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IRRC

The Pennsylvania Coalition for Informed Consent submits these comments concerning proposed regulations to 28 PA Code Ch.23:
3147 from the PA Department of Health
#3146 from the PA Department of Education (an identical submission of 3147 but submitted through the Dept of Ed.)

As the detailed proposal text is included in #3147, these comments correlate with the sections outlined in the form provided by the IRRC. References to "the Department" within this document refer to the Department of Health.

The Pennsylvania Coalition of Informed Consent is concerned about many aspects of these proposed regulation changes regarding school immunization in Pennsylvania.

The Department has decided to take action to correct statistical errors caused by years of insufficient data collection through the Department's flawed reporting system (which required data to be reported seven months before the students final deadline to turn their paperwork in to the schools). We are strong believers in facts and accuracy so we commend the Department for taking action to correct this important reporting error by shortening the provisional period and moving the reporting date back. We do not feel that it is appropriate for the Department to use this opportunity to increase the number of mandatory vaccinations or change the accepted proof of immunity for certain diseases. The reporting error should be corrected first, and then, after ACCURATE data is available, the Department should analyze these findings and determine if any further changes need to be proposed.

The Department cites a need for "herd immunity" as its reason for the introduction of new vaccines. They do not quantify exactly what the criteria is to achieve this goal. The original theory of herd immunity based on a study where 55% of the population had attained natural immunity to measles which then seemed to protect the remaining 45%.

Inspired by this discovery, the U. S. Public Health Service planned to vaccinate over 55% of the population against measles in the 1960s, fully expecting to eradicate it by 1967. When outbreaks continued, target

vaccination rates were increased to 70-75%, then 80%, and 90%,¹ to the current goal of 95%². In communities with 99% vaccine compliance, outbreaks still occur³.

The original herd immunity theory was founded on communities which had attained natural immunity through the course of an infection, not those with vaccine-induced response. Historically, children would experience illnesses from wild virus exposure, and non-vaccinated adults were naturally re-exposed to the wild virus as they cared for sick children, thus boosting the adults' natural immunity⁴. This type of immunity is generally lifelong and can be transmitted from mothers to infants through breastfeeding, in this way protecting them until they are old enough to acquire the wild virus naturally and begin building their own lifelong immunity.

Vaccines DO NOT replicate this natural cycle because:

- Mothers who received vaccines can have a lower concentration of virus-specific antibodies than mothers with naturally acquired immunity. For example, infants born to measles-vaccinated mothers have lower levels of maternal antibodies at birth and a shorter period of protection than infants of mothers who acquired measles naturally⁵.
- As viruses mutate over time, static vaccines offer limited protection from evolving disease strains⁶.
- Vaccine immunity is temporary and frequently ineffective, with up to 76% of people not responding to repeated vaccinations⁷. Populations with near 100% vaccination compliance are still experiencing outbreaks⁸. In 18 different measles outbreaks in North America, vaccinated children constituted 30%-100% of the measles cases⁹.
- Vaccination sometimes shifts disease occurrences from childhood to more vulnerable age groups, infants and the elderly, where they can be more serious¹⁰.
- Even after six doses of Tdap (Tetanus, Diphtheria, Pertussis), vaccine effectiveness declined to 34% after 2-4 years, likely contributing to increases in Pertussis among adolescents¹¹.

The Department also states that vaccine rates were found to be “lower than optimal.” This is vague and should be quantified.

The Department states that polio has not been eradicated, and while that is true globally, it has been declared eliminated in the US since 1979¹².

(7) The Department refers to children who are “medically unable to obtain a vaccination.” What is the average number of children in Pennsylvania who are in this category? The CDC is seeking to severely limit which conditions are eligible for a medical exemption.¹³ Requiring someone else to undergo a medical procedure that carries inherent risks for the sake of another individual is a novel concept in the United States where individual rights have always been honored. Upending this foundational principle should not be taken cavalierly. (12) We note that no surrounding states have a provisional period as short as five days. The average provisional period of nearby states is 58 days. We ask that the provisional period be changed from 240 days to 60 days.

