

3147

RECEIVED  
IRRC

Kathy Cooper

**From:** Cynthia Stolten <cindystolten@gmail.com>  
**Sent:** Saturday, May 07, 2016 1:36 PM  
**To:** IRRC  
**Cc:** cfindley@pa.gov; ra-stateboardofed@pa.gov  
**Subject:** 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.)

2016 MAY -9 AM 9:31

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.

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

Comment: 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. Oppose this change.

Comment: 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. Oppose this change.

Comment: 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. Oppose this change.

Comment: 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 vaccine manufacturer package inserts, 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. There are

Here are some studies on efficacy, adverse events, and conflicts of interest.

VAERS database found 18804 cases of adverse events from Meningococcal Vaccines

## **CONFLICTS & EFFICACY**

[http://journals.lww.com/pidj/Fulltext/2016/02000/Immunogenicity and Safety of a 3 and 4 dose.20.aspx](http://journals.lww.com/pidj/Fulltext/2016/02000/Immunogenicity_and_Safety_of_a_3_and_4_dose.20.aspx)

**February 2016** - Immunogenicity and Safety of a 3- and 4-dose Vaccination Series of a Meningococcal ACWY Conjugate Vaccine in Infants: Results of a Phase 3b, Randomized, Open-label Trial "**Four subjects withdrew from the study prematurely because of AEs: 1 subject in the ACWY3 group (Krabbe disease on day 117 after the third vaccination), 1 in the routine group (bronchiolitis on day 14 after the first vaccination) and 2 subjects in the ACWY4 group (both experienced convulsions). Of the 2 infants experiencing convulsions, the first suffered a severe seizure on day 38 after the fourth study vaccination and the second subject suffered a potential mild seizure on day 2 after the third study vaccination (this subject also suffered 2 SAEs of severe bronchiolitis—on day 17 after the first vaccination and day 46 after the second vaccination—both of which required hospitalization and a third SAE of a severe asthma attack on day 95 after the third vaccination).**"

- Peter M. Dull, MD is currently at the **Bill and Melinda Gates Foundation**, Seattle, Washington.
- Novartis Vaccines and Diagnostics, Inc. provided financial support for the conduct of the research, including study design as well as data collection, analysis and interpretation, and paid all costs associated with the manuscript development.
- L.H. and I.S. were **employees of Novartis group** companies and held stock ownership from the sponsoring company at the time of the study **but are now employees of GlaxoSmithKline group** companies.

- F.X. was a contractor associate at Novartis Vaccines and Diagnostics, Inc. but is now a contractor associate at GlaxoSmithKline LLC, United States.
- P.M.D. was a permanent employee of Novartis Vaccines and Diagnostics, Inc. during study conduct and data analysis and interpretation.
- The institutions of S.L.B., J.S., and H.G. received funding from Novartis Vaccines and Diagnostics, Inc. for study conduct.
- S.L.B. has received speaker fees from Novartis Vaccines and Diagnostics, Inc. and research grants from Pfizer, outside the submitted work.  
[http://journals.lww.com/pidj/Fulltext/2016/01000/Safety\\_and\\_Immunogenicity\\_of\\_a\\_Quadrivalent.19.aspx](http://journals.lww.com/pidj/Fulltext/2016/01000/Safety_and_Immunogenicity_of_a_Quadrivalent.19.aspx)

**January 2016** - Safety and Immunogenicity of a Quadrivalent Meningococcal Conjugate Vaccine and Commonly Administered Vaccines After Coadministration "Conclusions: **With no clinically relevant vaccine interactions or impact on vaccine reactogenicity or safety, these results support the coadministration of MenACWY-CRM with routine vaccines in all age groups.**"..."The institutions of R.G. and M.T. received funding from Novartis Vaccines and Diagnostics, Inc. for study conduct. R.G. has no other interests to declare. P.K., L.H., I.S. and E.Y. are employees of Novartis Pharmaceuticals. L.H., I.S. and E.Y. owns stock in the company. All studies were funded by Novartis Vaccines and Diagnostics, Inc. Medical Writing support for the finalization of this manuscript was provided by Zoetic Science, an Ashfield company. Funding for this support was provided by Novartis Vaccines and Diagnostics, Inc."

[http://journals.lww.com/pidj/Fulltext/2014/11000/Antibody\\_Persistence\\_After\\_Primary\\_and\\_Booster.20.aspx](http://journals.lww.com/pidj/Fulltext/2014/11000/Antibody_Persistence_After_Primary_and_Booster.20.aspx)

**November 2014** - Antibody Persistence After Primary and Booster Doses of a Quadrivalent Meningococcal Conjugate Vaccine in Adolescents (full text) "**After licensure of MenACWY-D, additional evidence indicated that many adolescents might not be protected for more than 5 years. Therefore, since 2010, ACIP has recommended a booster dose of MenACWY at age 16 years so that adolescents immunized at 11–12 years continue to be protected throughout the period of high disease risk (16–21 years).**

**The study was funded by Novartis Vaccines.** The institutions of R.B., K.R., and S.B. received grants from Novartis Vaccines and Diagnostics in support of this study. **The institution of R.B. received grants from Sanofi Pasteur, GSK, and Merck outside of this study. S.P., T.O., P.D., and I.S. are employed by Novartis Vaccines and Diagnostics, Inc.**

Address for correspondence: Roger Baxter, MD, Kaiser Permanente Vaccine Study Center, 1 Kaiser Plaza, Oakland, CA 94612. E-mail: Roger.baxter@kp.org.

