## 3147

FORM Letter H II

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IRRC

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To: IRR

**Subject:** Comments regarding IRRC #3146 & 3147

#### #1 - Change reporting deadline from October 15 to December 31. We support this change.

The later reporting date will give the DOH additional time to prepare more accurate records.

### #2 -Decrease the provisional period for student enrollment from 240 days to 5 days. We oppose this change.

While we support shortening the provisional period in an effort to correct reporting failures and ascertain accurate data, we find this change to be extreme. NO nearby states have such short provisional periods; their average is 58 days. Five days is not enough time to schedule appointments or for students who may be sick to recover before getting vaccinated. Parents will face stress and unnecessary expense as they make appointments and submit paperwork. A 60 day provisional period will give parents and sick children time to meet the requirements without undue stress. Given the later reporting date, a 60 day provisional period would not interfere with school data collection and analysis.

# #3 - Proof of natural immunity for chicken pox through having contracted the disease must now be provided by a doctor, physician's assistant, or nurse practitioner. <u>We oppose this change.</u>

It is irresponsible for the DOH to insist that a highly contagious child visit a medical facility where other children, including the medically fragile, will likely be present for the sole purpose of receiving an official chicken pox diagnosis. This move could increase the spread of the disease. 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 during a stressful time. Most families will also have the financial burden of all charges, or co-pays as well as laboratory fees. Additionally, this requirement creates an environment of distrust between the school staff and the parents as the parents' word is questioned.

#### #4 - Addition of Meningococcal vaccine for students entering 12th grade. We oppose this change.

The addition of this vaccine is not only unnecessary but would significantly raise costs and risks that far outweigh any possible benefit. The disease is extremely rare; the incidence rate for meningococcal disease, according to the CDC, is 0.3-0.5/100,000. According to the PA Department of Health EDDIE database, in 2014, there were only 16 new cases of meningitis. Vaccinating the estimated 147,040 seniors in 2014, would have cost parents and taxpayers over \$16,000,000. The CDC states that all serogroups of the disease are on the decline, including serogroup B, which is not even included in the vaccine

Earlier this legislative session, a bill was introduced to mandate this vaccine for students entering 12th grade. The legislature did not see the necessity of such a mandate and thus chose not to act. The Department of Health is seeking to circumvent the legislative process in enforcing mandates that are not supported by lawmakers. This vaccine is already available to anyone who wants it.

According to <u>vaccine manufacturer package inserts</u>, post marketing surveillance for the meningitis vaccine has shown the following: hypersensitivity reactions such as anaphylaxis/anaphylactic reaction, wheezing, difficulty breathing, upper airway swelling, urticaria, erythema, pruritus, hypotension, Guillain-Barré syndrome, paraesthesia, vasovagal syncope, dizziness, convulsion, facial palsy, acute disseminated encephalomyelitis, transverse myelitis, and myalgia.

### #5 - Inclusion of Pertussis vaccine for kindergarten admission. We oppose this change.

We are currently seeing outbreaks of pertussis among fully vaccinated populations. The CDC and top doctors are verifying the lack of efficacy and the early waning of any immunity provided by this vaccine. In February 2016, The American Academy of Pediatrics published that Tdap provided moderate defense against the illness (pertussis) during the first year after vaccination but not much longer. Immunity waned during the second year, and little protection remained 2 to 3 years after vaccination. It seems hasty to add a vaccine that is currently under scrutiny from the medical community to the requirements.

Meningitis and Tdap vaccines are pharmaceutical products that carry a risk of injury or death, a fact that was acknowledged by the U.S. Congress in 1986 when it passed the National Childhood Vaccine Injury Act. Since 1988, the federal vaccine injury compensation program created under that law has awarded more than \$3.2 billion to children and adults injured by vaccines or to families whose loved ones died from vaccine reactions, although two out of three who apply are denied compensation. The Institute of Medicine in a series of reports on vaccine safety spanning 25 years has acknowledged there is individual susceptibility to vaccine reactions for genetic, biological and environmental reasons that have not been fully defined by science, and doctors often cannot predict ahead of time who will be harmed. Long standing gaps in vaccine safety research and emerging evidence that certain vaccines do not prevent infection or transmission of disease, urgently require legal protection of physician's rights and parental rights regarding medical and religious exemptions to vaccination for minor children.

Vaccine Manufacturers for Meningitis Vaccines Have No Civil Liability. The 1986 law partially shielded drug companies selling vaccines in the U.S. from civil liability and, in 2011, the <u>US Supreme Court</u> completely shielded vaccine manufacturers from liability for FDA licensed and CDC recommended vaccines. There is no product liability or accountability for pharmaceutical companies marketing federally recommended and state mandated vaccines that injure Americans or cause their death, which makes <u>flexible medical and non-medical vaccine exemptions in vaccine policies and laws</u> the only way Americans can protect themselves and their children from vaccine risks and failures.

#6 - The DOH proposes to edit the current regulations by eliminating separate listings for measles, mumps, rubella, tetanus, diphtheria, and pertussis vaccines that are currently most commonly consumed as combination shots. Instead, they will only be listed in the regulations in their combination forms - MMR and TDaP. Evidence of Immunity is different for some of the vaccines and the proposed regulations are unclear. We oppose this change.

We feel that all antigens should be listed individually. This will simplify the amendment process should these combinations change in the future. We also want to ensure accuracy in data collection and publication. Some of these vaccines are still available singularly, and so listing each antigen individually is best and should not be changed. Each disease should individually list what can be given as evidence of immunity.

# #7 - There is no requirement for standardized language in communications regarding vaccine requirements. Change Requested.

Currently, each school district creates its own language in communicating with parents regarding vaccine requirements, provisional periods, and reporting. We request that the regulations be amended to require all schools to use uniform language provided by the DOH which will include the text of 28 PA CODE CH.23 stating the accepted exemptions for PA students.

#### #8 - Annex A lists enhanced "activated" polio vaccine. Change Requested.

This is incorrect and should be changed to enhanced "inactivated" polio vaccine.

#### #9 - Herd Immunity claims are given without clarification or verification. Change Requested.

**Comment:** The Department of Health bases their reasoning for increasing vaccination mandates on the theory of herd immunity which was first developed when studying individuals who had the wild diseases, not those who had been vaccinated. Disease outbreaks continue to occur in populations that have reached 100% vaccination rates, rendering this theory unreliable for massive vaccination requirements.

Thank you,