesthesia, hypoesthesia, Guillain-Barré syndrome, brachial neuritis, facial palsy, convulsion, syncope, myelitis**

• Cardiac disorders Myocarditis

• Skin and subcutaneous tissue disorders Pruritus, urticaria

• Musculoskeletal and connective tissue disorders Myositis, muscle spasm

• General disorders and administration site conditions Large injection site reactions (>50 mm), extensive limb swelling from the injection site beyond one or both joints Injection site bruising, sterile abscess

13. NON-CLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Adacel vaccine has not been evaluated for carcinogenic or mutagenic potential, or impairment of fertility.

4. HAEMOPHILUS INFLUENZAE TYPE B (HIB) - ActHIB

Insert webpage	https://www.vaccineshoppe.com/image.cfm?doc_id=11167&image_type=product_pdf
CDC webpage	http://www.cdc.gov/vaccines/hcp/vis/vis-statements/hib.html
CDC Info sheet excerpt	**Some people should not get this vaccine** A person who has ever had a life-threatening allergic reaction after a previous dose of Hib vaccine, OR has a severe allergy to any part of this vaccine, should not get Hib vaccine. Risks of a vaccine reaction With any medicine, including vaccines, there is a chance of side effects. These are usually mild and go away on their own. Serious reactions are also possible but are rare. Problems that could happen after any vaccine: Any medication can cause a severe allergic reaction. Such reactions from a vaccine are very rare, estimated at fewer than 1 in a million doses, and would happen within a few minutes to a few hours after the vaccination. **As with any medicine, there is a very remote chance of a vaccine causing a serious injury or DEATH.** (Can a medication, such as those for pain, cought or allergy, kill you if taken in the prescribed doses? No, but this vaccine cane). Older children, adolescents, and adults might also experience these problems after any vaccine: • Some people get severe pain in the shoulder and have difficulty moving the arm where a shot was given. This happens very rarely. The safety of vaccines is always being monitored. (Long term effects of vaccines are not studied) What if there is a serious reaction? What should I look for? • Look for anything that concerns you, such as signs of a **severe allergic reaction**, very high fever, or unusual behavior. Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would usually start a few minutes to a few hours after the vaccination. What should I do? If you think it is a severe allergic reaction or other emergency that can't wait, call 9-1-1 and get the person to the nearest hospital. **Otherwise, call your doctor.**
Live virus?	No
Insert's main hazards identified in Insert:	**Guillain-Barré syndrome; Anaphylaxis**, other allergic/hypersensitivity reactions (including urticaria, angioedema) (Anaphylaxis: **death** can occur within 30 minutes of onset); **Convulsions**
Studies on Carcinogenicity	None
Studies on Fertility	None
Deaths reported	None

EXCERPTS FROM VACCINE INSERT:

PRECAUTIONS / GENERAL

Epinephrine injection (1:1000) must be immediately available should an anaphylactic or other allergic reactions occur due to any component of the vaccine.

If **Guillain-Barré syndrome** has occurred within 6 weeks of receipt of a prior vaccine containing tetanus toxoid, the decision to give any tetanus toxoid-containing vaccine, including ActHIB or TriHIBit, should be based on careful consideration of the potential benefits and possible risks.

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY

ActHIB vaccine reconstituted with saline diluent (0.4% Sodium Chloride) or Tripedia vaccine (TriHIBit vaccine) has not been evaluated for its carcinogenic, mutagenic potential or impairment of fertility.

ADVERSE REACTIONS

More than 7,000 infants and young children (≤2 years of age) have received at least one dose of ActHIB vaccine during US clinical trials. Of these, **1,064 subjects 12 to 24 months of age who received ActHIB vaccine alone reported no serious or life threatening adverse reactions**. (This means that 5,936 [84.8%) of them did report serious or life threatening adverse reactions)

POST-MARKETING EXPERIENCE

The following events have been spontaneously reported during the post-approval use of ActHIB. Because these events are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to vaccine exposure.

• Immune System Disorders: **Anaphylaxis**, other allergic/hypersensitivity reactions (including urticaria, angioedema) (Anaphylaxis: **death** can occur within 30 minutes of onset. What if you are an hour away from medical attention?)

• Nervous System Disorders: **Convulsions**

• General Disorders and Administration Site Conditions: Extensive limb swelling, peripheral edema, pruritus, and rash

5. PNEUMOCOCCAL CONJUGATE OR POLYSACCHARIDE - Prevnar 13

Insert webpage	http://labeling.pfizer.com/ShowLabeling.aspx?format=PDF&id=501
CDC webpage	http://www.cdc.gov/vaccines/hcp/vis/vis-statements/pcv13.html
CDC Info sheet excerpt	***What You Need to Know*** Your doctor recommends that you, or your child, get a dose of PCV13 vaccine today. **(Incorrect and misleading statement. Vaccine manufacturers patent their vaccines and get CDC approval. In turn, the CDC makes them part of the "recommended" schedule for child vaccination and then instructs/orders physician to recommend, prescribe and give the vaccines to children)** Precautions **Anyone who has ever had a life-threatening allergic reaction to a dose of this vaccine**, to an earlier pneumococcal vaccine called PCV7 (or Prevnar), or to any vaccine containing diphtheria toxoid (for example, DTaP), **should not get PCV13**. **Anyone with a severe allergy to any component of PCV13 should not get the vaccine. Tell your doctor if the person being vaccinated has any severe allergies.** What are the risks of PCV13 vaccine? With any medicine, including vaccines, there is a chance of side effects. These are usually mild and go away on their own, but serious reactions are also possible. **Reported problems** associated with PCV13 vary by dose and age, but generally: • **About half of children became drowsy after the shot**, had a temporary loss of appetite, or had redness or tenderness where the shot was given. • About 1 out of 3 had swelling where the shot was given. • About 1 out of 3 had a mild fever, and about 1 in 20 had a higher fever (over 102.2°F). • Up to about 8 out of 10 became fussy or irritable. Adults receiving the vaccine have reported redness, pain, and swelling where the shot was given. Mild fever, fatigue, headache, chills, or muscle pain have also been reported. What if there is a serious reaction? **What should I look for?** • Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or behavior changes. Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would start a few minutes to a few hours after the vaccination. **What should I do?** • If you think it is a severe allergic reaction or other emergency that can't wait, call 9-1-1 or get the person to the nearest hospital. Otherwise, call your doctor.
Live virus?	No
Insert's main hazards identified in Insert:	**DEATH; acute anaphylactic reaction; SUDDEN INFANT DEATH SYNDROME; bronchiolitis; gastroenteritis; pneumonia; diarrhea, vomiting, and rash; crying, hypersensitivity reaction (including face edema, dyspnea, and bronchospasm), seizures (including febrile seizures), and urticaria or urticaria-like rash; Bronchiolitis, UTI, acute gastroenteritis, asthma, aspiration, breath holding,**

	influenza, inguinal hernia repair, viral syndrome, URI, croup, thrush, wheezing, choking, conjunctivitis, pharyngitis, colic, colitis, congestive heart failure; anaphylactoid reaction including **shock**
Studies on Carcinogenicity	Note noted, section 13 missing
Studies on Fertility	Note noted, section 13 missing
Deaths reported	**YES**

EXCERPTS FROM VACCINE INSERT:

5. WARNINGS AND PRECAUTIONS

Epinephrine and other appropriate agents used to manage immediate allergic reactions must be immediately available should an acute anaphylactic reaction occur following administration of Prevnar 13.

