Testimony Senate Health & Welfare Committee Wednesday April 22, 2015 H.98

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April 22, 2015

To the Honorable members of the Vermont Senate Health Committee Sen. Claire Ayer, Chair Sen. Virginia "Ginny" Lyons, Vice Chair Sen. Anthony Pollina Sen. Dick McCormack Sen. Brian Collamore, Clerk

Good morning Senators, thank you for allowing me to present testimony in your committee on the very controversial issue of vaccine choice, which, judging from the turnout for this hearing, is an issue of importance for many Vermonters, who, as the principle stakeholders in the outcome, would also greatly appreciate an opportunity to voice their concerns.

Aside from 11 years in Emergency Medicine in the mid-70's to mid-80s, and some volunteer work abroad, I have been involved in clinical practice here in Vermont for the last 44 years. My love for medicine has found an outlet in direct patient care in a primary care setting, and I currently maintain a small practice in Lyndonville.

As a practicing physician, free and informed consent to treatment of any sort is an absolute prerequisite to establish an atmosphere of trust and honest communication with my patients. Coercion has no place whatsoever.

I would like to review with you the Vermont state vaccination and exemption numbers as I believe there has been some confusion around these. Of the 89,460 students enrolled in public and private schools in 2013-2014, 3,479 (3.88%) had a philosophical exemption. That does not been those students were unvaccinated. Recall that a student must claim a philosophical exemption (PE) if he or she opts out of only one or two vaccinations, typically involving chickenpox and/or HepB. This means that many of those children counted as being exempt are in fact vaccinated.

When chickenpox and HepB were added to the schedule around 2008, the PE doubled from 2.5% to 5%. Some parents, after careful research, have elected to space out the vaccine schedule, and this usually also requires an exemption, but these children, like those provisionally admitted, do eventually catch up.

What really matters is the actual coverage for individual vaccines, and as you can see from the chart in your handout, the rates are already quite high when kids enter kindergarten. After the children admitted on a provisional basis are caught up, the rates for 1<sup>st</sup> grade all rise to over 96-97%, and coverage continues

to rise through the grades, reaching over 98% by grade 12.

I hope this makes it clear that vaccination rates among VT schoolchildren for all required vaccines are VERY high, already exceeding the CDC's 2020 95% aspirations. Therefore, there is no reason to remove parental choice on the basis of low vaccine coverage.

A brief word about the vaccine schedule itself. Referring to the graph in the handout, you can see that the number of vaccinations for children have increased significantly over the last 30 years, tripling since the early '80s, and doubling since 2000 (now 48 vaccine antigens given in 34 injections by the age of 6; 69 antigens in 54 injections by age 18). You can observe that the number of vaccines, all defined by the US Supreme Court as "unavoidably unsafe", rapidly increased in the late 1980's, immediately following passage of the National Childhood Vaccine Injury Act in 1986. This act was passed in response to growing numbers of lawsuits by parents, mostly stemming from deaths and severe neurological injuries caused by the whole cell pertussis component of the DPT vaccine.

This unprecedented law indemnified pharmaceutical companies from any and all liability in the event of an adverse vaccine reaction, and was a green light for liability-free vaccine development. Today, there are literally hundreds of vaccines in development, and the US already vaccinates more, and at a younger age, than any other country in the world. It is almost certain that over time more and more vaccinations will be added to an already burdensome schedule that has never been proven safe. Vaccine choice represents one of the few remaining safe-guards providing a very necessary, indeed crucial, check and balance to vaccine manufacturers' future ambitions.

Vaccine policy rests on the proverbial 3-legged stool, the legs being safety, efficacy, and the concept of herd immunity, in which an unvaccinated individual may contract and transmit disease to others in the herd who are not immune, for one reason or another.

This latter concern seems to have taken front seat in the minds of those advocating forced vaccination, but it is fair to ask if it is warranted, or even if it would work.

1. Diphtheria has all but disappeared in the US, but is still occurs in small numbers elsewhere. Contrary to what many assume, mortality from most infectious scourges like diptheria, measles, whooping cough, scarlet fever, and others was already in steep decline prior to the introduction of vaccination (see graph). Diphtheria has not been seen in Vermont since the 1950's, and the last case seen in the US was a decade ago. The vaccine is designed to neutralize the toxin produced by the diphtheria bacteria, but it has no effect on colonization of the respiratory tract or transmission to contacts. It, like tetanus toxoid, is for personal protection only, and vaccinated individuals can spread it just like unvaccinated persons.