¹https://www.researchgate.net/publication/11686637_Evaluating_the_benefits_of_increasing_measles_immunization_rates

² <http://business.financialpost.com/fp-comment/junk-science-week-vaccinating-the-herd>

³³ <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3930734/>

⁴ <http://www.vaccinationcouncil.org/2012/07/05/herd-immunity-the-flawed-science-and-failures-of-mass-vaccination-suzanne-humphries-md-3>

⁵ <https://jid.oxfordjournals.org/content/early/2013/04/29/infdis.jit143.full>

⁶ <https://www.sciencedaily.com/releases/2015/06/150625130251.htm>

⁷ <http://www.ncbi.nlm.nih.gov/pubmed/22423127>

⁸ <http://www.greenmedinfo.com/blog/2013-measles-outbreak-failing-vaccine-not-failure-vaccinate1>

⁹ <http://www.ncbi.nlm.nih.gov/pubmed/8053748>

¹⁰ <http://health.usnews.com/health-news/patient-advice/articles/2014/12/18/how-to-deal-with-childhood-diseases-as-an-adult?page=2>

¹¹ <http://dx.doi.org/10.1542/peds.2014-3358>

¹² <http://www.cdc.gov/polio/us/index.html>

¹³ <http://www.nvic.org/nvic-vaccine-news/may-2015/blackmail-and-the-medical-vaccine-exemption.aspx>

Also, the paragraph implies that the only other state with a 240-day provisional period has a high MMR rate because they do not have a religious/philosophical exemption. The Department states in (10) that PA schools have a “relatively low number of medical, philosophical, and religious exemptions”, further proving that the low vaccination rates are a reporting error and have nothing to do with exemptions, and therefore this statement should be removed as it misleads the reader to think that exemptions are a factor in these MMR percentage statistics, which they are not.

(14) Solicitation of input from the public were not carried out in a manner that would allow the most affected parties – parents of school age children in PA – to participate and comment. Publishing a notice of a public meeting in the PA bulletin is insufficient advertising to reach the public. Parents will be affected and have not been properly involved in the process as the law and regulations suggest they should. Although technically following procedure, the Department should have advertised more broadly to parents as to how they could comment.

(15) As noted here, ALL students in PA are affected by these changes, including those who homeschool and cyber school. Students who do not attend a traditional public school should be exempt from following the immunization regulations as they will not be contributing to the schools’ “herd immunity”. Most other states do not require home educated students to abide by these regulations. It does not follow the logic of the herd immunity defense. Pennsylvania is one of only four states to require homeschoolers to provide proof of immunity to state officials. (17) The Department describes the manner in which each party will be financially impacted by these changes but does not do its due diligence in providing any actual data. We feel that this is a very important question and that it needs to be addressed in detail with numbers as the financial and economic impact of this, with co-pays, lost work hours, lab fees, more reporting procedures and personnel hours, will easily total several million dollars, which is most definitely significant and warranting further exploration.

(18) The Department fails to describe any adverse effects from the introduction of these regulations. This is unsatisfactory. When medical procedures and children are in play, every detail must be considered.

In regards to mandating an additional meningococcal vaccine for 12th grade entry, these factors must also be considered:

According to the CDC Pink Book, the meningococcal bacteria become invasive only rarely. “In a small proportion (less than 1%) of colonized persons, the organism penetrates the mucosal cells and enters the bloodstream.” The CDC states that all serogroups of the disease are on the decline. Serogroup B, not included in the vaccine, declined along with the serogroups included in the vaccine “for reasons that are not known.” Also, “The communicability of *N. meningitidis* is generally limited. In studies of households in which a case of meningococcal disease has occurred, only 3%-4% of households had secondary cases.” Furthermore, “In the United States, meningococcal outbreaks account for less than 2% of reported cases (98% of cases are sporadic).” Therefore, transmission in the school setting is very unlikely. The disease is extremely rare. The incidence rate for meningococcal disease, according to the CDC, is 0.3-0.5/100,000¹⁴

- Meningococcal Disease is very rare in the United States. In our population of 308 million, there are between 1400 and 3000 cases every year that fluctuate with natural cycles¹⁵. Between 10 and 15% of the cases are fatal with another 10 to 20% ending with brain damage or loss of limbs.