6.1 Clinical Trials Experience With Prevnar 13 in Children 6 Weeks Through 17 Years of Age

The safety of Prevnar 13 was evaluated in 13 clinical trials in which 4,729 infants … received at least one dose of Prevnar 13.

Serious Adverse Events in All Infant and Toddler Clinical Studies

Serious adverse events were collected throughout the study period for all 13 clinical trials. **This reporting period is longer than the 30-day post-vaccination period used in some vaccine trials. The longer reporting period may have resulted in serious adverse events being reported in a higher percentage of subjects than for other vaccines.** (This means that they admit that being that long-term studies are never conducted on vacciens, that more serious effects can result from vaccination, they are just not apparently interested in carrying out any of them)

The most commonly reported serious adverse events were in the 'Infections and infestations' system organ class including **bronchiolitis** (0.9%, 1.1%), **gastroenteritis**, (0.9%, 0.9%), and **pneumonia** (0.9%, 0.5%) for Prevnar 13 and Prevnar respectively. (Gastroenteritis: inflammation of the stomach and intestines, typically resulting from bacterial toxins or viral infection and causing vomiting and diarrhea)

There were 3 (0.063%) deaths among Prevnar 13 recipients, and 1 (0.036%) death in Prevnar recipients, all as a result of **sudden infant death syndrome** (SIDS). (Study was done on 4,729 vaccinees, 4 recipients died, equal to 1 in every 1,182).

Unsolicited Adverse Reactions in the Three US Infant and Toddler Safety Studies

The following were determined to be adverse drug reactions based on experience with Prevnar 13 in clinical trials. **Reactions occurring in greater than 1% of infants and toddlers: diarrhea, vomiting, and rash**. (Only states MORE than 1% with no estimated/actual cap)

10 Reactions occurring in less than 1% of infants and toddlers: crying, hypersensitivity reaction (including face edema, dyspnea, and bronchospasm), seizures (including febrile seizures), and urticaria or urticaria-like rash.

(face edema: the buildup of fluid in the tissues of the **face**.**Swelling** may also affect the neck and upper arms)

Serious Adverse Events in Adult Clinical Studies

From 1 month to 6 months after an initial study dose, **serious adverse events were reported in 1.2%-5.8% of subjects vaccinated during the studies** with Prevnar 13 and in 2.4%- 5.5% of subjects vaccinated with PPSV23. One case of erythema multiforme occurred 34 days after receipt of a second dose of Prevnar 13. **Twelve of 5,667 (0.21%) Prevnar 13 recipients and 4 of 1,391 (0.29 %) PPSV23 recipients DIED**. Deaths occurred between Day 3 and Day 309 after study vaccination with Prevnar 13 or PPSV23.

6.3 Clinical Trials Experience With Prevnar in Infants and Toddlers

Adverse events reported in clinical trials with Prevnar that occurred within 3 days of vaccination in infants and toddlers and resulted in emergency room visits or hospitalizations, but were not presented in Section 6.1 as adverse reactions for Prevnar 13 are listed below: **Bronchiolitis, UTI, acute gastroenteritis, asthma, aspiration, breath holding, influenza, inguinal hernia repair, viral syndrome, URI, croup, thrush, wheezing, choking, conjunctivitis, pharyngitis, colic, colitis, congestive heart failure** (can lead to death), roseola, sepsis.

6.4 Post-marketing Experience With Prevnar 13 in Infants and Toddlers The following adverse events have been reported through passive surveillance since market introduction of Prevnar 13. Because these events are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to the vaccine. The following adverse events were included based on one or more of the following factors: severity, frequency of reporting, or strength of evidence for a causal relationship to Prevnar 13 vaccine.

Administration site conditions:

Vaccination-site dermatitis, vaccination-site pruritus, vaccination-site urticaria

Blood and lymphatic system disorders:

Lymphadenopathy localized to the region of the injection site

Cardiac Disorders:

Cyanosis Immune system disorders: Anaphylactic/anaphylactoid reaction including shock

Nervous System Disorders: Hypotonia

Skin and subcutaneous tissue disorders: Angioneurotic edema, erythema multiforme

Respiratory: Apnea Vascular Disorders: Pallor

6. INACTIVATED POLIOVIRUS (IPV) - IPOL

Insert webpage	https://www.vaccineshoppe.com/image.cfm?doc_id=5984&image_type=product_pdf
CDC webpage	http://www.cdc.gov/vaccines/hcp/vis/vis-statements/ipv.html
CDC Info sheet excerpt	**Some people should not get IPV or should wait.** **These people should not get IPV:** • **Anyone with a life-threatening allergy to any component of IPV**, including the antibiotics neomycin, streptomycin or polymyxin B, should not get polio vaccine. • Anyone who had a **severe allergic reaction** to a previous polio shot should not get another one. **What are the risks from IPV?** Some people who get IPV get a sore spot where the shot was given. IPV has not been known to cause serious problems, and most people don't have any problems at all with it. However, any medicine could cause a serious side effect, such as a severe allergic reaction or even death. The risk of polio vaccine causing serious harm is extremely small. **What if there is a serious reaction?** **What should I look for?** • Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or behavior changes. Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would start a few minutes to a few hours after the vaccination.
Live virus?	No
Insert's main hazards identified in Insert:	**DEATH; Guillain-Barré Syndrome; Anorexia and vomiting; lymphadenopathy; allergic reaction, anaphylactic reaction, and anaphylactic shock; convulsion, febrile convulsion;**
Studies on Carcinogenicity	No
Studies on Fertility	No
Deaths reported	**Yes**

EXCERPTS FROM VACCINE INSERT:

WARNINGS

Although no causal relationship between IPOL vaccine and **Guillain-Barré Syndrome (GBS)** has been established, (28) **GBS has been temporally related to administration of another inactivated poliovirus vaccine. Deaths have been reported in temporal association with the administration of IPV.**

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY

Long-term studies in animals to evaluate carcinogenic potential or impairment of fertility have not been conducted.