- 2. As mentioned above, the tetanus vaccine is meant to neutralize the bacterial toxin, it will not prevent infection by Clostridia bacteria, nor is it a communicable disease, so an unvaccinated child is not infectious and not a danger to others.
- 3. We all remember pertussis from 2012. There were large outbreaks in numerous states, Vermont having one of the highest per capita. Predictably the outbreaks here and elsewhere were blamed on a small number of unvaccinated children, but when it became apparent that 90+% of reported cases were fully vaccinated, opinions had to be revised. Recent scientific studies have revealed that a vaccine-resistant strain had appeared which had a selective advantage in vaccinated children, and that those fully vaccinated were also more likely to be infected than unvaccinated children. Furthermore, animal primate studies showed that the acellular vaccine was not capable of preventing bacterial colonization and transmission to contacts. This is why the strategy of "cocooning" to protect very young infants (i.e., vaccinating the adults in close contact with the child) has been abandoned in Australia and elsewhere.

There is now broad scientific consensus that there are problems with the current acellular vaccine, and that vaccinated, not unvaccinated children, drove the recent outbreaks

- 4. Hepatitis B is a blood born virus that is not a public health problem at all among Vermont school children. Also, it does not spread in a community setting, especially among school children who are unlikely to be engaging in sex or IV drug use. If children who are carrying hepatitis B are allowed in school, what can be the justification for denying a child, who has not had the required course of HepB vaccination, entry to school?
- 5. IPV: Polio is no longer a problem in the US, the last case of wild polio seen in 1979, when the CDC reports vaccine rates were at just 59.7%. The live oral vaccine has since been discontinued in favor of the safer inactivated polio vaccine. The IPV prevents illness but not colonization of the intestines by polio virus, and thus will not prevent transmission should a case of wild polio make its way back into this country. A person vaccinated with IPV can infect others if colonized. The OPV was responsible for polio eradication, not the current IPV.
- 6. There is the problem of vaccine virus shedding by those recently vaccinated with live viral vaccines (MMR, Varicella, FluMist, Shingles, Rotovirus) effecting those immunocompromised.
- 7. There is also the issue, common to all vaccines, of persons who fail to respond to a vaccine, as well as immunity that wanes over time and that may not respond well on revaccination. And since we do not routinely check antibody titers in students, there is no sure way of knowing who is actually immune.

To illustrate the problems of protecting the immune-compromised child in the classroom, please refer to the classroom slide in your handouts. The child claiming a philosophical exemption (circled, crossed out, and sadly kicked out of class in this slide), appears be the least of the concerns for such a vulnerable child.

To summarize:

- 1. Vaccination coverage is high in Vermont schools,demonstrating that Act 157 has been successful
- 2. Because of very real risks associated with some vaccines, and because more and more vaccines will certainly be added to the schedule, recourse to the right to exempt will be increasingly important.
- 3. The idea that an unvaccinated child poses a threat is overly simplistic and controversial.
- 4. Finally, and most importantly, trust between doctors and patients will suffer great, perhaps irreversible, harm if force is injected into the relationship.

Respectfully, Sandy Reider, MD

## "Birth to 18 Vaccine Schedule"



## A small minority (only 3.88%) of Vermont school students have a philosophical exemption on file.

2013 Immunization Regulations called for measure of 1<sup>st</sup> grade rates as better indicator vs. kindergarten rates (Act 157)

### Percent of Vermont children immunized by vaccine in kindergarten and first grade, 2013–14 school year



The Vermont Annual Immunization Status Report

Chart from www.healthvermont.gov



Data from www.healthvermont.gov

## Percent of VT School Children Vaccinated, First and Eighth Grades, 2013-2014 School Year



Data from www.healthvermont.gov



Data from www.healthvermont.gov



Chart from www.healthvermont.gov



# Eliminating students with Philosophical Exemption does NOT protect the immune compromised



S Shedder, recent MMR, Varicella, or FluMist recipient – up to 28 days post vaccination via viral shedding – FluMist is administered in schools!

