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For the attention of: 7 January 2015
Secretary Sylvia Mathews Burwell
US Department of Health and Human Services

Secretary Burwell

RE: The government mandated second dose of Merck Measles/Mumps/Rubella (MMR) live vaccine and the National Vaccine Injury Compensation Program Authorizing Legislation Sec. 300aa-26

I understand that the US Department of Health and Human Services (HHS) has a role in the National Vaccine Injury Compensation Program (NVICP)[1] and that, in your role as Secretary of the HHS, you have a responsibility to "*develop and disseminate vaccine information materials for distribution by health care providers to the legal representatives of any child or to any other individual receiving a vaccine set forth in the Vaccine Injury Table*".[2]

I suggest that relevant vaccine information re the Merck Measles/Mumps/Rubella (MMR) vaccine *is not being provided*, i.e. the option of antibody titre testing to verify immunisation after vaccination with the *first dose* of live MMR vaccine. As a result 'informed consent' is not being properly obtained before this medical intervention, and it is likely many children are being over-vaccinated with the mandated *second dose* of live MMR vaccine.

Currently the Advisory Committee on Immunization Practices recommends that children in the United States receive **two doses** of live measles/mumps/rubella (MMR) vaccines at 12-15 months and 4-6 years.[3] As a result of the ACIP's 'recommendation', **two MMR vaccine doses are mandated in many US states**.[4]

However, according to the **Merck M-M-R II Information Sheet**, it appears most seronegative children are likely to be immune after ***one dose*** of effective live MMR vaccine.[5] [6] [7]

I suggest the blanket 'recommendation' for ***two doses*** of live MMR vaccine by the Advisory Committee on Immunization Practices, and subsequent government mandates, **contravenes the Authorizing Legislation of the US National Vaccine Injury Compensation Program, Sec. 300aa-26[8], as relevant information about the option of antibody titre testing is not being provided to citizens in most jurisdictions before revaccination with the second dose of live MMR vaccine. As a result, many likely already immune children are being unnecessarily over-vaccinated with the *second dose* of live MMR vaccine.**

It is notable that in the state of New Jersey in the United States, the health department provides information on antibody titre testing. The Antibody Titer Law (Holly's Law)[9] allows parents to seek testing to determine a child's immunity to measles, mumps and rubella *before receiving the second dose of MMR vaccine*. The law was enacted in response to the death of five year old Holly Marie Stavola who died of encephalopathy which she developed seven days after receiving her second dose of MMR vaccine. Holly's family campaigned for this law, wishing they had known about the option of the antibody titre test before Holly's arbitrary revaccination with the second dose of live MMR vaccine.[10]

This information about the option of antibody titre testing to verify immunisation after live MMR vaccination should be available to all citizens, not just those in the state of New Jersey. All parents should be informed of the reportedly high seroconversion rates after live MMR vaccination at the appropriate age, i.e. after maternally derived antibodies have waned. All parents should be properly informed about the risks and benefits of individual vaccine products.

Secretary Burwell, I understand you have a responsibility to act on this matter, as outlined in NVICP Authorizing Legislation Sec. 300aa-26. Vaccine Information[11] which states:

-STATUTE-
(a) General rule
Not later than 1 year after December 22, 1987, ***the Secretary shall develop and disseminate vaccine information materials for distribution by health care providers to the legal representatives of any child or to any other individual receiving a vaccine set forth in the Vaccine Injury Table.*** Such materials shall be published in the Federal Register and may be revised.
(b) Development and revision of materials
Such materials shall be developed or revised –
(1) after notice to the public and 60 days of comment thereon, and

(2) in consultation with the Advisory Commission on Childhood Vaccines, appropriate health care providers and parent organizations, the Centers for Disease Control and Prevention, and the Food and Drug Administration.

(c) Information requirements

The information in such materials shall be based on available data and information, shall be presented in understandable terms and shall include –

(1) a concise description of the benefits of the vaccine,

(2) a concise description of the risks associated with the vaccine,

(3) a statement of the availability of the National Vaccine Injury Compensation Program, and

(4) such other relevant information as may be determined by the Secretary.

(d) ***Health care provider duties***

On and after a date determined by the Secretary which is –

(1) after the Secretary develops the information materials required by subsection (a) of this section, and

(2) not later than 6 months after the date such materials are published in the Federal Register,

each health care provider who administers a vaccine set forth in the Vaccine Injury Table shall provide to the legal representatives of any child or to any other individual to who such provider intends to administer such vaccine a copy of the information materials developed pursuant to subsection (a) of this section, supplemented with visual presentations or oral explanations, in appropriate cases. Such materials shall be provided prior to the administration of such vaccine.

(My emphasis.)

In regards to providing ***"a concise description of the benefits of the vaccine"***, **there are no benefits to the individual if the individual is already immune. Most children are likely to be immune after the first dose of *effective* live MMR vaccine**, particularly the measles and rubella components, **which can be verified with an antibody titre test for those parents/individuals who want evidence of immunisation.**

It is notable that the CDC Vaccine Information Statement for the MMR Vaccine 'What You Need to Know'[12], provides no information re antibody titre testing. This is a serious omission which I suggest contravenes NVICP Authorizing Legislation Sec. 300aa-26.[13]

In regards to providing ***"a concise description of the risks associated with the vaccine"***, there are risks, i.e. possible adverse reactions, as detailed in the **Merck M-M-R II Information Sheet**.[14] Reports of adverse events after MMR vaccination have also been submitted to VAERS (the Vaccine Adverse Event Reporting System).[15] **Are healthcare providers bringing this information to the attention of parents (and other individuals)?**

The VAERS database contains reports of children of four years and over who have experienced adverse events after vaccination with the MMR vaccine. As it is likely many of these children had already been vaccinated with an MMR vaccine at 12-15 months of age, it is likely they were already immune and they underwent revaccination for no benefit (that is if the Merck M-M-R II vaccine product is as **effective as claimed**, **a matter which is currently the subject of a lawsuit in the US in regards to the mumps virus component of the vaccine**[16]). It is also notable that reports of adults suffering adverse events after MMR vaccination are recorded in the VAERS database, which again raises the question whether these people were offered the option of antibody titre testing before MMR vaccination.