ADVERSE REACTIONS

Body System As A Whole

In earlier studies with the vaccine grown in primary monkey kidney cells, transient local reactions at the site of injection were observed. (3) Erythema, induration and pain occurred in 3.2%, 1% and 13%, respectively, of vaccinees within 48 hours postvaccination. **Temperatures of ≥39°C (≥102°F) were reported in 38% of vaccinees.** Other symptoms included irritability, sleepiness, fussiness, and crying. Because IPV was given in a different site but concurrently with Diphtheria and Tetanus Toxoids and Pertussis Vaccine Adsorbed (DTP), these systemic reactions could not be attributed to a specific vaccine. However, these systemic reactions were comparable in frequency and severity to that reported for DTP given alone without IPV. (12) **Although no causal relationship has been established, deaths have occurred in temporal association after vaccination of infants with IPV.** (37)

Digestive System

Anorexia and vomiting occurred with frequencies not significantly different as reported when DTP was given alone without IPV or OPV. (12)

Nervous System

Although no causal relationship between IPOL vaccine and **GBS** has been established, (28) **GBS has been temporally related to administration of another inactivated poliovirus vaccine.**

Post-marketing Experience

The following adverse events have been identified during postapproval use of IPOL vaccine. Because these events are reported voluntarily from a population of uncertain size, it may not be possible to reliably estimate their frequency or establish a causal relationship to vaccine exposure. Adverse events were included based on one or more of the following factors: severity, frequency of reporting or strength of evidence for a causal relationship.

- *Blood and lymphatic system disorders:* **lymphadenopathy**
- *General disorders and administration site conditions:* agitation, injection site reaction including injection site rash and mass
- *Immune system disorders:* type **I hypersensitivity including allergic reaction, anaphylactic reaction, and anaphylactic shock**
- *Musculoskeletal and connective tissue disorders:* arthralgia, myalgia
- *Nervous system disorders:* **convulsion, febrile convulsion, headache, paresthesia**, and somnolence
- *Skin and subcutaneous tissue disorders:* rash, urticaria

7. MEASLES-MUMPS-RUBELLA (MMR) - M-M-R II

Insert webpage	http://www.merck.com/product/usa/pi_circulars/m/mmr_ii/mmr_ii_pi.pdf
CDC webpage	http://www.cdc.gov/vaccines/hcp/vis/vis-statements/mmr.html
CDC Info sheet excerpt	**Some people should not get MMR vaccine or should wait.** • Anyone who has ever had a life-threatening allergic reaction to the antibiotic neomycin, or any other component of MMR vaccine, should not get the vaccine. • Anyone who had a life-threatening allergic reaction to a previous dose of MMR or MMRV vaccine should not get another dose. **What are the risks from MMR vaccine?** A vaccine, like any medicine, is capable of causing serious problems, such as severe allergic reactions. **The risk of MMR vaccine causing serious harm, or death, is extremely small**. **Moderate problems** • Seizure (jerking or staring) caused by fever (about 1 out of 3,000 doses) • Temporary pain and stiffness in the joints, mostly in teenage or adult women (up to 1 out of 4) • **Temporary low platelet count, which can cause a bleeding disorder (about 1 out of 30,000 doses)** **Severe problems (very rare)** • **Serious allergic reaction (less than 1 out of a million doses)** (Contradicted by their own study) • **Several other severe problems have been reported after a child gets MMR vaccine, including:** ○ **Deafness** ○ **Long-term seizures, coma, or lowered consciousness** ○ **Permanent brain damage** **What if there is a serious reaction?** What should I look for? • Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or behavior changes. Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would start a few minutes to a few hours after the vaccination.
Live virus?	Yes
Insert's main hazards identified in Insert:	**DEATH; Guillain-Barré Syndrome**; **febrile convulsions**; **afebrile convulsions or seizures**; **ataxia; aseptic meningitis; atypical measles; Vasculitis**; **Pancreatitis; diarrhea; vomiting; parotitis; nausea; Diabetes mellitus; Thrombocytopenia; Anaphylaxis and anaphylactoid reactions; angioneurotic edema** (including peripheral or facial edema; **bronchial spasm; arthritis; Chronic arthritis; Encephalitis**; encephalopathy; **measles; polyneuritis**; **polyneuropathy; ocular palsies (A rare disease that gradually destroys nerve cells in the parts of the brain that control eye movements, breathing, and muscle coordination); Pneumonia**; pneumonitis; Stevens-Johnson syndrome; **Nerve deafness; Retinitis**; optic neuritis; papillitis; retrobulbar neuritis; conjunctivitis;

Studies on Carcinogenicity	No
Studies on Fertility	No
Deaths reported	YES

EXCERPTS FROM VACCINE INSERT:

PRECAUTIONS

General

Adequate treatment provisions, including epinephrine injection (1:1000), should be available for immediate use should an anaphylactic or anaphylactoid reaction occur.

As for any vaccine, vaccination with M-M-R II may not result in protection in 100% of vaccinees.

Carcinogenesis, Mutagenesis, Impairment of Fertility

M-M-R II has not been evaluated for carcinogenic or mutagenic potential, or potential to impair fertility.

ADVERSE REACTIONS

The following adverse reactions are listed in decreasing order of severity, without regard to causality, within each body system category and have been reported during clinical trials, with use of the marketed vaccine, or with use of monovalent or bivalent vaccine containing measles, mumps, or rubella:

Body as a Whole

Panniculitis; **atypical measles**; fever; syncope; headache; dizziness; malaise; irritability.

Cardiovascular System

Vasculitis.

Digestive System

Pancreatitis; diarrhea; vomiting; parotitis; nausea.

Endocrine System

Diabetes mellitus.

Hemic and Lymphatic System

Thrombocytopenia (see WARNINGS, *Thrombocytopenia*); purpura; regional lymphadenopathy; leukocytosis.

Immune System

Anaphylaxis and anaphylactoid reactions have been reported as well as related phenomena such as angioneurotic edema (including peripheral or facial edema) and **bronchial spasm in individuals with or without an allergic history.**

Musculoskeletal System

Arthritis; arthralgia; myalgia.

Chronic arthritis has been associated with wild-type rubella infection and has been related to persistent virus and/or viral antigen isolated from body tissues. **Only rarely have vaccine recipients developed chronic joint symptoms**. (But they do happen)

Nervous System
Encephalitis; encephalopathy; **measles** inclusion body encephalitis (MIBE) (see CONTRAINDICATIONS); subacute sclerosing panencephalitis (SSPE); **Guillain-Barré Syndrome** (GBS); acute disseminated encephalomyelitis (ADEM); transverse myelitis; **febrile convulsions**; **afebrile convulsions or seizures**; **ataxia** (Loss of control of body movement); **polyneuritis**; **polyneuropathy** (A general degeneration of peripheral nerves that spreads toward the center of the body); **ocular palsies (A rare disease that gradually destroys nerve cells in the parts of the brain that control eye movements, breathing, and muscle coordination);** paresthesia.

