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For the attention of:

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Dr Jonathan Temte
Chair, Advisory Committee on Immunization Practices (ACIP)
Professor of Family Medicine, University of Wisconsin School of Medicine and Public Health

Professor Temte

**RE: CHALLENGING MANDATED REVACCINATION OF CHILDREN WITH THE
MEASLES/MUMPS/RUBELLA (MMR) VACCINE 'BOOSTER' SECOND DOSE**

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.¹ As a result of the ACIP's recommendation, **two MMR vaccine doses are mandated in many US states.**²

However, according to the Merck M-M-R II Information Sheet, most seronegative children are likely to be immune after **one dose** of live MMR vaccine.³

In regards to measles vaccination, the Advisory Committee on Immunization Practices report on MMR vaccination (June 2013) admits that: "**The second dose of measles-containing vaccine primarily was intended to induce immunity in the small percentage of persons who did not seroconvert after vaccination with the first dose of vaccine (primary vaccine failure).**"⁴

Given that most children are likely to be immunised after the first dose of live MMR vaccine, I question whether parents are being given the opportunity to properly give their 'informed consent' to the second dose of live MMR vaccine, also often described as a 'booster'.⁵ This question is particularly pertinent as adverse events have been reported after MMR vaccination.

I request that the Advisory Committee on Immunization Practices respond to me on this matter, and I provide further supporting information below.

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.*"⁶ (My emphasis.)

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.**"⁷ 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.

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).⁸

Are healthcare providers informing parents (and other individuals) of the high likelihood of seroconversion after the first dose of live MMR vaccine, i.e. that most vaccinees are likely to be immune after the first dose of live MMR vaccine, given at the appropriate age?

Are healthcare providers informing parents (and other individuals) of the option of antibody titre testing to verify a response to MMR vaccination? It is possible that some careful parents (and other individuals) may prefer to pay for antibody titre testing before having the medical intervention of repeated MMR vaccination. Parents of small children (and other individuals) might be surprised to discover that vaccination 'best practice' for companion animals is now more advanced than that for children, with international vaccination guidelines for dogs re live vaccines recommending antibody titre testing rather

than an arbitrary 'booster', i.e. **"...the principles of 'evidence-based veterinary medicine' would dictate that testing for antibody status (for either pups or adult dogs) is a better practice than simply administering a vaccine booster on the basis that this should be 'safe and cost less'"**.⁹

The blanket recommendation for **two** live MMR vaccine doses by the Advisory Committee on Immunization Practices **appears to be at odds with the Authorizing Legislation of the US National Vaccine Injury Compensation Program, Sec. 300aa-26**, i.e. legal representatives of any child or any individual receiving a vaccine set forth in the Vaccine Injury Table should be provided with information on the vaccine, including **"a concise description of the benefits of the vaccine"** and **"a concise description of the risks associated with the vaccine"**.¹⁰

In regards to **"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 live MMR vaccine dose**, particularly the measles and rubella components. This can be verified with an antibody titre test for those parents/individuals who want evidence of a response.

In regards to **"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.¹¹ Reports of adverse events after MMR vaccination have also been submitted to VAERS (the Vaccine Adverse Event Reporting System).¹² **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, they were likely already immune (i.e. if the Merck M-M-R II vaccine is as effective as claimed), and they underwent revaccination for no benefit. (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.)

VAERS is a passive surveillance system to which adverse events after vaccination are voluntarily reported. The FDA has acknowledged that **"VAERS is a crude tool"** and that **adverse events are likely to be under-reported**.¹³ In regards to the lack of safety information re the MMR vaccine, the Cochrane Collaboration's systematic review of MMR vaccination notes: **"The design and reporting of safety outcomes in MMR vaccine studies, both pre- and post-marketing, are largely inadequate."**¹⁴ I suggest there has been inadequate research undertaken on the possibly deleterious long-term effects of repeated vaccination, **and that unnecessary vaccination should be avoided.**

Professor Temte, I again question whether parents (and other individuals) are being properly informed by healthcare providers about MMR vaccination, in accordance with the Authorizing Legislation of the US National Vaccine Injury Compensation Program, Sec. 300aa-26, and whether 'informed consent' is being obtained before this medical intervention.

As the US Advisory Committee on Immunization Practices is responsible for making recommendations on vaccine use, recommendations which have far-reaching impact not just in the United States, but are also influential around the world, **I would appreciate your urgent response on this matter to my email address eliz.hart25@gmail.com**

Sincerely
Elizabeth Hart

***Please note this letter will be circulated to other parties.**

References: (All links accessible as at 5 March 2014.)

¹ 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>

² Centers for Disease Control and Prevention. School and Childcare Vaccination Surveys. School Vaccination Requirements, Exemptions & Web links: <http://www2a.cdc.gov/nip/schoolsurv/schimmrgmt.asp>

³ 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

⁴ 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 page 3.)

⁵ For example, the CDC “Measles Vaccination: Who Needs It?” webpage states: “A second dose of the vaccine is recommended to protect those 5% who did not develop immunity in the first dose and to give “booster” effect to those who did develop an immune response.” <http://www.cdc.gov/vaccines/vpd-vac/measles/vacc-in-short.htm> I question the benefit of this so-called ‘booster’ effect for children who are already immune, particularly to measles and rubella.

⁶ *Op cit.* M-M-R[®] II. Information Sheet: http://www.merck.com/product/usa/pi_circulars/m/mmr_ii/mmr_ii_pi.pdf

⁷ *Ibid.*

⁸ *Op cit.* Prevention of Measles, Rubella, Congenital Rubella Syndrome, and Mumps: <http://www.cdc.gov/mmwr/pdf/rr/rr6204.pdf> (See pages 7-11.)

⁹ Day, M.J., Horzinek, M.C., Schultz, R.D. World Small Animal Veterinary Association’s (WSAVA) Guidelines for the Vaccination of Dogs and Cats. Journal of Small Animal Practice. Vol. 51. June 2010: <http://www.wsava.org/sites/default/files/VaccinationGuidelines2010.pdf> (See page 7.)

¹⁰ 300aa-26. Vaccine information. National Vaccine Injury Compensation Program: <http://www.hrsa.gov/vaccinecompensation/authoringleg.pdf>

¹¹ *Op cit.* M-M-R[®] II. Information Sheet: http://www.merck.com/product/usa/pi_circulars/m/mmr_ii/mmr_ii_pi.pdf

¹² Vaccine Adverse Event Reporting System (VAERS): <http://vaers.hhs.gov/data/index>

¹³ <http://www.fda.gov/downloads/Safety/MedWatch/UCM168497.pdf>

¹⁴ Demicheli V, Rivetti A, Debalini MG, Di Pietrantonj C. Vaccines for measles, mumps and rubella in children. Cochrane Database of Systematic Reviews 2012, Issue 2. Art. No.: CD004407. DOI:

10.1002/14651858.CD004407.pub3. <http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD004407.pub3/abstract>