ĤFP R₽

- HIV + Legally allowed in school and medical privacy protected
- HepB + Legally allowed in school and medical privacy protected
  - **FVS** Fully vaccinated child sick with common cold, strep, bronchitis, etc.
  - FV Fully vaccinated immune status unknown

#### Legally allowed in school – Unknown immunity status (May or may not threaten I)

- PA Provisional admittance, not fully vaccinated (7.9% is > than PE rate)
- **PW** Vaccinated for pertussis but immunity has waned
  - L Low responder (vaccinated but antibody response low, not immune)
- N Non-responder (vaccinated but no antibody response, not immune, 7% of MMR recipients)
- ME Medically exempt not fully vaccinated

Immune Compromised

PE Philosophical exemption, could be fully vaccinated but missing only 1 dose (First grade PE rates: DTaP 2.6%, Polio 2.9%, MMR 3.1%, HepB 3.3%, Chicken Pox 4.3%)

*Removing students with PEs does NOT protect the immune compromised, is discriminatory and denies healthy children the right to a free public education.* 

| 2013-14 PUBLIC SCHOOLS DATA |            |                                     |                              |                              |                               |                                   | grade level data |           |                      |               |                     | 2013-14 PRIVATE SCHOOLS DATA |            |                                     |                              |                              |                               |                                   | grade level data |           |                      |             |                           |
|-----------------------------|------------|-------------------------------------|------------------------------|------------------------------|-------------------------------|-----------------------------------|------------------|-----------|----------------------|---------------|---------------------|------------------------------|------------|-------------------------------------|------------------------------|------------------------------|-------------------------------|-----------------------------------|------------------|-----------|----------------------|-------------|---------------------------|
|                             |            | DTaP/Tdap<br>Exempt<br>(Philosophic | Polio<br>Exempt<br>(Philosop | MMR<br>Exempt<br>(Philosophi | Hep B<br>Exempt<br>(Philosoph | Varicella<br>Exempt<br>(Philosoph | Exempt           | Exempt    | Exempt<br>Philosophi | i Provisional | Provisio<br>Admitta |                              |            | DTaP/Tdap<br>Exempt<br>(Philosophic | Polio<br>Exempt<br>(Philosop | MMR<br>Exempt<br>(Philosophi | Hep B<br>Exempt<br>(Philosoph | Varicella<br>Exempt<br>(Philosoph | Exempt           | Exempt    | Exempt<br>Philosophi | Provisional | Provisional<br>Admittance |
| Grade                       | Enrollment | al)                                 | hical)                       | cal)                         | ical)                         | ical)                             | Medical          | Religious | cal                  | Admittance    | no IZ Rec           | Grade                        | Enrollment | al)                                 | hical)                       | cal)                         | ical)                         | ical)                             | Medical          | Religious | cal                  | Admittance  | no IZ Record              |
| Kinder                      | 6304       | 159                                 | 181                          | 192                          | 205                           | 264                               | 9                | 8         | 333                  | 479           | 24                  | Kinder                       | 467        | 48                                  | 52                           | 56                           | 59                            | 57                                | 2                | 5         | 66                   | 57          | 17                        |
|                             |            | 36.05%                              | 39.78%                       | 38.95%                       | 62.88%                        | 43.42%                            | 0.14%            | 0.13%     | 5.28%                | 7.60%         | 0.38%               |                              |            | 48.00%                              | 52.00%                       | 54.90%                       | 62.11%                        | 53.27%                            | 0.43%            | 1.07%     | 14.13%               | 12.21%      | 3.64%                     |
| First                       | 6296       | 154                                 | 174                          | 179                          | 192                           | 260                               | 14               | 8         | 312                  | 156           | 5                   | First                        | 377        | 17                                  | 22                           | 25                           | 25                            | 30                                | 0                | 2         | 35                   | 23          | 0                         |
|                             |            | 65.25%                              | 67.18%                       | 71.03%                       | 74.13%                        | 73.03%                            | 0.22%            | 0.13%     | 4.96%                | 2.48%         | 0.08%               |                              |            | 54.84%                              | 62.86%                       | 64.10%                       | 67.57%                        | 56.60%                            | 0.00%            | 0.53%     | 9.28%                | 6.10%       | 0.00%                     |
| Second                      | 6,014      | N/A                                 | N/A                          | N/A                          | N/A                           | N/A                               | 21               | 3         | 297                  | 116           | 8                   | Second                       | 382        | N/A                                 | N/A                          | N/A                          | N/A                           | N/A                               | 1                | 3         | 38                   | 34          | 3                         |
|                             |            | N/A                                 | N/A                          | N/A                          | N/A                           | N/A                               | 0.35%            | 0.05%     | 4.94%                | 1.93%         | 0.13%               |                              |            | N/A                                 | N/A                          | N/A                          | N/A                           | N/A                               | 0.26%            | 0.79%     | 9.95%                | 8.90%       | 0.79%                     |