Cases of aseptic meningitis have been reported to VAERS following measles, mumps, and rubella vaccination. Although a causal relationship between the Urabe strain of mumps vaccine and aseptic meningitis has been shown, there is no evidence to link Jeryl Lynn™ mumps vaccine to aseptic meningitis.

Respiratory System
Pneumonia; pneumonitis (see CONTRAINDICATIONS); sore throat; cough; rhinitis.
Skin
Stevens-Johnson syndrome; erythema multiforme; urticaria; rash; measles-like rash; pruritis. Local reactions including burning/stinging at injection site; wheal and flare; redness (erythema); swelling; induration; tenderness; vesiculation at injection site.
Special Senses — Ear
Nerve deafness; otitis media.
Special Senses — Eye
Retinitis; optic neuritis; papillitis; retrobulbar neuritis; conjunctivitis.
Urogenital System
Epididymitis; orchitis.

Other
Death from various, and in some cases unknown, causes has been reported rarely following vaccination with measles, mumps, and rubella vaccines; however, a causal relationship has not been established in healthy individuals (see CONTRAINDICATIONS).

8. VARICELLA (CHICKENPOX) - Varivax

Insert webpage	http://www.merck.com/product/usa/pi_circulars/v/varivax/varivax_pi.pdf
CDC webpage	http://www.cdc.gov/vaccines/hcp/vis/vis-statements/varicella.html
CDC Info sheet excerpt	**Some people should not get chickenpox vaccine or should wait.** People should not get chickenpox vaccine if they have ever had a life-threatening allergic reaction to a previous dose of chickenpox vaccine or to gelatin or the antibiotic neomycin. **What are the risks from chickenpox vaccine?** A vaccine, like any medicine, is capable of causing serious problems, such as severe allergic reactions. The risk of chickenpox vaccine causing serious harm, or death, is extremely small. **Moderate problems** Seizure (jerking or staring) caused by fever (very rare). **Severe problems** Pneumonia (very rare)
Live virus?	Yes
Insert's main hazards identified in Insert:	**Transmission of vaccine virus; Guillain-Barré syndrome; Encephalitis**; cerebrovascular accident; **transverse myelitis; anaphylaxis** (including anaphylactic shock) and related phenomena such as angioneurotic edema, facial edema, and peripheral edema; **aplastic anemia**; **thrombocytopenia; Varicella;** ataxia; non-febrile seizures; aseptic meningitis; dizziness; paresthesia; **pneumonia, pneumonitis; herpes zoster;**
Studies on Carcinogenicity	Note noted
Studies on Fertility	Not noted
Deaths reported	No

EXCERPTS FROM VACCINE INSERT:

5. WARNINGS AND PRECAUTIONS

Adequate treatment provisions, including epinephrine injection (1:1000), should be available for immediate use should anaphylaxis occur.

5.4 Risk of Vaccine Virus Transmission

Post-marketing experience suggests that transmission of vaccine virus may occur rarely between healthy vaccinees who develop a varicella-like rash and healthy susceptible contacts. Transmission of vaccine virus from a mother who did not develop a varicella-like rash to her newborn infant has been reported.

Due to the concern for transmission of vaccine virus, vaccine recipients should attempt to **avoid whenever possible close association with susceptible high-risk individuals for up to six weeks** following vaccination with VARIVAX. Susceptible high-risk individuals include:

- Immunocompromised individuals;
- **Pregnant women without documented history of varicella or laboratory evidence of prior infection;**
- **Newborn infants of mothers without documented history of varicella or laboratory evidence of prior infection and all newborn infants born at <28 weeks gestation regardless of maternal varicella immunity.**

In addition, **adverse events occurring at a rate of ≥1%** are listed in decreasing order of frequency: upper respiratory illness, cough, irritability/nervousness, fatigue, disturbed sleep, diarrhea, loss of appetite, vomiting, otitis, diaper rash/contact rash, headache, teething, malaise, abdominal pain, other rash, nausea, eye complaints, chills, lymphadenopathy, myalgia, lower respiratory illness, allergic reactions (including allergic rash, hives), stiff neck, heat rash/prickly heat, arthralgia, eczema/dry skin/dermatitis, constipation, itching.
Pneumonitis has been reported rarely (<1%) in children vaccinated with VARIVAX.
Febrile seizures have occurred at a rate of <0.1% in children vaccinated with VARIVAX.

6.2 Post-Marketing Experience
Broad use of VARIVAX could reveal adverse events not observed in clinical trials.
The following additional adverse events, regardless of causality, have been reported during post-marketing use of VARIVAX:
Body as a Whole
Anaphylaxis (including anaphylactic shock) and related phenomena such as angioneurotic edema, facial edema, and peripheral edema.
Eye Disorders
Necrotizing retinitis (in immunocompromised individuals).
Hemic and Lymphatic System
Aplastic anemia; **thrombocytopenia** (Deficiency of platelets in the blood. This causes bleeding into the tissues, bruising, and slow blood clotting after injury) (including idiopathic thrombocytopenic purpura (ITP).
Infections and Infestations
Varicella (vaccine strain).
Nervous/Psychiatric
Encephalitis; cerebrovascular accident; **transverse myelitis** (A rare inflammatory disease causing injury to the spinal cord with varying degrees of weakness, sensory alterations, and autonomic dysfunction [the part of the nervous system that controls involuntary activity, such as the heart, breathing, the digestive system, and reflexes]); **Guillain-Barré syndrome**; Bell's palsy (paralysis of the facial nerve); ataxia; non-febrile seizures; aseptic meningitis; dizziness; paresthesia.
Respiratory
Pharyngitis; **pneumonia/pneumonitis**.
Skin
Stevens-Johnson syndrome; erythema multiforme; Henoch-Schönlein purpura; secondary bacterial infections of skin and soft tissue, including impetigo and cellulitis; **herpes zoster**.

11 DESCRIPTION

VARIVAX [Varicella Virus Vaccine Live] is a preparation of the Oka/Merck strain of live, attenuated varicella virus. The virus was initially obtained from a child with wild-type varicella, then introduced into human embryonic lung cell cultures, adapted to and propagated in embryonic guinea pig cell cultures and finally propagated in human diploid cell cultures (WI-38).

