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For the attention of: 6 September 2013

Dr Paul A Offit,
Professor of Pediatrics, Perelman School of Medicine,
University of Pennsylvania; and
Chief, Division of Infectious Diseases / Director, Vaccine Education Center,
The Children's Hospital of Philadelphia; and
Board Director, The Foundation for Vaccine Research

Professor Offit

RE: QUESTIONING THE ETHICS OF MANDATED VACCINATION OF CHILDREN WITH THE MEASLES/MUMPS/RUBELLA (MMR) 'BOOSTER' SECOND DOSE

I am contacting you in your capacity as an expert in infectious diseases and childhood vaccination to query the ethics of mandated revaccination of likely already immune children with a second dose of the live Measles/Mumps/Rubella (MMR) vaccine (misleadingly termed a 'booster'), and general lack of advice re the availability of a blood test (i.e. an antibody titre test) to verify a response to vaccination with the live MMR vaccine.

I suggest that parents of small children are not being properly informed of the option for antibody titre testing rather than an arbitrary second dose of live MMR vaccine. Two doses of MMR vaccine are mandated in many US states¹, and also in other countries such as Australia². These mandates conflict with the obligation for 'informed consent' before vaccination.

Parents of small children might be surprised to discover that vaccination 'best practice' for companion animals is now more advanced than that for children, with vaccination guidelines for dogs re live vaccines recommending 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'". 3

Professor Offit, given your high standing in this area, I request your assistance in bringing attention to this anomaly, which I discuss further below.

1. Paul Offit, the MMR 'booster', and antibody titre testing...

Professor Offit, you are on the record acknowledging that antibody titre testing is an option rather than an arbitrary second dose of MMR vaccine in this Expert Answer on the <u>babycenter.com</u> website: <u>"Does my</u> child still need a booster shot if a blood test shows that he's already immune to a disease?".

In your response on the babycenter.com website you note:

"Not having a booster is an option (although an expensive one) for the MMR booster...The first dose of the MMR vaccine, which your child should receive at 12 to 15 months successfully immunizes 95 percent of children against measles, mumps, and rubella...To find out whether your child has responded to the first MMR shot, you can have the doctor do a blood test called an "antibody titer"...If your child's test shows that he has the MMR antibodies, he doesn't need a booster shot..."

Professor Offit, you acknowledge that most children will be immunised after the first dose of MMR vaccine, and that "to catch those few who slip through the cracks, the Centers for Disease Control and Prevention recommends a second, or "booster", shot between the ages of 4 and 6". A recent CDC/ACIP report on MMR vaccination 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)."

As most children are likely to be immune after the first dose of live MMR vaccine, there is no evidence that these already immune children benefit from a second so-called 'booster' dose, and I suggest it is confusing and misleading to use this terminology to describe the second MMR dose.

2. Mandated vaccination with two doses of MMR vaccine

Professor Offit, you say "the Centers for Disease Control and Prevention recommends a second, or "booster", shot between the ages of 4 and 6". A search of the CDC's database on School Vaccination Requirements, Exemptions and Web links indicates that many US states require two doses of MMR vaccine search of the CDC's database on School Vaccination Requirements, Exemptions and Web links indicates that many US states require two doses of MMR vaccine is mandated by the state.

According to the <u>Authorizing Legislation</u> of the <u>US National Vaccine Injury Compensation Program</u>, Sec. 300aa-26, 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

As many US states are *requiring* that children have *two* doses of MMR vaccine, I question whether parents of children are being properly informed that only *one* dose of effective live MMR vaccine, given at the appropriate age, is likely to provide immunity? I also question whether information on the availability of antibody titre testing is being given to the parents of children, or to other people who may be pressured to have a second arbitrary dose of MMR vaccine, so they can make an informed decision on whether to have a second MMR dose or an antibody titre test? As a second dose of MMR vaccine is mandated for children in many jurisdictions I suggest this seems unlikely.

Professor Offit, it is notable that your <u>Vaccine Education Center webpage discussing the MMR</u> on The Children's Hospital of Philadelphia website¹¹ (updated in April 2013) makes no reference to the option of antibody titre testing to verify a response to MMR vaccination.

3. Vaccination 'best practice' now more advanced for companion animals than for children...

Professor Offit, parents of small children might be surprised to discover that **vaccination 'best practice' for dogs is now more advanced than that for children**.

It is pertinent to note that <u>vaccination guidelines for dogs</u> with 'live' vaccines for parvovirus, distemper virus and adenovirus acknowledge that:

"...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'."

The World Small Animal Veterinary Association's (WSAVA) most recent vaccination guidelines for puppies notes: "The presence of circulating antibodies indicates that the dog is immune, and revaccination (with core vaccines) is not required. You may decide to titre test before giving the 12 month booster, as this may show that boosting is unnecessary. Two new in-practice titre-testing kits are now available which will allow your vet to do a titre test very quickly, without sending the blood sample to a laboratory." (My emphasis.)