| Third                       | 6,264      | N/A                                 | N/A                          | N/A                          | N/A                           | N/A                               | 19               | 4         | 305                  | 125           | 10                  | Third                        | 410        | N/A                                 | N/A                          | N/A                          | N/A                           | N/A                               | 1                | 6         | 44                   | 31          | 7                         |
|                             |            | N/A                                 | N/A                          | N/A                          | N/A                           | N/A                               | 0.30%            | 0.06%     | 4.87%                | 2.00%         | 0.16%               |                              |            | N/A                                 | N/A                          | N/A                          | N/A                           | N/A                               | 0.24%            | 1.46%     | 10.73%               | 7.56%       | 1.71%                     |
| Fourth                      | 6,158      | N/A                                 | N/A                          | N/A                          | N/A                           | N/A                               | 21               | 6         | 246                  | 134           | 13                  | Fourth                       | 449        | N/A                                 | N/A                          | N/A                          | N/A                           | N/A                               | 1                | 2         | 50                   | 17          | 1                         |
| <b>5161</b>                 | 6.100      | N/A                                 | N/A                          | N/A                          | N/A                           | N/A                               | 0.34%            | 0.10%     | 3.99%                | 2.18%         | 0.21%               |                              |            | N/A                                 | N/A                          | N/A                          | N/A                           | N/A                               | 0.22%            | 0.45%     | 11.14%               | 3.79%       | 0.22%                     |
| Fitth                       | 6,109      | N/A                                 | N/A                          | N/A                          | N/A                           | N/A                               | 15               | 10        | 232                  | 11/           | 19                  | Fifth                        | 500        | N/A                                 | N/A                          | N/A                          | N/A                           | N/A                               | 4                | 2         | 52                   | 30          | /                         |
| Chath                       | 6.177      | N/A                                 | N/A                          | N/A                          | N/A                           | N/A                               | 0.25%            | 0.16%     | 3.80%                | 1.92%         | 0.31%               | et.ut.                       | 170        | N/A                                 | N/A                          | N/A                          | N/A                           | N/A                               | 0.80%            | 0.40%     | 10.40%               | 6.00%       | 1.40%                     |
| Sixtn                       | 6,177      | N/A                                 | N/A                          | N/A                          | N/A                           | N/A                               | 15               | 0.00%     | 220                  | 120           | 0.000               | Sixth                        | 4/8        | N/A                                 | N/A                          | N/A                          | N/A                           | N/A                               | 1                | 4         | 44                   | 32          | 6                         |
| Foundth                     | 6.140      | N/A                                 | N/A                          | N/A                          | N/A<br>105                    | N/A<br>122                        | 0.24%            | 0.08%     | 3.00%                | 1.94%         | 0.08%               | Courseth                     | 500        | N/A                                 | N/A                          | N/A                          | N/A                           | N/A                               | 0.21%            | 0.84%     | 9.21%                | 6.69%       | 1.26%                     |
| Seventh                     | 0,149      | 27.42%                              | 71 219/                      | 72 4 49/                     | 65.639/                       | 43.63%                            | 0.100/           | 9         | 201                  | 400           | 4                   | Seventn                      | 598        | 33                                  | 33                           | 32                           | 3/                            | 34                                | 2                | 1         | 4/                   | 09          | 14                        |
| Eighth                      | 6 170      | 27.4370                             | 71.2170                      | 73.4470                      | 104                           | 110                               | 12               | 0.1570    | 19/                  | 157           | 0.077               | Fichth                       | 633        | 42.5170                             | 33.00%                       | 30.14%                       | 35.06%                        | 42.50%                            | 0.55%            | 0.17%     | 7.00%                | 11.34%      | 2.3470                    |
| Lightin                     | 0,170      | 49.48%                              | 66.67%                       | 69.81%                       | 70.75%                        | 57.49%                            | 0.21%            | 0.11%     | 2 98%                | 2 54%         | 0.05%               | Lighth                       | 022        | 41 33%                              | 47.69%                       | 52.46%                       | 43.90%                        | 28 55%                            | 0.64%            | 0.64%     | 7.40%                | 17 38%      | 2 73%                     |