10. MENINGOCOCCAL CONJUGATE OR POLYSACCHARIDE - Menactra

Insert webpage	http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM131170.pdf
CDC webpage	http://www.cdc.gov/vaccines/hcp/vis/vis-statements/mening.html
CDC Info sheet excerpt	**Some people should not get meningococcal vaccine or should wait.** • Anyone who has ever had a severe (life-threatening) allergic reaction to a previous dose of MCV4 or MPSV4 vaccine should not get another dose of either vaccine. • Anyone who has a severe (life threatening) allergy to any vaccine component should not get the vaccine. **What are the risks from meningococcal vaccines?** A vaccine, like any medicine, could possibly cause serious problems, such as severe allergic reactions. The risk of meningococcal vaccine causing serious harm, or death, is extremely small. **Brief fainting spells and related symptoms (such as jerking or seizure-like movements) can follow a vaccination.** They happen most often with adolescents, and they can result in falls and injuries. **Severe problems** **Serious allergic reactions, within a few minutes to a few hours of the shot, are very rare.** **What if there is a serious reaction?** What should I look for? • Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or behavior changes. Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would start a few minutes to a few hours after the vaccination.
Live virus?	No
Insert's main hazards identified in Insert:	**Guillain-Barré Syndrome**; **paraesthesia, vasovagal syncope, dizziness, convulsion, facial palsy, acute disseminated encephalomyelitis, transverse myelitis**;
Studies on Carcinogenicity	No
Studies on Fertility	No
Deaths reported	No

EXCERPTS FROM VACCINE INSERT:
5 WARNINGS AND PRECAUTIONS

5.1 Guillain-Barré Syndrome
Persons previously diagnosed with **Guillain-Barré syndrome (GBS)** may be at increased risk of GBS following receipt of Menactra vaccine. The decision to give Menactra vaccine should take into account the potential benefits and risks.

GBS has been reported in temporal relationship following administration of Menactra vaccine. (1) (2) The risk of GBS following Menactra vaccination was evaluated in a post-marketing retrospective cohort study [*Post-Marketing Experience (6.2)*].

5.2 Preventing and Managing Allergic Vaccine Reactions
Epinephrine and other appropriate agents used for the control of immediate allergic reactions must be immediately available should an acute anaphylactic reaction occur.

5.4 Limitations of Vaccine Effectiveness
Menactra vaccine may not protect all recipients.

6 ADVERSE REACTIONS
Serious Adverse Events in All Safety Studies
Serious adverse events (SAEs) were reported during a 6-month time period following vaccinations in individuals 9 months through 55 years of age. In children who received Menactra vaccine at 9 months and at 12 months of age, SAEs **occurred at a rate of 2.0% - 2.5%. In 20 participants** who received one or more childhood vaccine(s) (without co-administration of 21 Menactra vaccine) at 12 months of age, **SAEs occurred at a rate of 1.6% - 3.6%**, depending on the 22 number and type of vaccines received.

6.2 Post-Marketing Experience
This list includes serious events and/or events which were included based on severity, frequency of reporting or a plausible causal connection to Menactra vaccine. Because these events were reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency or establish a causal relationship to vaccination.

Immune System Disorders
Hypersensitivity reactions such as anaphylaxis/anaphylactic reaction, wheezing, difficulty breathing, upper airway swelling, urticaria, erythema, pruritus, hypotension

Nervous System Disorders
Guillain-Barré syndrome, paraesthesia, vasovagal syncope, dizziness, convulsion, facial palsy, acute disseminated encephalomyelitis, transverse myelitis

Musculoskeletal and Connective Tissue Disorders
Myalgia

Post-marketing Safety Study
Of 72 medical chart-confirmed GBS cases, none had received Menactra vaccine within 42 days prior to symptom onset. An additional 129 potential cases of GBS could not be confirmed or excluded due to absent or insufficient medical chart information. In an analysis that took into account the missing data, estimates of the attributable risk of GBS ranged from 0 to 5 additional cases of GBS per 1,000,000 vaccines within the 6-week period following vaccination. (5 in 1,000,000 equals one in every 200,000)

13 NON-CLINICAL TOXICOLOGY
13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
Menactra vaccine has not been evaluated for carcinogenic or mutagenic potential, or for impairment of fertility.

11. HEPATITIS A - VAQTA

Insert webpage	http://www.merck.com/product/usa/pi_circulars/v/vaqta/vaqta_pi.pdf
CDC webpage	http://www.cdc.gov/vaccines/hcp/vis/vis-statements/hep-a.html
CDC Info sheet excerpt	**Some people should not get hepatitis A vaccine or should wait.** - Anyone who has ever had a severe (life threatening) allergic reaction to a previous dose of hepatitis A vaccine should not get another dose. - Anyone who has a severe (life threatening) allergy to any vaccine component should not get the vaccine. -**All hepatitis A vaccines contain alum**, and some hepatitis A vaccines contain 2-phenoxyethanol. **What are the risks from hepatitis A vaccine?** A vaccine, like any medicine, could possibly cause serious problems, such as severe allergic reactions. The risk of hepatitis A vaccine causing serious harm, or death, is extremely small. **Severe problems** **Serious allergic reaction, within a few minutes to a few hours after the shot** (*very rare*). **What if there is a serious reaction? What should I look for?** - Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or behavior changes. - Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would start a few minutes to a few hours after the vaccination.
Live virus?	No
Insert's main hazards identified in Insert:	**Guillain-Barré syndrome; cerebellar ataxia; encephalitis; Thrombocytopenia; measles-like/rubella-like rash; varicella-like rash; rash morbilliform; Menstruation disorders**
Studies on Carcinogenicity	No
Studies on Fertility	No
Deaths reported	No

EXCERPTS FROM VACCINE INSERT:

5 WARNINGS AND PRECAUTIONS

5.1 Prevention and Management of Allergic Vaccine Reactions

Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of the vaccine *[see Contraindications (4)]*.

5.4 Limitations of Vaccine Effectiveness

Vaccination with VAQTA may not result in a protective response in all susceptible vaccinees.

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

Allergic Reactions

Local and/or systemic allergic reactions that occurred in <1% of over 10,000 children/adolescents or adults in clinical trials regardless of causality included: injection-site pruritus and/or rash; bronchial constriction; asthma; wheezing; edema/swelling; rash; generalized erythema; urticaria; pruritus; eye irritation/itching; dermatitis

The following additional unsolicited local adverse reactions and systemic adverse events were observed at a common frequency of ≥1% to <10% in any individual clinical study. This listing includes only the adverse reactions not reported elsewhere in the label. These local adverse reactions and systemic adverse events occurred among recipients of VAQTA alone or VAQTA given concomitantly within 14 days following any dose of VAQTA across four clinical studies.

Eye disorders: Conjunctivitis
Gastrointestinal disorders: Constipation; vomiting
General disorders and administration site conditions: Injection-site bruising; injection-site ecchymosis
Infections and infestations: Otitis media; nasopharyngitis; rhinitis; viral infection; croup; pharyngitis streptococcal; laryngotracheobronchitis; viral exanthema; gastroenteritis viral; roseola
Metabolism and nutrition disorders: Anorexia
Psychiatric disorders: Insomnia; crying
Respiratory, thoracic and mediastinal disorders: Cough; nasal congestion; respiratory congestion
Skin and subcutaneous tissue disorders: Rash vesicular; **measles-like/rubella-like rash; varicellalike rash; rash morbilliform**

***Serious Adverse Events (Children 12 through 23 Months of Age):* Across the five studies conducted in subjects 12-23 months of age, 0.7% (32/4374) of subjects reported a serious adverse event following any**
dose of VAQTA, and 0.1% (5/4374) of subjects reported a serious adverse event judged to be vaccine related by the study investigator.

The following additional unsolicited systemic adverse events were observed among recipients of VAQTA that occurred within 14 days at a common frequency of ≥1% to <10% following any dose not reported elsewhere in the label. These adverse reactions have been reported across 4 clinical studies.

Musculoskeletal and connective tissue disorders: Back pain; stiffness
Reproductive system and breast disorders: **Menstruation disorders**

6.2 Post-Marketing Experience

The following additional adverse events have been reported with use of the marketed vaccine (Does not provide numbers of persons affected). Because these reactions are reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency or establish a causal relationship to a vaccine exposure.

Blood and lymphatic disorders: Thrombocytopenia.
Nervous system disorders: Guillain-Barré syndrome; cerebellar ataxia; encephalitis.

13 NONCLINICAL TOXICOLOGY
13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
VAQTA has not been evaluated for its carcinogenic or mutagenic potential, or its potential to impair fertility.

12. ROTAVIRUS - RotaTeq

Insert webpage	http://www.merck.com/product/usa/pi_circulars/r/rotateq/rotateq_pi.pdf
CDC webpage	http://www.cdc.gov/vaccines/hcp/vis/vis-statements/rotavirus.html
CDC Info sheet excerpt	**Some babies should not get this vaccine** **A baby who has had a life-threatening allergic reaction to a dose of rotavirus vaccine should not get another dose. A baby who has a severe allergy to any part of rotavirus vaccine should not get the vaccine.** With a vaccine, like any medicine, there is a chance of side effects. These are usually mild and go away on their own. **Serious side effects are also possible but are rare**. **Risks of a vaccine reaction** With a vaccine, like any medicine, there is a chance of side effects. These are usually mild and go away on their own. Serious side effects are also possible but are rare. Most babies who get rotavirus vaccine do not have any problems with it. But some problems have been associated with rotavirus vaccine: **Serious problems** following rotavirus vaccine: **Intussusception is a type of bowel blockage that is treated in a hospital, and could require surgery**. It happens "naturally" in some babies every year in the United States, and usually there is no known reason for it. (The vaccine?) There is also a small risk of **intussusception** from rotavirus vaccination, usually within a week after the 1st or 2nd vaccine dose. **This additional risk is estimated to range from about 1 in 20,000 to 1 in 100,000 US infants who get rotavirus vaccine.** **Problems that could happen after any vaccine:** Any medication can cause a severe allergic reaction. Such reactions from a vaccine are very rare, estimated at fewer than 1 in a million doses, and usually happen within a few minutes to a few hours after the vaccination. As with any medicine, there is **a very remote chance of a vaccine causing a serious injury or death.** **What if there is a serious problem? What should I look for?** For **intussusception**, look for signs of stomach pain along with **severe crying**. Early on, these episodes could last just a few minutes and come and go several times in an hour. Babies might pull their legs up to their chest. **Your baby might also vomit several times or have blood in the stool, or could**

	appear weak or very irritable. These signs would usually happen during the first week after the 1st or 2nd dose of rotavirus vaccine, but look for them any time after vaccination. Look for anything else that concerns you, such as signs of a **severe allergic reaction, very high fever, or unusual behavior.** **Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, or unusual sleepiness**. These would usually start a few minutes to a few hours after the vaccination.
Live virus?	Yes
Insert's main hazards identified in Insert:	**DEATH; sudden infant death syndrome; Anaphylactic reaction; Transmission of vaccine virus; Anaphylactic reaction; Intussusception (including death); Kawasaki disease** (a disease occurring primarily in young children and giving rise to a rash, glandular swelling, and **sometimes damage to the heart**.)
Studies on Carcinogenicity	No
Studies on Fertility	No
Deaths reported	**YES**

EXCERPTS FROM VACCINE INSERT:

5 WARNINGS AND PRECAUTIONS

5.1 Managing Allergic Reactions

Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of the vaccine.

5.3 Intussusception

Following administration of a previously licensed live rhesus rotavirus reassortant vaccine, an increased risk of intussusception was observed.1 In a post-marketing observational study in the US cases of intussusception were observed in temporalassociation within 21 days following the first dose of RotaTeq, with a clustering of cases in the first 7 days. *[See Adverse Reactions (6.2).]* In worldwide passive post-marketing surveillance, cases of intussusception have been reported in temporal association with RotaTeq. *[See Adverse Reactions (6.2).]*

5.5 Shedding and Transmission

Transmission of vaccine virus strains from vaccines to non-vaccinated contacts has been observed post-marketing.

6 ADVERSE REACTIONS

6.1 Clinical Studies Experience

71,725 infants were evaluated in 3 placebo-controlled clinical trials including 36,165 infants in the group that received RotaTeq and 35,560 infants in the group that received placebo.

Serious Adverse Events

Across the clinical studies, 52 deaths were reported. There were 25 deaths in the RotaTeq recipients compared to 27 deaths in the placebo recipients. The most commonly reported cause of death was sudden infant death syndrome, which was observed in 8 recipients of RotaTeq and 9 placebo recipients.

6.2 Post-Marketing Experience

The following adverse events have been identified during post-approval use of RotaTeq from reports to the Vaccine Adverse Event Reporting System (VAERS). Reporting of adverse events following immunization to VAERS is voluntary, and the number of doses of vaccine administered is not known; therefore, it is not always possible to reliably estimate the adverse event frequency or establish a causal relationship to vaccine exposure using VAERS data. In post-marketing experience, the following adverse events have been reported following the use of RotaTeq:

Immune system disorders:
Anaphylactic reaction
Gastrointestinal disorders:
Intussusception (including death)
Hematochezia
Gastroenteritis with vaccine viral shedding in infants with **Severe Combined Immunodeficiency Disease (SCID)**
Skin and subcutaneous tissue disorders:
Urticaria
Angioedema
Infections and infestations:
Kawasaki disease (A disease of unknown cause, occurring primarily in young children and giving rise to a rash, glandular swelling, and **sometimes damage to the heart**.)
Transmission of vaccine virus strains from vaccine recipient to non-vaccinated contacts.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

RotaTeq has not been evaluated for its carcinogenic or mutagenic potential or its potential to impair fertility.

13. HUMAN PAPILLOMAVIRUS (HPV) - Gardasil

Insert webpage	http://www.merck.com/product/usa/pi_circulars/g/gardasil/gardasil_pi.pdf
CDC webpage	http://www.cdc.gov/vaccines/hcp/vis/vis-statements/hpv-gardasil-9.html
CDC Info sheet excerpt	**Some people should not get this vaccine** Anyone who has had a severe, life-threatening allergic reaction to a dose of HPV vaccine should not get another dose. Anyone who has a severe (life threatening) allergy to any component of HPV vaccine should not get the vaccine. **Risks of a vaccine reaction** With any medicine, including vaccines, there is a chance of side effects. These are usually mild and go away on their own, but serious reactions are also possible. **Mild or moderate problems following Gardasil-9:** **(This CDC vaccine pamphlet only lists specific mild and moderate reactions, even though the statement below tells you that you can get a serious injury or die after vaccination)** **Problems that could happen after any vaccine:** **People sometimes faint after a medical procedure, including vaccination**. Some people get severe pain in the shoulder and have difficulty moving the arm where a shot was given. This happens very rarely. Any medication can cause a severe allergic reaction. Such reactions from a vaccine are very rare, estimated at fewer than 1 in a million doses, and would happen within a few minutes to a few hours after the vaccination. As with any medicine, there is a very **remote chance of a vaccine causing a serious injury or death.** **What if there is a serious reaction?** What should I look for? Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or unusual behavior. Signs of a **severe allergic reaction** can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would usually start a few minutes to a few hours after the vaccination.
Live virus?	No

Insert's main hazards identified in Insert:	**DEATH; Anaphylaxis (Anaphylaxis** is a serious allergic **reaction** that is rapid in onset and **may cause death**); **Guillain-Barré syndrome; Pulmonary embolus** (a condition in which one or more arteries in the lungs become blocked by a blood clot); **anaphylactic/anaphylactoid reactions; pulmonary tuberculosis; pancreatitis; pancreatic cancer; breast cancer; acute renal failure; post-operative pulmonary embolism;** systemic **lupus erythematosus** (an inflammatory autoimmune disease causing scaly red patches on the skin, especially on the face, and sometimes affecting connective tissue in the internal organs); **nasopharyngeal cancer; motor neuron disease (a progressive degenerative disease involving the motor neurons and causing weakness and wasting of the muscles), paralysis, seizures**, syncope; **pancreatitis, vomiting; Deep venous thrombosis** (Deep vein thrombosis [DVT] occurs when a blood clot (thrombus) forms in one or more of the deep veins in your body, usually in your legs. Deep vein thrombosis is a serious condition because blood clots in your veins can break loose, travel through your bloodstream and lodge in your lungs, blocking blood flow [pulmonary embolism])
Studies on Carcinogenicity	No
Studies on Fertility	No
Deaths reported	**YES**

EXCERPTS FROM VACCINE INSERT:

5 WARNINGS AND PRECAUTIONS

5.2 Managing Allergic Reactions

Appropriate medical treatment and supervision must be readily available in case of anaphylactic reactions following the administration of GARDASIL.

6 ADVERSE REACTIONS

Overall Summary of Adverse Reactions

Headache, fever, nausea, and dizziness; and local injection site reactions (pain, swelling, erythema, pruritus, and bruising) occurred after administration with GARDASIL.

Syncope (temporary loss of consciousness caused by a fall in blood pressure) , sometimes associated with tonic-clonic movements and other seizure-like activity, has been reported following vaccination with GARDASIL and may result in falling with injury; observation for 15 minutes after administration is recommended. *[See Warnings and Precautions (5.1).]*

Anaphylaxis has been reported following vaccination with GARDASIL. (Anaphylaxis is a serious allergic **reaction** that is rapid in onset and **may cause death)**

Serious Adverse Reactions in the Entire Study Population

Across the clinical studies, 258 individuals (GARDASIL N = 128 or 0.8%; placebo N = 130 or 1.0%) **out of 29,323** (GARDASIL N = 15,706; AAHS control N = 13,023; or saline placebo N = 594) individuals (9- through 45-year-old girls and women; and 9- through 26-year-old boys and men) **reported a serious systemic adverse reaction. (29,323 ÷ 258 = 1 out of 113.65).**

Of the entire study population (29,323 individuals), 0.04% of the reported serious systemic adverse reactions were judged to be vaccine related by the study investigator. (Who are the study investigators whose job it is to present the data in the most safe and acceptable way?) The most frequently (frequency of 4 cases or greater with either GARDASIL, AAHS control, saline placebo, or the total of all three) reported serious systemic adverse reactions, regardless of causality, were:

Headache [0.02% GARDASIL (3 cases) vs. 0.02% AAHS control (2 cases)],
Gastroenteritis [0.02% GARDASIL (3 cases) vs. 0.02% AAHS control (2 cases)],
Appendicitis [0.03% GARDASIL (5 cases) vs. 0.01% AAHS control (1 case)],
Pelvic inflammatory disease [0.02% GARDASIL (3 cases) vs. 0.03% AAHS control (4 cases)],
Urinary tract infection [0.01% GARDASIL (2 cases) vs. 0.02% AAHS control (2 cases)],
Pneumonia [0.01% GARDASIL (2 cases) vs. 0.02% AAHS control (2 cases)],
Pyelonephritis [0.01% GARDASIL (2 cases) vs. 0.02% AAHS control (3 cases)],
Pulmonary embolism [0.01% GARDASIL (2 cases) vs. 0.02% AAHS control (2 cases)].
One case (0.006% GARDASIL; 0.0% AAHS control or saline placebo) of bronchospasm; and 2 cases (0.01% GARDASIL; 0.0% AAHS control or saline placebo) of asthma were reported as serious systemic adverse reactions that occurred following any vaccination visit.

Deaths in the Entire Study Population
Across the clinical studies, 40 deaths (GARDASIL N = 21 or 0.1%; placebo N = 19 or 0.1%) were reported in 29,323 (1 in every 733 persons vaccinated died)

In addition, there were 2 cases of sepsis, 1 case of **pancreatic cancer,** 1 case of arrhythmia, 1 case of **pulmonary tuberculosis**, 1 case of hyperthyroidism, 1 case of **post-operative pulmonary embolism and acute renal failure**, 1 case of traumatic brain injury/cardiac arrest, 1 case of systemic **lupus erythematosus** (an inflammatory autoimmune disease causing scaly red patches on the skin, especially on the face, and sometimes affecting connective tissue in the internal organs), 1 case of cerebrovascular accident, 1 case of **breast cancer**, and 1 case of **nasopharyngeal cancer** in the group that received GARDASIL;

6.2 Postmarketing Experience
The following adverse events have been spontaneously reported during post-approval use of GARDASIL.

Respiratory, thoracic and mediastinal disorders: **Pulmonary embolus**.
Gastrointestinal disorders: Nausea, **pancreatitis**, **vomiting**.
General disorders and administration site conditions: Asthenia, chills, **death**, fatigue, malaise.
Immune system disorders: Autoimmune diseases, hypersensitivity reactions including **anaphylactic/anaphylactoid reactions (Anaphylaxis Definition Anaphylaxis** is a rapidly progressing, life-threatening allergic **reaction)**, bronchospasm, and urticaria.
Musculoskeletal and connective tissue disorders: Arthralgia, myalgia.
Nervous system disorders: Acute disseminated encephalomyelitis, dizziness, **Guillain-Barré syndrome**, headache, **motor neuron disease (a progressive degenerative disease involving the motor neurons and causing weakness and wasting of the muscles), paralysis, seizures**, syncope (including syncope associated with tonic-clonic movements and other seizure-like activity) sometimes resulting in falling with injury,transverse myelitis.