(**Note:** Industry funded vaccination guidelines for dogs and cats also inappropriately use the term 'booster' and 'boosting' in relation to modified live virus (MLV) vaccines. Refer to <u>my letter to Professor Ronald Schultz</u>¹⁴, a member of the World Small Animal Veterinary Association's Vaccination Guidelines Group, on this matter, copy also attached. While the companion animal vaccination guidelines are compromised in that they are industry-funded, they are nevertheless a groundbreaking initiative, with their concept of categorising 'core', 'non-core' and 'not recommended' vaccines.)

Professor Offit, you suggest that antibody titre testing is "expensive (more than \$100), and experts contend there's no downside to a second shot." 15.

I suggest it is parents' prerogative to make the decision on whether to arbitrarily revaccinate or seek a titre test to verify a response to vaccination (i.e. 'evidence-based medicine'). If the option of titre testing was more widely known it would likely become less expensive, and possibly in-clinic testing could be developed, similar to that <u>now available for pets</u>¹⁶.

4. Vaccination and safety matters

Professor Offit, you say "experts contend there's no downside to a second shot". 17

The Cochrane Collaboration's <u>systematic review of MMR vaccination</u> notes that: "The design and reporting of safety outcomes in MMR vaccine studies, both pre- and post-marketing, are largely inadequate."

I suggest there has been inadequate research undertaken on the possibly deleterious long-term effects of unnecessary vaccination.

Again, experts in companion animal vaccination appear to be more progressive and careful about the indiscriminate use of vaccine products than promoters of human vaccination.

For instance, veterinary academics and veterinarians <a href="https://have.ncb.nlm.nih.gov/have-ncb.nlm.nih.gov/ha

While WSAVA Vaccination Guidelines Group member Professor Ronald Schultz acknowledges that <u>"vaccination should be considered an important medical practice"</u> he also <u>cautions on the overuse of vaccines</u>:

"I tell practitioners that vaccines are drugs, albeit biological drugs. I remind them that they would not consider it good medicine to give an unnecessary pharmaceutical drug on a recurring basis. I think it is even worse to give a vaccine, or biological drug, that isn't necessary. The possible adverse consequences of a vaccine generally far outweigh the adverse consequences of a pharmaceutical drug. A pharmaceutical drug is usually much more restricted in its action. However, each time we stimulate an immune response, we have to look at the effect on all body systems—not only on antibody responses or cell-mediated immunity, but also on interactions with the endocrine system and the nervous system." (My emphasis.)

It is notable that the WSAVA 2010 vaccination guidelines for dogs and cats warn "we should aim to reduce the 'vaccine load' on individual animals in order to minimize the potential for adverse reactions to vaccine products". The WSAVA 2010 guidelines also acknowledge that "there is gross under-reporting of vaccine-associated adverse events which impedes knowledge of the ongoing safety of these products". The WSAVA 2013 vaccination guidelines advise "it is important to give as few vaccines as possible…" and "…any reaction to a vaccine that is not needed is unacceptable". 28

Professor Offit, we are on a slippery slope when the state dictates questionable medical interventions for citizens (including 'pre-citizens', i.e. children). I suggest the arbitrary second dose of the MMR vaccine, often inappropriately described as a 'booster', is a questionable medical intervention.

Given your expertise in the area of infectious diseases and vaccines, and your acknowledgement of the option of antibody testing for MMR, I would greatly appreciate your response on this matter to my email address: eliz.hart25@gmail.com

I also suggest this is a matter that could be raised during your current Vaccines course on Coursera.²⁹

Sincerely
Elizabeth Hart
http://over-vaccination.net/

cc:

 Professor Alan Cohen, Physician-in-Chief and Chair, Department of Pediatrics, Perelman School of Medicine, University of Pennsylvania

- Professor Simon Wain-Hobson, Board Chair, The Foundation for Vaccine Research
- Professor Brian Martin, Social Sciences, University of Wollongong
- Laureate Professor Peter Doherty, Microbiology and Immunology, University of Melbourne
- Sir Gus Nossal, Chair of the Oversight Committee for the Australian Academy of Science publication "The Science of Immunisation: Questions and Answers"
- Dr Vittorio Demicheli, Cochrane Vaccines Field
- Dr James Wood, School of Public Health & Community Medicine, University of New South Wales
- Professor Ronald Schultz, WSAVA Vaccination Guidelines Group
- Professor Michael Day, Chairperson, WSAVA Vaccination Guidelines Group
- Professor Emeritus Marian Horzinek, previous member of the WSAVA Vaccination Guidelines Group
- Professor Jolle Kirpensteijn, EB Liaison, WSAVA Vaccination Guidelines Committee
- Professor Hailme Tsuilmoto, WSAVA Vaccination Guidelines Group
- Professor Richard Squires, WSAVA Vaccination Guidelines Group
- Professor Emeritus Richard Ford, member of the AAHA Canine Vaccination Guidelines Task Force
- Bea Mies, independent advocate for judicial vaccine use

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

Endnotes/References: (All links accessible as at 6 September 2013.)