| Ninth                       | 6,292      | N/A                                 | N/A                          | N/A                          | N/A                           | N/A                               | 12               | 4         | 148                  | 152           | 14                  | Ninth                        | 1.074      | N/A                                 | N/A                          | N/A                          | N/A                           | N/A                               | 3                | 2         | 49                   | 75          | 2.7376                    |
|                             | -,         | N/A                                 | N/A                          | N/A                          | N/A                           | N/A                               | 0.19%            | 0.06%     | 2.35%                | 2.42%         | 0.22%               |                              | 2,074      | N/A                                 | N/A                          | N/A                          | N/A                           | N/A                               | 0.28%            | 0.19%     | 4.56%                | 6.98%       | 2.05%                     |
| Tenth                       | 6,169      | N/A                                 | N/A                          | N/A                          | N/A                           | N/A                               | 9                | 9         | 177                  | 138           | 25                  | Tenth                        | 1.235      | N/A                                 | N/A                          | N/A                          | N/A                           | N/A                               | 2                | 2         | 51                   | 99          | 36                        |
|                             |            | N/A                                 | N/A                          | N/A                          | N/A                           | N/A                               | 0.15%            | 0.15%     | 2.87%                | 2.24%         | 0.41%               |                              |            | N/A                                 | N/A                          | N/A                          | N/A                           | N/A                               | 0.16%            | 0.16%     | 4.13%                | 8.02%       | 2.91%                     |
| Eleventh                    | 6,176      | N/A                                 | N/A                          | N/A                          | N/A                           | N/A                               | 13               | 8         | 119                  | 125           | 12                  | Eleventh                     | 1,292      | N/A                                 | N/A                          | N/A                          | N/A                           | N/A                               | 4                | 1         | 31                   | 77          | 19                        |
|                             |            | N/A                                 | N/A                          | N/A                          | N/A                           | N/A                               | 0.21%            | 0.13%     | 1.93%                | 2.02%         | 0.19%               |                              |            | N/A                                 | N/A                          | N/A                          | N/A                           | N/A                               | 0.31%            | 0.08%     | 2.40%                | 5.96%       | 1.47%                     |
| Twelfth                     | 6,068      | N/A                                 | N/A                          | N/A                          | N/A                           | N/A                               | 14               | 4         | 113                  | 138           | 22                  | Twelfth                      | 1,230      | N/A                                 | N/A                          | N/A                          | N/A                           | N/A                               | 3                | 5         | 33                   | 66          | 14                        |
|                             |            | N/A                                 | N/A                          | N/A                          | N/A                           | N/A                               | 0.23%            | 0.07%     | 1.86%                | 2.27%         | 0.36%               |                              |            | N/A                                 | N/A                          | N/A                          | N/A                           | N/A                               | 0.24%            | 0.41%     | 2.68%                | 5.37%       | 1.14%                     |
|                             |            |                                     |                              |                              |                               |                                   |                  |           |                      |               |                     |                              |            |                                     |                              |                              |                               |                                   |                  |           |                      |             |                           |
| Total                       | 80,346     | 533                                 | 523                          | 539                          | 606                           | 766                               | 186              | 85        | 2,893                | 2,363         | 164                 | Total                        | 9,114      |                                     |                              |                              |                               |                                   | 28               | 39        | 586                  | 687         | 163                       |
|                             |            |                                     |                              |                              |                               |                                   |                  |           |                      |               |                     |                              |            |                                     |                              |                              |                               |                                   |                  |           |                      |             |                           |