¹⁴<http://www.cdc.gov/vaccines/pubs/surv-manual/chpt08-mening.html>.

¹⁵AAP Committee on Infectious Diseases. Prevention and Control of Meningococcal Disease: Recommendations for Use of Meningococcal Vaccines in Pediatric Patients. Pediatrics August 1, 2005; 116(2): 495-505.

- According to the Department's EDDIE database system, in 2014, there were only 16 newly diagnosed cases of meningitis in Pennsylvania.
- It is not easy to develop invasive meningococcal disease¹⁶. You must be susceptible and have regular close personal contact, such as sharing a toothbrush with or kissing person, who is colonizing meningococcal organisms.
- The federal Vaccine Adverse Events Reporting System (VAERS), which includes only a small fraction of the health problems that occur after vaccination in the U.S.^{17,18}, reports 1799 severe adverse effects resulting from the meningococcal vaccine, which only began use in 2005¹⁹. When the Haemophilus influenzae type B vaccine (HIB) is included, that number jumps to 62,676 has recorded more than 2,000 serious health problems, hospitalizations and injuries following meningococcal shots, including 33 deaths with half of the deaths occurring in children under age six³⁴.
- The manufacturer product inserts for meningococcal vaccine list the following adverse events reported during clinical trials or post licensure: irritability, abnormal crying, fever, drowsiness, fatigue, injection site pain and swelling, sudden loss of consciousness (syncope), diarrhea, headache, joint pain, Guillain Barre Syndrome, brain inflammation, convulsions, and facial palsy^{20 21 22}.
- The vaccine only has an 80-85% efficacy rate²³. After two years to five years, the vaccine has been found to be, at best, only about 58 percent effective^{24 25}.
- There are 5 distinct different types of meningitis²⁶. However, the CDC recommended dose of meningococcal vaccine only contains four strains of the bacterial type (A, C, W-35, Y)²⁷ The vaccine does not contain strain B, which is the strain associated with more than 50 percent of meningococcal cases and deaths²⁸, especially in children under five years old²⁹.
- The meningitis vaccines contain neurotoxins such as formaldehyde, aluminum hydroxide, polysorbate 80, and thimerosal (multi-dose vial only) among others³⁰ and contains inherent risk as it is an invasive medical procedure with documented side effects³¹.
- At any given time, up to 20 to 40% of the population is asymptotically colonizing meningococcal organisms in our nasal passages and throats, which boosts our innate immunity to invasive bacterial infection^{32 33}.
- By the time American children enter adolescence, the vast majority have asymptotically developed immunity that protects them.
- PA already mandates 25 doses of 12 vaccines³⁴.

¹⁶CDC. Meningitis Questions & Answers.

¹⁷Braun M. Vaccine adverse event reporting system (VAERS): usefulness and limitations. Johns Hopkins Bloomberg School of Public Health.

¹⁸Rosenthal S, Chen R. The reporting sensitivities of two passive surveillance systems for vaccine adverse events. *Am J Public Health* 1995; 85: pp. 1706-9.

¹⁹<http://www.medalerts.org/vaersdb/findfield.php>

²⁰Sanofi-Pasteur. Menactra Product Information Insert.

²¹Novartis. Menveo Product Manufacturer Insert.

²²Sanofi Pasteur. Menommune Product Manufacturer Insert.

²³<http://www.ncbi.nlm.nih.gov/pubmed/21206392>

²⁴CDC. Updated Recommendations for Use of Meningococcal Conjugate Vaccines – ACIP, 2010. *JAMA* 2011; 305(13): 1291-1293.

²⁵Cohn A. Epidemiology of Meningococcal Disease in the U.S. Presentation to the FDA Vaccines & Related Biological Products Advisory Committee (VRBPAC). Transcript of April 6, 2011 Meeting. Pg 55-59.

²⁶<http://www.musa.org/faq>

²⁷CDC. Meningococcal Disease and College Students. *MMWR* June 30, 2000; 48(RR07): 11-20.

²⁸CDC. Meningococcal Disease and College Students. *MMWR* June 30, 2000; 48(RR07): 11-20.

