Dear Oregon Legislators,

Below I have shared section 13 from one of each vaccines per the CDC schedule.

Some of which the section had been removed. I question why this information was removed from the product insert. This is information that is not to be hidden for full informed consent. Anyhow, you will see not one vaccine has been tested for Carcinogenesis, Mutagenesis, or impaired fertility! That being said who will be liable for the outcome of this tragedy, taking parents rights away? As of 1986 the pharmaceutical industry who manufacturer these vaccines are not liable for damages! Will the state take responsibility once parents see the outcome of much needed testing? When there is risk their must be choice! If no choice someone needs to be held responsible! Please consider this information below when discussing HB 3063!!

## Dynavax HepB

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility HEPLISAV-B has not been evaluated for carcinogenicity, mutagenic potential or male infertility in animals. Vaccination of female rats with a vaccine formulation containing 2.5 mcg HBsAg and 3000 mcg CpG 1018 adjuvant had no effect on fertility [see Use in Specific Populations (

## **Rotary Rotavirus**

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility ROTARIX has not been evaluated for carcinogenic or mutagenic potential, or for impairment of fertility.

## dTap Sanofi Pasteur

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

## FLUARIX QUADRIVALENT Glaxo Smith Kline

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility FLUARIX QUADRIVALENT has not been evaluated for carcinogenic or mutagenic potential or male infertility in animals. Vaccination of female rats with FLUARIX QUADRIVALENT had no effect on fertility [see Use in Specific Populations (8.1)]

PNEUMOVAX® 23 (pneumococcal vaccine polyvalent) SECTION 13 REMOVED!

#### Pneumococcal (polysaccharide) SECTION 13 REMOVED

12 CLINICAL PHARMACOLOGY 12.1 Mechanism of Action PNEUMOVAX 23 induces type-specific antibodies that enhance opsonization, phagocytosis, and killing of pneumococci by leukocytes and other phagocytic cells. The levels of antibodies that correlate with protection against pneumococcal disease have not been clearly defined.

14 CLINICAL STUDIES 14.1 Effectiveness The protective efficacy of pneumococcal vaccines containing six (types 1, 2, 4, 8, 12F, and 25) or twelve (types 1, 2, 3, 4, 6A, 8, 9N, 12F, 25, 7F, 18C, and 46) capsular polysaccharides was investigated in two controlled studies in South Africa in male novice gold miners ranging in age from 16 to 58 years, in whom there was a high attack rate for pneumococcal pneumonia and bacteremia.{4} In both studies, participants in the control groups received either meningococcal polysaccharide serogroup A vaccine or saline placebo. In both studies, attack rates for vaccine type pneumococcal pneumonia were observed for the period from 2 weeks through about 1 year after vaccination. Protective efficacy was 76% and 92%, respectively, for the 6- and 12-valent vaccines, for the capsular types represented. Three similar studies in South African young adult male novice gold miners were carried out by

PREVNAR 13 (Pneumococcal 13-valent Conjugate Vaccine [Diphtheria CRM197 Protein]) Pneumococcal

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility Prevnar 13 has not been evaluated for the potential to cause carcinogenicity, genotoxicity, or impairment of male fertility. In a study in rabbits, no vaccine-related effects were found regarding reproductive performance including female fertility [see Use in Specific Populations

#### FLULAVAL QUADRIVALENT

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility FLULAVAL QUADRIVALENT has not been evaluated for carcinogenic, mutagenic potential, or male infertility in animals. Vaccination of female rats with FLULAVAL QUADRIVALENT had no effect on fertility

MMR could not find section 13

Shingles SHINGRIX (Zoster Vaccine Recombinant, Adjuvanted)

13 NONCLINICAL TOXICOLOGY 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility SHINGRIX has not been evaluated for its carcinogenic or mutagenic potential. Vaccination of female rats with SHINGRIX had no effect on fertility [see Use in Specific Populations (8.1)]. In a male fertility study, rats were vaccinated with 0.1 mL of SHINGRIX (a single human dose is 0.5 mL) on 42, 28, and 14 days prior to mating. There were no effects on male fertility.

HAVRIX (Hepatitis A Vaccine) injectable suspension, for intramuscular 13 NONCLINICAL TOXICOLOGY 13.1Carcinogenesis, Mutagenesis, Impairment of Fertility HAVRIX has not been evaluated for its carcinogenic potential, mutagenic potential, or potential for impairment of fertility.

Diphtheria Toxoid Sanofi Pasteur Inc. 26 April 2018, v0.4 284 Menactra® Menactra®, Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine Solution for Intramuscular Injection

3 14 13 NON-CLINICAL TOXICOLOGY 15 Carcinogenesis, Mutagenesis, Impairment of Fertility 16 Menactra has not been evaluated for carcinogenic or mutagenic potential, or for impairment of 17 male

fertility. A developmental animal toxicity study showed that Menactra had no effects on 18 female fertility in mice [see Pregnancy (8.1)].

Td TENIVAC (Tetanus and Diphtheria Toxoids Adsorbed)

13 NONCLINICAL TOXICOLOGY 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility TENIVAC vaccine has not been evaluated for carcinogenic or mutagenic potential or impairment of fertility.

## hpv GARDASIL 9

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility GARDASIL 9 has not been evaluated for the potential to cause carcinogenicity, genotoxicity or impairment of male fertility. GARDASIL 9 administered to female rats had no effects on fertility [see Pregnancy (8.1)].

## hpv GARDASIL

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility GARDASIL has not been evaluated for the potential to cause carcinogenicity or genotoxicity. GARDASIL administered to female rats at a dose of 120 mcg total protein, which is equivalent to the recommended human dose, had no effects on mating performance, fertility, or embryonic/fetal survival. The effect of GARDASIL on male fertility has been studied in male rats at an intramuscular dose of 0.5 mL/rat/occasion (120 mcg total protein which is equivalent to the recommended human dose). One group of male rats was administered GARDASIL once, 3 days prior to cohabitation, and a second group of male rats was administered GARDASIL three times, at 6 weeks, 3 weeks, and 3 days prior to cohabitation. 13 There were no treatment-related effects on reproductive performance including fertility, sperm count, and sperm motility. There were no treatment-related gross or histomorphologic and weight changes on the testes.

# meningitidis group b 13 NONCLINICAL TOXICOLOGY

Trumenba has not been evaluated for carcinogenic or mutagenic potential or impairment of fertility in males. Vaccination of female rabbits with Trumenba had no effect on fertility [see <u>Pregnancy</u> (8.1)].

## Pneumococcal polysaccharide PNEUMOVAX 23

**SECYION 13 REMOVED** 

12.1 Mechanism of Action PNEUMOVAX 23 induces type-specific antibodies that enhance opsonization, phagocytosis, and killing of pneumococci by leukocytes and other phagocytic cells. The levels of antibodies that correlate with protection against pneumococcal disease have not been clearly defined. 14 CLINICAL STUDIES 14.1 Effectiveness The protective efficacy of pneumococcal vaccines containing six (types 1, 2, 4, 8, 12F, and 25) or

#### Polio Sanofi Pasteur v 0.1 059 IPOL

CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY 16 Long-term studies in animals to evaluate carcinogenic potential or impairment of fertility have not 17 been conducted.

323 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility 324 INFANRIX has not been evaluated for carcinogenic or mutagenic potential, or for impairment of 325 fertility.

Please consider this and vote NO on HB 3063 Kay Jorissen