- Total Enrollment: 89,460
- No. of children with an exemption\* on file = 3,479

= 3.88% of VT school children with an exemption\*

\*exemption could be for only one vaccine dose out of: 5 DTaP, 1 TdaP, 4 polio, 2 MMR, 3 HepB, 2 chickenpox

#### **MEASLES – pages 1-2**

#### WHOOPING COUGH – pages 2-5

#### **MEASLES / MMR VACCINE | Recent science**

**Response of Viral Specific CD4 T Cells to in vitro Stimulation with Vaccine and Wild Measles Virus Strains in Vaccinated and Naturally Infected Subjects:** "...it is increasingly being considered that antibody-based definitions of vaccine success or failure may be incomplete."— <u>Czescik et al, Polish Journal of Microbiology, 2014</u>

**Outbreak of measles among persons with prior evidence of immunity, New York City, 2011**: In the NYC outbreak of 2011, "The index patient had 2 doses of measlescontaining vaccine; of 88 contacts, 4 secondary patients were confirmed who had either 2 doses of measles-containing vaccine or a past positive measles IgG antibody." — <u>Rosen</u> <u>et al., Clinical Infectious Disease, 2014</u>

Largest Measles Epidemic in North America in a Decade—Quebec, Canada, 2011: Contribution of Susceptibility, Serendipity, and Super spreading Events: Detailed analysis of Quebec outbreak revealed under-diagnosis and under-reporting of measles in fully vaccinated persons. The mean age of case patients was 15 years and incidence was highest in adolescents and 20% of them had received 2-doses of vaccine as recommended. — De Serres et al., Journal of Infectious Disease, 2013

Waning of Maternal Antibodies Against Measles, Mumps, *Rubella, and Varicella in Communities With Contrasting Vaccination Coverage:* "Children of mothers vaccinated against measles and, possibly, rubella have lower concentrations of maternal antibodies and lose protection by maternal antibodies at an earlier age than children of mothers in communities that oppose vaccination. <u>This increases the risk of disease transmission in</u> <u>highly vaccinated populations</u>."— <u>Waaijenborg et al, Journal of Infectious Diseases, 2013</u>

**The Re-Emergence of Measles in Developed Countries: Time to Develop the Next-Generation Measles Vaccines?:** "Receiving less attention, however, is the issue of vaccine failure...At the same time, measles vaccine has a failure rate measured in a variety of studies at 2–10%...As a result, measles is re-emerging as a public health threat, and our current tool for prevention has limitations that increasingly look to be significant enough that sustained elimination, much less eradication, are unlikely."—Poland et al. <u>Vaccine</u>

Loss of maternal protection as a consequence of the vaccination program was well documented in the literature as recently as 2009.

**Implications of vaccination and waning immunity**: Implications of vaccination and waning immunity: "In the absence of vaccination, lifelong immunity is maintained through frequent encounters with infection, which act to boost the waning immune memory (this agrees with the findings of Whittle et al. 1999). However, when vaccination is introduced the prevalence of infection declines, which in turn reduces the amount of boosting and hence the level of immunity (in agreement with Muller 2001). What is more

surprising is that the interaction between <u>vaccination and waning immunity can lead to</u> pronounced epidemic cycles in which the peak levels of infection can be of the orders of magnitude greater than the mean."—<u>Heffernan and Keeling, Proceedings of the Royal</u> Society B, 2009

**Modeling the Impact of Subclinical Measles Transmission in Vaccinated Populations** with Waning Immunity: "Several studies have shown that measles epidemics can occur even in highly vaccinated populations (1-4). A variety of factors are likely to be contributory to this observation including failure to seroconvert and waning of vaccineinduced immunity (5). It is well documented from outbreak investigations that current measles vaccines protect between 90-95 percent of vaccinees from typical measles (3, 6-8). However, evidence is accumulating which suggests that vaccine derived immunity might be less protective than previously assumed. There is a growing concern that among individuals who respond to vaccine, a substantial proportion are or will become susceptible to clinical (symptomatic) or subclinical (asymptomatic) infection."— Mossing, et al, Americal Journal of Epidemiology, 1999,