²⁹Cohn A. Epidemiology of Meningococcal Disease in the U.S. Presentation to the FDA Vaccines & Related Biological Products Advisory Committee (VRBPAC). Transcript of April 6, 2011 Meeting. Pages 50-52.

³⁰<http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf>

³¹<http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM131170.pdf>

³²Tan L KK, Cadone GM, Borrow R. Advances in the development of vaccines against Neisseria meningitidis. *NEJM* April 22, 2010; 362(16): 1511-1520.

³³Manchanda V. Gupta S., Bhalla P. Meningococcal Disease: History, Epidemiology, Pathogenesis, Clinical Manifestations, Diagnosis, Antimicrobial Susceptibility and Prevention. *Indian Journal of Medical Microbiology* 2006; 24(1): 7-19

³⁴http://www.portal.state.pa.us/portal/server.pt/community/immunizations/14141/school_children_immunizations/557995

- The Meningococcal vaccine is currently available to anyone who would like to use it. Earlier this year, proposed SB 797 sought to add this exact vaccine to the list of necessary vaccines for school aged children and it failed in the legislature. The legislature had their chance to add it and they did NOT. It is not appropriate for the DOH to try to circumvent the legislative process by adding it in this way.

In regards to requiring additional pertussis vaccines, it must also be noted that the Herd Immunity theory can only apply to communicable diseases with vaccines that prevent transmission. A 2013 study by Warfel et al concludes that the current acellular pertussis vaccine does not prevent colonization or transmission³⁵. The FDA stated in a press release following this study that “This research suggests that although individuals immunized with an acellular pertussis vaccine may be protected from disease, they may still become infected with the bacteria without always getting sick and are able to spread infection to others, including young infants who are susceptible to pertussis disease.”³⁶ In light of this, the pertussis vaccine in use today is inherently unable to meet the criteria for herd immunity theory. As the vaccine is currently under scrutiny for lack of efficacy, we do not feel that it is appropriate to add it to the requirements.³⁷ We also feel very strongly that the pertussis vaccine should remain as a separate section in the regulations because it is highly possible that the vaccine type or procedure used may be altered in the near future and combining it with the Tetanus and Diphtheria antigens in one paragraph will make future changes more difficult while creating no notable benefit now.

(19)(21) These questions is glossed over and not adequately answered. According to a thorough CDC study, the average cost of a pertussis outbreak is approximately \$2,172 per case. In 2014, PA had 813 reported cases of pertussis. Approximately 50% of those are in school aged individuals. The total cost based on these numbers is \$882,918³⁸.

Rather than do its own research, the Department borrows data based on a CA measles outbreak while skimming over the actual costs that will be incurred by the state by simply stating that “The Commonwealth would incur some costs...” These costs need to be specifically addressed. Also, it is incomplete to calculate costs of a vaccine program without including the costs incurred due to adverse reactions to the vaccines which can include Guillian Barre Syndrome, encephalopathy, and paralysis, all of which require a lifetime of care at a high cost to both the family and the state.

(22)Proof of natural immunity for chicken pox through having contracted the disease must now be provided by a Medical Doctor, Physician’s Assistant, or Nurse Practitioner.

This is objectionable for several reasons. It is irresponsible of the Department to insist that a child with a highly contagious, though generally mild disease, visit a medical facility where other children, including those who are medically fragile, will likely be present and thus at high risk to contract it. Not all families have existing relationships with the list of specified medical workers, and this provision could force a family to enter into a new contractual relationship with unknown medical staff within a few days. Most families will also have the financial burden of all charges, or co-pays as well as laboratory fees. Lastly, we feel that this creates an environment of distrust between the school staff and the parents as the parents’ word is questioned. The ability of parents to give medical history of chicken pox should not be removed.