Secretary Burwell, I request that you take urgent steps to ensure that parents and other individuals are properly informed of the option of antibody titre testing to verify immunisation after the first dose of *effective* live MMR vaccine, rather than be arbitrarily subjected to potential over-vaccination with a second dose of live MMR vaccine.

I request your acknowledgement of receipt of this letter, and your response on this matter to my email address: **elizmhart@gmail.com**

Yours sincerely
Elizabeth Hart

References: (All links accessible as at 7 January 2015.)

[1] National Vaccine Injury Compensation Program: http://www.hrsa.gov/vaccinecompensation/index.html
[2] Sec. 300aa-26. Vaccine information. National Vaccine Injury Compensation Program: http://www.hrsa.gov/vaccinecompensation/authoringleg.pdf

[3] Recommended Immunization Schedules for Persons Aged 0 Through 18 Years, United States, 2014: http://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf

[4] Centers for Disease Control and Prevention. School and Childcare Vaccination Surveys. School Vaccination Requirements, Exemptions & Web links: http://www2a.cdc.gov/nip/schoolsurv/schimmrqmt.asp

[5] According to the Information Sheet for Merck's M-M-R II (Measles, Mumps, and Rubella Virus Vaccine Live) *"clinical studies of 284 triple seronegative children, 11 months to 7 years of age, demonstrated that M-M-R II is highly immunogenic and generally well tolerated. In these studies,* ***a single injection of the vaccine induced measles hemagglutination-inhibition (HI) antibodies in 95%, mumps neutralizing antibodies in 96%, and rubella HI antibodies in 99% of susceptible persons."*** Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc. M-M-R® II. (Measles, Mumps, and Rubella Virus Vaccine Live). Information Sheet. 9912202: http://www.merck.com/product/usa/pi_circulars/m/mmr_ii/mmr_ii_pi.pdf

[6] No reference to published details of the "clinical studies of 284 triple seronegative children" is provided in Merck's M-M-R II Information Sheet. However, the ACIP report on MMR vaccination appears to support Merck's information re the high seroconversion rate after primary vaccination, particularly in regards to the measles and rubella components of the MMR vaccine, (although there appears to be some ambiguity about the effectiveness of the mumps component of the MMR vaccine): Prevention of Measles, Rubella, Congenital Rubella Syndrome, and Mumps, 2013. Summary Recommendations of the Advisory Committee on Immunization Practices (ACIP). Centers for Disease Control and Prevention Morbidity and Mortality Weekly Report. Vol. 62, No.4. June 14, 2013: http://www.cdc.gov/mmwr/pdf/rr/rr6204.pdf **(See pp 7-11.)**

[7] *Op cit*. The Merck M-M-R II Information Sheet also notes: ***"…a small percentage (1-5%) of vaccinees may fail to seroconvert after the primary dose".*** It is my understanding that failure to seroconvert after vaccination with the primary dose is most likely due to interference of maternally derived antibodies, i.e. if the child is vaccinated at an age before maternally derived antibodies have waned. Other reasons could be problems with the effectiveness of the vaccine product that results in vaccine failure, or that the individual is a poor responder.

[8] Sec. 300aa-26. Vaccine information. National Vaccine Injury Compensation Program: http://www.hrsa.gov/vaccinecompensation/authoringleg.pdf

[9] Antibody Titer Law – Information for Parents. (Holly's Law) (NJSA 26:2N-8-11), passed on January 14, 2004, concerns vaccination of children with the Measles, Mumps, Rubella (MMR) vaccine. The law allows parents to seek testing to determine a child's immunity to measles, mumps, and rubella, before receiving the second dose of the vaccine. This brochure has been prepared by the New Jersey Department of Health and Senior Services to assist parents in making the decisions related to the MMR vaccine and the test: http://www.state.nj.us/health/cd/documents/antibody_titer_law.pdf

[10] HopeFromHolly. Providing NJ physicians and Parents with more knowledge about childhood vaccines: http://hopefromholly.com/blog/our-purpose/

[11] Sec. 300aa-26. Vaccine information. National Vaccine Injury Compensation Program: http://www.hrsa.gov/vaccinecompensation/authoringleg.pdf

[12] CDC Vaccine Information Statement – MMR Vaccine What You Need to Know. Dated 4/20/2012: http://www.cdc.gov/vaccines/hcp/vis/vis-statements/mmr.pdf

[13] Sec. 300aa-26. Vaccine information. National Vaccine Injury Compensation Program: http://www.hrsa.gov/vaccinecompensation/authoringleg.pdf

[14] *Op cit.* M-M-R® II. Information Sheet: http://www.merck.com/product/usa/pi_circulars/m/mmr_ii/mmr_ii_pi.pdf

[15] Vaccine Adverse Event Reporting System (VAERS): http://vaers.hhs.gov/data/index

[16] **Lawsuits claiming Merck lied about mumps vaccine efficacy headed to trial**. FierceVaccines, 9 September 2014: http://www.fiercevaccines.com/story/lawsuits-claiming-merck-lied-about-mumps-vaccine-efficacy-headed-trial/2014-09-09