**The future of measles in highly immunized populations. A modeling approach**: "The results of this study suggest that measles elimination in the United States has been achieved by an effective immunization program aimed at young susceptibles combined with a highly, naturally immunized adult population. However, despite short-term success in eliminating the disease, long-range projections demonstrate that the proportion of susceptibles in the year 2050 may be greater than in the pre-vaccine era. Present vaccine technology and public health policy must be altered to deal with this eventuality." — Levy, Am J Epidemiol (1984)

#### WHOOPING COUGH/ DTap VACCINE | Recent science

"The advantages and disadvantages of routine immunization of infants against whooping cough have been debated since 1933" <u>British Medical</u> <u>Journal Editorial, 1974</u>.

- <u>Martin et al, Clin Infect Diseases, 2015</u>: Patients who had received at least one dose of vaccine had a significantly higher odds of having PRN- B pertussis compared with unvaccinated patients.

Acellular pertussis vaccines protect against disease but fail to prevent infection and transmission in a nonhuman primate model: In this study, whooping cough vaccine failed to prevent infection & transmission in animal testing. Vaccinated animals asymptomatically carried the infectious bacteria for 42 days, longer than any of the other groups studied (including infected but unvaccinated animals). The infected but unvaccinated animals did not carry the bacteria upon re-infection. — Warfel et al., Proceedings of the National Academy of Science, 2014:

**Rapid Increase in Pertactin-deficient** *Bordetella pertussis* Isolates, Australia: Rapid Increase in Pertactin-deficient Bordetella pertussis Isolates explains that evolution of B. pertussis may be occurring in response to "vaccine selection pressure."—CDC <u>http://wwwnc.cdc.gov/eid/article/20/4/13-1478\_article.htm</u> CDC April 2014

"Clearly it is a red light in terms of how well the vaccination works," said Peter McIntyre, study author and director of the National Centre for Immunisation Research and Surveillance of Vaccine Preventable Diseases. "The fact that they have arisen independently in different countries suggests it's a response to the vaccine," said Ms Lam, of the University of NSW school of biotechnology and biomolecular sciences.

Summer 2014 <u>Statement from Professor Arthur Reingold</u>, Head of Epidemiology at UC Berkeley's School of Public Health:

"You can be immunized and protected against getting the disease, pertussis, but still have the organism in your nose and throat and spread it to others. Or you can have a very mild illness that is caused by pertussis that causes you to cough, and thereby infect others. So the immunity is not 100 percent from the pertussis vaccine. And what it means is any kind of herd immunity—the way we see, for example, much more powerfully with measles—really can't be relied upon."

Resurgence of Pertussis. As reported at the May 2013 BSC meeting, the recent resurgence in pertussis cases has been associated with waning immunity over time in persons who received the acellular pertussis vaccine (which is administered as the pertussis component of DTaP vaccine). However, a recent study suggests another explanation for decreased vaccine effectiveness: an increase in *Bordetella pertussis* isolates that lack pertactin (PRN)--a key antigen component of the acellular pertussis vaccine. A study that screened *B. pertussis* strains isolated between 1935 and 2012 for gene insertions that prevent production of PRN found significant increases in PRN-deficient isolates throughout the United States.<sup>2</sup> The earliest PRN-deficient strain was isolated in 1994; by 2012, the percentage of PRN-deficient isolates was more than 50%.

To assess the clinical significance of these findings, CDC used an IgG anti-PRN ELISA and other assays (PCR amplification, sequencing, and Western blots) to characterize 752 *B. pertussis* strains isolated in 2012 from six Enhanced Pertussis Surveillance Sites<sup>3</sup> and from epidemics in Washington and Vermont. Findings indicated that 85% of the isolates were PRN-deficient and vaccinated patients had significantly higher odds than unvaccinated patients of being infected with PRN-deficient strains. Moreover, when patients with up-to-date DTaP vaccinations were compared to unvaccinated patients, the odds of being infected with PRN-deficient strains increased, suggesting that PRN-bacteria may have a selective advantage in infecting DTaP-vaccinated persons.