<http://www.thelancet.com/journals/laninf/article/PIIS1473-3099%2813%2970345-1/fulltext?>

**March 2014** - UK poised to make decision on 4CMenB vaccine (full text) "In a letter to The Lancet shortly after the JCVI's interim statement, **Steve Black, a paediatrician based at Cincinnati Children's Hospital in Ohio, USA, pointed to the failure of modelling to predict the cost effectiveness of several vaccines before their introduction in the USA.** Most strikingly, the cost per quality-adjusted life-year saved by the pneumococcal conjugate vaccine was estimated to be more than US\$80 000 in the prelicensure cost effectiveness analysis, but the actual cost was shown

to be ten-times lower when the true effects of the vaccine were known after it was introduced."..."**Novartis had placed great expectations on the UK, because the country has had a progressive meningitis C vaccination programme**", says Timo Vesikari, of the University of Tampere Medical School in Finland and a lead investigator on several clinical trials of 4CMenB. "**The meningitis B problem in the UK is at least of the same magnitude as meningitis C was when the vaccination programme was started in 1999**", he continues. That programme, says Moxon, **was introduced with no population-based efficacy study, no knowledge of herd immunity, and no economic analysis preceding its adoption for routine use**. And yet, he contends, it has been "one of public health's great success stories".

## **ADVERSE EVENTS**

<http://jmedicalcasereports.biomedcentral.com/articles/10.1186/s13256-015-0536-5>

**April 1, 2015** - An unusual occurrence of Kleine-Levin syndrome in a man with refractory immune thrombocytopenic purpura: a case report (full text) "**Kleine-Levin syndrome is an extremely rare neurological entity characterized by recurrent episodes of hypersomnia which are sometimes associated with compulsive hyperphagia and behavioral changes. Autoimmunity has recently been proposed as a factor contributing to its pathogenesis**. Immune thrombocytopenic purpura is a relatively common autoimmune disease showing a lot of complexity and uncertainty regarding its treatment regimens and its refractory nature in some cases. A 32-year-old Persian White man visited his private hematologist complaining of recent episodes of epistaxis and appearance of petechial lesions **24 hours after receiving a meningococcal vaccine**"

<http://www.biomedcentral.com/content/pdf/1471-2334-13-116.pdf>

**March 5, 2013** - Immune response, antibody persistence, and safety of a single dose of the quadrivalent meningococcal serogroups A, C, W-135, and Y tetanus toxoid conjugate vaccine in adolescents and adults: results of an open, randomised, controlled study (pdf) "**Non-inferiority of the MenACWY-TT vaccine over the MenACWY polysaccharide vaccine, in terms of incidence of solicited and unsolicited grade 3 general symptoms reported within four days after vaccination, was demonstrated. Of note, clinically relevant severe general symptoms and vaccine-related events are most likely to occur during the four-day post-vaccination period**. However, the incidence of any **grade 3 symptoms seemed higher in the participants who received the MenACWY-TT vaccine than the MenACWY polysaccharide vaccine and this observation was driven by the local injection site reactions.**

<http://www.nap.edu/read/13164/chapter/1>

**August 2011**- IOM Adverse Effects of Vaccines Evidence and Causality (full text) "**Evidence Convincingly Supports a Causal Relationship: The MMR vaccine is linked to a disease called measles inclusion body encephalitis, which in very rare cases can affect people whose immune systems are compromised and usually occurs within a year of acute measles infection or vaccination. The MMR vaccine also is linked to febrile seizures, which are a type of seizure that occurs in infants and young children in association with fever. Febrile seizures are generally benign and hold no long-term consequences. Six types of vaccines—MMR, varicella zoster, influenza, hepatitis B, meningococcal, and tetanus containing vaccines—are linked to anaphylaxis. The committee also found convincing evidence of a causal relationship between injection of vaccine, independent of the antigen involved, and two types of adverse events, including syncope, or fainting, and deltoid bursitis, or frozen shoulder, characterized by shoulder pain and loss of motion.**

<http://pediatrics.aappublications.org/content/112/6/e491.full>

**December 1, 2003** - Henoch-Schonlein Purpura Following a Meningococcal Vaccine (full text) "There have been several reports of vasculitis following various immunizations. HSP has been associated with the influenza vaccine and measles vaccine. 14 LCV has been associated with the pneumococcal vaccine, and vasculitis has been reported after hepatitis B and bacillus Calmette-Guérin vaccines. Although a relationship between the vaccination and the development of HSP may be coincidental, past reports of temporally associated vaccinations and vasculites without other identifiable etiologies or historical factors set a precedent for association, albeit with different vaccines and antigens."

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

Comment: 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 US Supreme Court 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 flexible medical and non-medical vaccine exemptions in vaccine policies and laws 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.

Comment: 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.

Comment: 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.

Comment: 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.

Sincerely,  
Cynthia Stolten  
1139 W. Locust Street  
Scranton PA, 18504  
570-346-1555