### **APPENDIX 2**

# Part 1: Adverse Events that are Causally linked to Vaccines by the Institute of Medicine (IOM)

Of the 158 most common serious injuries reported to have been caused by vaccines the following 14 have been <u>causally linked</u> to diphtheria, tetanus, pertussis, measles, mumps, rubella, varicella, polio, hepatitis B, or Hib vaccines [Informed Consent Action Network (ICAN) Section IV]:

acute encephalopathy
chronic arthritis
acute arthritis
shock and unusual shock-like state
anaphylaxis
protracted inconsolable crying
death
thrombocytopenia
Guillain-Barre syndrome (GBS)
pneumonia,
meningitis,
hepatitis
MBE,

febrile seizures

Examples of the other 144 serious AE's that are plausibly caused by vaccines and <u>have been listed on the PI's for vaccines for decades</u> but the IOM has not investigated with properly designed causality studies include:

Demyelinating diseases of the central nervous system, for e.g. multiple sclerosis (autoimmune disease), sterility, insulin-dependent diabetes mellitus (autoimmune), SIDS, chronic neurologic damage, learning disabilities and attention-deficit disorder, haemolytic anemia, autism, neuropathies, Chrohn's disease, ulcerative colitis, inflammatory bowel disease, polyneuropathy, Chronic Fatigue Syndrome (CFS), Narcolepsy.

Some of these are listed on the <u>Prescribing Information</u> (PI) for the MMR vaccine below:

# Part 2: The Adverse Events that have occurred after receiving the Merck & CO., INC MMR II Vaccine (May 2017).

- Panniculitis or vasculitis (Kawasaki disease)
- Atypical measles
- Encephalopathy or encephalitis
- Anaphylaxis and anaphylactoid reactions, angioneurotic edema and bronchial spasm.
- Seizures
- Febrile convulsions and afebrile convulsions
- Idiopathic Thrombocytopenic Purpura (ITP) (causally linked to measles vaccine)
- Subacute sclerosing panencephalitis (SSPE)
- Guillain-Barre Syndrome (GBS), myositis
- Muscle in-coordination (ataxia)
- Otitis media
- Ocular palsies
- Optic neuritis (including partial or total blindness)
- Retinitis, otitis media, bronchial spasms, fever, headaches, joint pain, juvenile arthritis (autoimmune), rheumatoid arthritis and arthritis (acute and chronic)
- Transverse myletis
- Thrombocytopenia (blood clotting disorders and spontaneous bleeding)
- Leukocytosis, lymphadenopathy, Stephen-Johnson syndrome, pancreatitis, urticaria
- Aseptic meningitis, pneumonia, pneumonitis, parotitis
- Erythema multiforme
- Rhinitis
- Transverse myelitis
- Diabetes mellitus (autoimmune), immune system disorders
- Death

Vaccine ingredients that are not listed (or described) on some government vaccine ingredient lists for MMR II vaccine include:

### 1. A Description of the Ingredients in the Growth Mediums for the Live Virus's:

Whilst ingredients of the manufacturing process are mostly filtered out from the final product it is known that trace amounts of these components are sometimes found in the vaccines.

The **Rubella Virus** Vaccine Live component, Wistar RA 27/3 strain (1000 CCID) is grown in a medium of WI-38 <u>human diploid lung fibroblasts</u>.

The **Measles and Mumps** Virus Vaccine Live components are grown in <u>chick embryo cell</u> culture.

The growth medium for measles and mumps is Medium 199 that includes a salt solution, vitamins, amino acids and <u>fetal bovine serum</u>, sucrose, phosphate, glutamate, <u>neomycin</u> (antibiotic) and recombinant human albumin (rDNA) - this is defined as DNA molecules formed by laboratory methods of genetic engineering, such as molecular cloning, in order to bring together genetic material from multiple sources thus creating a recombined sequence of DNA that would not otherwise be found in biological organisms.

## 2. Ingredients that are not mentioned on some Ingredients Lists in each 0.5 ml dose of MMR II vaccine include:

Fetal bovine serum (<1 ppm)

25 mcg of neomycin (stated as 'residual' and not as an amount on the government sheet), recombinant (rDNA) human albumin (0.3 mg)

other buffer and media ingredients – not stated

#### Contraindications to MMR vaccine stated on the PI include:

Hypersensitivity to any component of the vaccine including gelatine.

Anaphylactic or anaphylactoid reactions to neomycin (antibiotic) (each dose of reconstituted vaccine contains approx 25mcg of neomycin).

Febrile respiratory illness or other active febrile infection.

Individuals with a family history of congenital or hereditary immunodeficiency, until the immune competence of the potential vaccine recipient is demonstrated.

#### Warnings

Live measles vaccine and live mumps vaccine are produced in chick embryo cell culture. Persons with a history of anaphylactic, anaphylactoid or other immediate reactions (e.g. hives, swelling of the mouth and throat, difficulty breathing, hypotension or shock) subsequent to egg ingestion may be at an enhanced risk of immediate-type hypersensitivity reactions after receiving vaccines containing traces of chick embryo antigen. The potential risk to benefit ratio should be carefully considered before considering vaccination in such cases.

The AAP states 'Persons who have experienced anaphylactic reactions to topically or systematically administered neomycin should not receive measles vaccine.'