Above is from: Meeting of the Board of Scientific Counselors, Office of Infectious Diseases, Centers for Disease Control and Prevention. Tom Harkins Global Communication Center, Atlanta, Georgia: February 2013 Statement made at the National Vaccine Advisory Committee meeting from Pertussis Epidemiology and Vaccination in the United States (Thomas Clark, M.D., M.P.H. of the CDC) <u>http://www.hhs.gov/nvpo/nvac/meetings/2013/feb2013\_certified\_minutes.pdf</u>

"Dr. Clark also did not believe the problem is related to unvaccinated children, because it occurred nationally and is widespread, and because the majority of those affected were vaccinated. CDC is discussing whether a single repeat Tdap dose would be effective. There is potential for developing new or improved vaccines to better control pertussis in the long term, Dr. Clark concluded."

<u>Pertussis: Challenges Today and for the Future</u>, 2013: According to expert Dr. James Cherry, the universal use of pertussis vaccines has been associated with genetic changes

in circulating B. pertussis strains. —Cherry et al., <u>http://www.plospathogens.org/article/info%3Adoi%2F10.1371%2Fjournal.ppat.1003418</u>

"There are five possible reasons for the resurgence: 1) genetic changes in B. pertussis; 2) a decrease in vaccine efficacy; 3) a more rapid occurrence of waning immunity; 4) increased recognition and reporting of pertussis; and 5) newer laboratory diagnostic tests."

- <u>Klein, et al, N Eng J Med 2012</u>, Waning Protection after Fifth Dose of Acellular Pertussis Vaccine in Children

## The following additional information was already shared with Vermont Legislators in 2012:

#### USA/Washington

"Early waning of immunity might be contributing to increasing population-level susceptibility." <u>http://jama.jamanetwork.com/article.aspx?articleid=1362036</u>

#### USA/California

"In early 2010, a spike in cases appeared at Kaiser Permanente in San Rafael, and it was soon determined to be an outbreak of whooping cough -- the largest seen in California in more than 50 years. Witt had expected to see the illnesses center around unvaccinated kids, knowing they are more vulnerable to the disease. "We started dissecting the data. What was very surprising was the majority of cases were in fully vaccinated children. That's what started catching our attention," said Witt. <u>http://www.reuters.com/article/2012/04/03/us-whoopingcough-idUSBRE8320TM20120403</u>

#### <u>Israel</u>

"Pertussis is considered an endemic disease, characterized by an epidemic every 2–5 years. This rate of exacerbations has not changed, even after the introduction of mass vaccination – a fact that indicates the efficacy of the vaccine in preventing the disease but not the transmission of the causative agent (B. pertussis) within the population."<u>http://www.ima.org.il/imaj/ar06may-2.pdf</u>

#### Netherlands

"An important issue is whether vaccination has selected for the *ptxP3* strains. Several lines of evidence support this contention." "Based on mathematical modeling, vaccines designed to reduce pathogen growth rate and/or toxicity may result in the evolution of pathogens with higher levels of virulence" The authors "propose that waning immunity and pathogen adaptation have contributed to the resurgence of pertussis, although other factors such as increased awareness and improved diagnostics have also played a role."<u>http://wwwnc.cdc.gov/eid/article/15/8/08-1511\_article.htm</u>

#### **Finland**

"Pertussis is an infectious disease of the respiratory tract caused by *Bordetella pertussis*. Despite the introduction of mass vaccination against pertussis in Finland in 1952, pertussis has remained an endemic disease with regular epidemics." and "During the last decade, the number of pertussis cases has increased in countries with high vaccination coverage rates including Finland."<u>http://www.ncbi.nlm.nih.gov/pmc/articles/</u> PMC1233997/

"Reemergence of pertussis has been observed in many countries with high vaccination coverage. In the United States, reported cases of pertussis in adolescents and adults have increased since the 1980s, despite increasingly high rates of vaccination in infants and children. At the same time, clinical *B. pertussis* isolates have become antigenically divergent from vaccine strains. This observation has raised the question of whether vaccination has caused selection for the variant strains, and whether the reemergence of pertussis in vaccinated populations is due to vaccination not protecting against these antigenic variants as effectively as it protects against vaccine type strains. On the other hand, vaccine-induced immunity wanes over time, and pertussis is not only a childhood disease but also a frequent cause of prolonged illness in adults and adolescents today."<u>http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3294326/</u>