(23) As per the paragraph of explanation following the chart (which contains no data), the box allocated for estimated cost to the state government, the total should read AT LEAST \$1,701,253. The CDC Pink Book lists

³⁵<http://www.ncbi.nlm.nih.gov/pubmed/24277828>

³⁶<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm376937.htm>

³⁷<http://www.npr.org/sections/health-shots/2015/05/05/404407258/whooping-cough-vaccines-protection-fades-quickly>

³⁸<http://www.cdc.gov/pertussis/downloads/pertuss-surv-report-2014.pdf>

results of clinical trials of Menactra (MenACWY-D). Of all reported MenACWY-D events, 6.6% were coded as serious (i.e., resulted in death, life-threatening illness, hospitalization, prolongation of hospitalization, or permanent disability). Serious events included headache, fever, vomiting, and nausea. A total of 24 deaths (0.3%) were reported.³⁹

If the 147,040 twelfth graders are given Menactra vaccine, can we expect 6.6% (9,704) to experience serious side effects and .3% of that number (29) to die? Clearly, this mandate will most benefit vaccine manufacturers, who just happen to have offices in Pennsylvania. The Department did not include care costs for the estimated 9,704 students who could suffer an adverse reaction to the vaccine. Clearly, this could easily amount to millions more as many of the reactions will cause lifelong health problems.

The box allocated for estimated cost to regulated population should include co-pays for at least 868,823 students (those not eligible for the Vaccines for Children program), as students entering 12th grade previously had no other requirement for a doctor's visit (such as a physical or other vaccinations) and thus will incur the office visit fee estimated at \$20. This totals \$17,376,460. The Department mentions that over 50% of students are eligible for the Vaccines for Children program, but they do not say how many are using it. More economic data and details about the popularity and funding of this program is requested.

(28) Because we do know that the total percentage of students filing vaccine exemptions is approximately only 3%, we must realize that the low rate of MMR % vaccination for kindergarteners is substantially inaccurate. It would seem that the responsible thing to do in light of these errors is to correct the reporting and then, based on ACCURATE data, determine whether further action is necessary to reach the (unspecified) herd immunity goal.

Annex A Section 23.83

1. Combination vaccines are listed instead of single antigens. For clarity and any future vaccine changes, we ask that the Department list each vaccine individually. Contraindications to the pertussis vaccine are listed for initial school entry, but not for the newly proposed 7th grade Tdap. Allowances for students with contraindications to pertussis should be listed.
2. Poliomyelitis. The Department listed that "oral polio vaccine or enhanced activated polio vaccine" be given. This should be changed to enhanced inactivated polio vaccine.
3. iii The Evidence of immunity statement is not clear. We request that each vaccine be listed separately along with clear guidelines as what can be submitted as evidence of immunity (laboratory testing, parental verification, medical personnel verification).

Section 23.85

1. Children with no previous vaccines could be required to receive 9-10 vaccines within 5 days of school starting if the Department is successful in lowering the provisional period to their request. Giving any child this many vaccines in a 5 day period could easily overwhelm their system which is another reason that 60 days should be the minimum provisional period.
2. Students who are transferring are only allowed 30 days to get their immunization records to the school. In some cases, 30 days might not be enough time and students may be pressured to get duplicate vaccines. We request that all transferring students are given 60 days to complete the transfer before being barred from school.

The Department only offers data relating to the change in provisional period. They MUST be made to provide data for their reasoning to increase the number of required vaccines. The proposal to force a medical procedure on every student in the Commonwealth is a very serious undertaking and MUST be considered with the utmost scrutiny. We ask that data be provided also relating to proof of immunity. Is there data showing that written

³⁹ <http://www.cdc.gov/vaccines/pubs/pinkbook/mening.html>

notes from parents stating their child had the chicken pox have been found to be untrue? Is there data showing that parents are no longer capable of identifying chicken pox?

Every aspect of the proposed changes MUST be supported by data. Again, we find the Department to be vague and lacking in their answer to the question posed by IRRC.

Currently, each school district creates its own language in communicating with parents regarding vaccine requirements, provisional periods, and reporting. Schools regularly misinform parents by not advising them that medical and religious exemptions are available. We request that the regulations be amended to require ALL schools to use uniform language provided by the Department of Health which will include the text of 28 PA CODE CH.23 stating the accepted medical and religious exemptions for PA students.

In closing, we would like to urge all oversight personnel to comb through these comments and consider the seriousness of the matter. Mandating medical procedures that carry risks for ALL Pennsylvania students is not something to be taken lightly. The implications of these regulations will have serious impacts on the majority of PA families as well as the Commonwealth itself.

Sincerely,

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