during the current Federal election campaign, e.g. "Rudd closes immunisation loophole", The Australian, 18 August 2013: http://www.theaustralian.com.au/news/nation/rudd-closes-immunisation-loophole/story-e6frg6nf-1226699080977 and "Labor to cut tax benefit for parents who don't immunise children", ABC News, 22 August 2013:

http://www.abc.net.au/news/2013-08-18/labor-to-cut-tax-benefit-for-parent-who-don27t-immunise-childr/4894390 and "Opposition" Leader Tony Abbott backs Prime Minister Kevin Rudd's tougher stance on vaccination 'in principle'", News.com.au, 18 August

http://www.news.com.au/national-news/federal-election/opposition-leader-tony-abbott-backs-prime-minister-kevin-rudd8217s-tougherstance-on-vaccination-8216in-principle8217/story-fnho52ip-1226699358041

http://www.chop.edu/service/vaccine-education-center/a-look-at-each-vaccine/mmr-measles-mumps-and-rubella-vaccine.html

http://www.abc.net.au/radionational/programs/healthreport/food-allergy/2954588

¹ A search of the CDC's database on School Vaccination Requirements, Exemptions and Web links indicates that many US states **require** two doses of MMR vaccine¹, i.e. vaccination is mandated by the state: http://www2a.cdc.gov/nip/schoolsurv/schimmrqmt.asp In Australia vaccination is linked to government benefits, i.e. there is a financial inducement to vaccinate. See "Immunisation" Related Payments for Parents" on the Immunise Australia website: http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/related-payments Vaccination has also been a topic

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 Paul Offit. Does my child still need a booster shot if a blood test shows that he's already immune to a disease? Expert Answers. Babycenter.com. (Undated.): http://www.babycenter.com/404_does-my-child-still-need-a-booster-shot-if-a-blood-test-show_1463679.bc Ibid.

Ibid.

Summary Recommendations of the Advisory Committee on Immunization Practices (ACIP). Prevention of Measles, Rubella, Congenital Rubella Syndrome, and Mumps, 2013. Centers for Disease Control and Prevention Morbidity and Mortality Weekly Report. Recommendations and Reports / Vol. 62 / No. 4, June 14, 2013: http://www.cdc.gov/mmwr/pdf/rr/rr6204.pdf

Op. cit. Paul Offit. Does my child still need a booster shot if a blood test shows that he's already immune to a disease?

⁹ 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

³⁰⁰aa-26. Vaccine information. National Vaccine Injury Compensation Program:

http://www.hrsa.gov/vaccinecompensation/authoringleg.pdf

11 A Look at Each Vaccine: MMR (Measles, Mumps and Rubella) Vaccine. Vaccine Education Center. The Children's Hospital of Philadelphia:

Op. cit. Day, M.J. et al 2010: http://www.wsava.org/sites/default/files/VaccinationGuidelines2010.pdf

¹³ Vaccination Guidelines for New Puppy Owners. WSAVA Vaccination Guidelines Group. 2013:

http://users.on.net/~peter.hart/WSAVA%20Puppy%20Vax%20Guidelines%20May%202013.pdf

Letter to Professor Ronald Schultz, complaining about the use of the word 'booster' in the WSAVA Vaccination Guidelines, also including discussion about titre testing. Overview accessible on my 'over-vaccination' website, including a link to the full letter: http://over-vaccination.net/2013/08/21/over-vaccination-of-dogs-with-unnecessary-boosters/

Op. cit. Paul Offit. Does my child still need a booster shot if a blood test shows that he's already immune to a disease?

¹⁶ See for example VacciCheck as described on the Biogal website: http://biogal.co.il/vaccicheck-2

¹⁷ Op. cit. Paul Offit. Does my child still need a booster shot if a blood test shows that he's already immune to a disease?

¹⁸ 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

Titer Testing And Vaccination: A New Look at Traditional Practices. A Roundtable Discussion. Veterinary Healthcare Communications, 2002:

http://www.synbiotics.com/Products/CompanionAnimals/Canine/TiterCHEK-CDV-CPV-TiterTesting/96-0460-RoundTableDiscussion.pdf Child allergy rates at 'epidemic proportions'. Sydney Morning Herald, 9 March 2010:

http://www.smh.com.au/national/child-allergy-rates-at-epidemic-proportions-20100309-pus2.html

Chain reaction – in less than a generation, food allergies in children – some of them potentially fatal – have reached epidemic levels.

GoodWeekend, 23 July 2011.

22 Kemp, AS, Mullins, RJ, Weiner, JM. The allergy epidemic: what is the Australian response? Medical Journal of Australia. Vol. 185, No. 4, 21 August 2006.
²³ Food Allergy. The Health Report, ABC Radio National, 30 May 2011:

http://www.mcri.edu.au/media/55207/newsletter 2011_06_04.pdf

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Dp. cit. Vaccination Guidelines for New Puppy Owners. 2013:
http://users.on.net/~peter.hart/WSAVA%20Puppy%20Vax%20Guidelines%20May%202013.pdf

Vaccines. Paul A. Offit, MD. Coursera: https://www.coursera.org/course/vaccines

²⁴ HealthNuts Research Update 2011. Murdoch Children's Research Institute: