## **BREAKDOWN OF CHILDHOOD VACCINE INSERTS' PRE-LICENSING STUDIES**

VACCINE/Breakdown Tables Groups Compared	VACCINE MANUFACTURER & BRAND NAME	# In Study	Monitor Period	Saline Placebo Group	Cancer Study	Fertility Study
Hepatitis B / None In two sets of studies, there were only vaccinated children. In a third set they compared those that received three doses with a group that received two doses	Merck: Recombivax HB	147 1,252 Unk.	5 d	No	No	No
Diphtheria, tetanus, acellular pertussis (DTaP or Tdap) / Yes Three studies in US, 4,198: participants were enrolled to receive four consecutive doses of Pentacel. Fourth study in Canada, 1,782 participants previously vaccinated with three doses of Pentacel received a fourth dose. Compared vaccine with other vaccines	(a) Sanofi Pasteur: Pentacel	5,980 1,782	3 d	No	No	No
Diphtheria, tetanus, acellular pertussis (DTaP or Tdap) / Yes Compares Daptacel vaccine to DT and DTP	(b) Sanofi Pasteur: DAPTACEL	8,197	14 d 2 months	No	No	No
Diphtheria, tetanus, acellular pertussis (DTaP or Tdap) /Yes Compared Adacel to DECAVAC (Tetanus and Diphtheria Toxoids Adsorbed; manufactured by Sanofi Pasteur Inc., Swiftwater, PA)	(c) Sanofi Pasteur: <u>Adacel</u>	7,143	14 d 6 months	No	No	No
Haemophilus influenzae type b (Hib) / Yes Compares groups that received 1, 2 and 3 doses of DAPTACEL + IPOL + ActHIB Vaccines with a group that received DAPTACEL + ActHIB Vaccines	Sanofi Pasteur: ActHIB	110 1,454	48 hrs. 3 d 30 d	No	No	No
Pneumococcal conjugate or polysaccharide / Tables Compares Prevnar 13 with Prevnar	Pfizer: Prevnar 13	7,489	4 d 7 d	No	No	No
Inactivated poliovirus (IPV) / Yes Compares IPV only schedules and sequential IPV- OPV schedules; compares IPOL with IPOL + DTP	Sanofi Pasteur: IPOL	+700 + 3,000 (exact number not reported)	18 Months	No	No	No

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VACCINE/Breakdown Tables Groups Compared	VACCINE MANUFACTURER & BRAND NAME	# In Study	Monitor Period	Saline Placebo Group	Cancer Study	Fertility Study
Measles-mumps-rubella (MMR) / No No pre-license studies reported	Merck: M-M-R II	Unk.	Unk.	No	No	No
Varicella (chickenpox) / Yes Says no placebo-controlled group in current vaccine. Mentions placebo-controlled group, but the placebo contained 45 mg of neomycin, an antibiotic with serious side effects	Merck: Varivax	11,000 914	42 d	No	No	No
Meningococcal conjugate or polysaccharide / Yes Compares Menactra vaccine to Menactra + PCV7a + MMRVb + HepA, and PCV7a + MMRVb + HepA	Sanofi Pasteur: Menactra	3,721	7 d	No	No	No
Hepatitis A / Yes Compares VAQTA vaccine to VAQTA + ProQuad + Prevnar concomitantly - Only solicited reactions	Merck: <u>VAQTA</u>	+10,000 (exact number not reported)	14 d 5 d	No	No	No
Rotavirus / Yes Mentions Placebo group, but the Placebo contained Polysorbate 80 and many other substances In 42 day period 52 deaths reported	Merk: RotaTeq	71,725	42 d	No	No	No
Human Papillomavirus (HPV) / Yes Compares Gardasil group to AAHS and Saline Placebo groups, but reports AAHS and Saline Placebo groups as one unit The Saline Placebo group (594) had zero Systemic Autoimmune Disorders reported. See Plotkin Deposition transcript, pages 197 to 202, at https://tinyurl.com/Plotkin-Deposition-Transcript; see also Deposition video at https://tinyurl.com/HPV-Placebo-Study	Merck: Gardasil	18,083  Placebo  Group = 594  (3.29% of total)	14 d	Yes	No	No