Infections and infestations: cellulitis.
Vascular disorders: Deep venous thrombosis (Deep vein thrombosis [DVT] occurs when a blood clot (thrombus) forms in one or more of the deep veins in your body, usually in your legs. Deep vein thrombosis is a serious condition because blood clots in your veins can break loose, travel through your bloodstream and lodge in your lungs, blocking blood flow [pulmonary embolism])

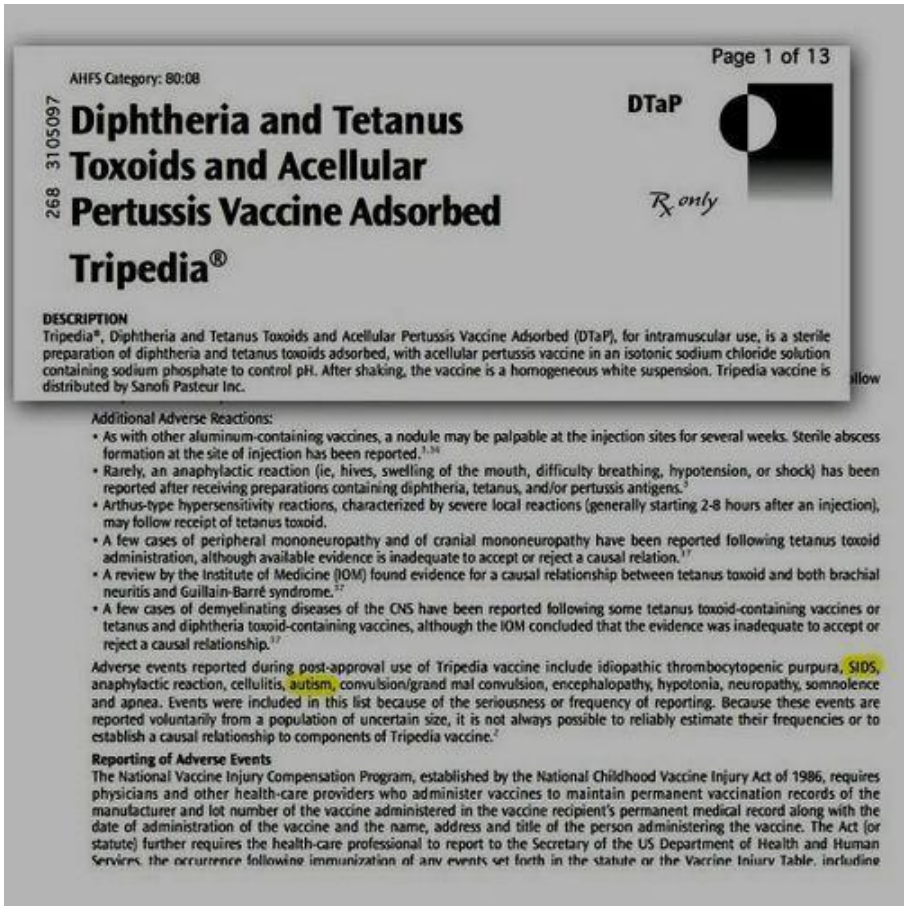
13 NONCLINICAL TOXICOLOGY
13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
GARDASIL has not been evaluated for the potential to cause carcinogenicity or genotoxicity.

INFLUEZA (RB: No personal review at this time. One note though: There are some claims made that the majority of the Vaccine Court cases at this time are related to flu vaccines)

Influenza Shot insert at: LINK	bioCSL Pty Ltd.	bioCSL

AUTISM AND SIDS CAUSED BY DTaP VACCINE:

The only vaccine manufacturer to ever admit to a relationship between its vaccine and Autism, as well as Sudden Infant Death Syndrom (SIDS), was by the manufacturer of Tripedia, but it was soon taken out of the market. Here is a photo of the pertinent part of the insert.



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AHFS Category: 80:08

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Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed Tripedia®

DTaP

℞ only

DESCRIPTION
Tripedia®, Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed (DTaP), for intramuscular use, is a sterile preparation of diphtheria and tetanus toxoids adsorbed, with acellular pertussis vaccine in an isotonic sodium chloride solution containing sodium phosphate to control pH. After shaking, the vaccine is a homogeneous white suspension. Tripedia vaccine is distributed by Sanofi Pasteur Inc.

Additional Adverse Reactions:
- As with other aluminum-containing vaccines, a nodule may be palpable at the injection sites for several weeks. Sterile abscess formation at the site of injection has been reported.[1-16]
- Rarely, an anaphylactic reaction (ie, hives, swelling of the mouth, difficulty breathing, hypotension, or shock) has been reported after receiving preparations containing diphtheria, tetanus, and/or pertussis antigens.[3]
- Arthus-type hypersensitivity reactions, characterized by severe local reactions (generally starting 2-8 hours after an injection), may follow receipt of tetanus toxoid.
- A few cases of peripheral mononeuropathy and of cranial mononeuropathy have been reported following tetanus toxoid administration, although available evidence is inadequate to accept or reject a causal relation.[17]
- A review by the Institute of Medicine (IOM) found evidence for a causal relationship between tetanus toxoid and both brachial neuritis and Guillain-Barré syndrome.[17]
- A few cases of demyelinating diseases of the CNS have been reported following some tetanus toxoid-containing vaccines or tetanus and diphtheria toxoid-containing vaccines, although the IOM concluded that the evidence was inadequate to accept or reject a causal relationship.[17]

Adverse events reported during post-approval use of Tripedia vaccine include idiopathic thrombocytopenic purpura, SIDS, anaphylactic reaction, cellulitis, autism, convulsion/grand mal convulsion, encephalopathy, hypotonia, neuropathy, somnolence and apnea. Events were included in this list because of the seriousness or frequency of reporting. Because these events are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequencies or to establish a causal relationship to components of Tripedia vaccine.[2]

Reporting of Adverse Events
The National Vaccine Injury Compensation Program, established by the National Childhood Vaccine Injury Act of 1986, requires physicians and other health-care providers who administer vaccines to maintain permanent vaccination records of the manufacturer and lot number of the vaccine administered in the vaccine recipient's permanent medical record along with the date of administration of the vaccine and the name, address and title of the person administering the vaccine. The Act (or statute) further requires the health-care professional to report to the Secretary of the US Department of Health and Human Services, the occurrence following immunization of any events set forth in the statute or the Vaccine Injury Table, including