Kathy Cooper

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2016 MAY 10 M 9: 37 To: IRRC; cfindley@pa.gov; ra-statebordofed@pa.gov

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Subject: Comments to proposed regs by DOE (IRRC 3146), DOH (IRRC 3147) re: vaccination of

school children

To Whom it May Concern:

I am opposed to the regulations proposed by the Departments of Health (#3147) and Education (#3146), to changes in vaccination requirements for school children, with the exception of extension of reporting periods. Detailed comments below:

COMMENTS TO PROPOSED AMENDMENTS:

1. IRRC Regulatory Analysis question #9 asks if there are any relevant federal or state court decisions. However, at no point does the proposal acknowledge the Vaccine Act of 1985, which removed liability from manufacturers, and created the "Vaccine Court."

It is absolutely relevant for Pennsylvania law and policymakers to be familiar with the fact that Pennsylvania families cannot sue vaccine manufacturers if they are injured by a vaccine, no matter how rare one believes potential injury may be. This is true even for design defects (as opposed to an individual adverse reaction), which one Pennsylvania family learned by weaving their case all the way to the Supreme Court of the United States in an attempt to be compensated for injury. Bruesewitz v Wyeth, 131 S Ct 1068 (2011) http://www.supremecourt.gov/opinions/10pdf/09-152.pdf.

All decisions issued by special masters under the Vaccine Injury Compensation Program through the Court of Federal Claims (commonly known as "Vaccine Court") are relevant to these proposed regulations. These decisions represent only a small fraction of known cases of vaccine injury in the United States. Since 1988, to date there have been almost 17,000 petitions filed, 4,637 of which have been compensated, for a total of over \$3.3 Billion in compensation to individuals and families. Many of these petitions are filed by Pennsylvania families.

Select decisions can be accessed at: http://www.uscfc.uscourts.gov/aggregator/sources/7. The most recent statistical information from the US Dept of Health and Human Services on petitions for vaccine injury is linked here: http://www.hrsa.gov/vaccinecompensation/data/statisticsreport.pdf

Compensation is paid by the U.S. Government, from a trust funded by taxes on vaccines. The 1985 Vaccine Act removed from manufacturers all liability for vaccine injury. This includes Merck, which has offices in Pennsylvania. PA law and policy makers should note that Merck is currently defending its MMR vaccine against federal antitrust lawsuits in the Eastern District of Pennsylvania. Employee scientists and physicians claim data regarding efficacy of the MMR was falsified, the drug mislabeled, and information intentionally concealed, which has implications for the federally granted monopoly to manufacture the MMR vaccine recommended by the federal government, and mandated by all US states for entry into schools.

http://blogs.wsj.com/pharmalot/2014/09/10/did-merck-unfairly-monopolize-the-market-for-a-mumps-vaccine/

Merck's MMR is also the subject of national controversy as a separate whistleblower claim. William Thompson, PhD, a senior CDC scientist has come forward as a whistleblower, claiming to have firsthand information about

suppressed data linking the MMR vaccine to onset of autism. http://morganverkamp.com/statement-of-william-w-thompson-ph-d-regarding-the-2004-article-examining-the-possibility-of-a-relationship-between-mmr-vaccine-and-autism/. This is especially significant as the tainted study in question was one relied upon by the Institute of Medicine during their investigation into the question of whether the MMR has any cause for concern at all with respect to diagnoses on the autism spectrum, where they concluded there was no link. https://www.focusforhealth.org/dr-brian-hooker-statement-william-thompson/

2. It is inappropriate, inefficient, costly and dangerous to amend 23.83(b) to reflect combination shots currently available.

Pennsylvania agencies should continue to address each antigen individually. In terms of state economics and time, individual antigen references in regulations will reduce the need to change the regulations each time the combinations or individual antigen booster recommendations change. It will eliminate a need for additional language to accommodate children from other countries who are able to access the single antigen shots.

Referencing to combination shots rather than individual antigen further reinforces the misinformed and dangerous concept that vaccines are one-size-fits-all. Vaccines are a medical treatment, and need to be given in consultation with medical providers in light of individual medical needs. Simply because multiple antigens are given in combo shot does not mean all antigens combined are appropriate for each child. Nor does it indicate that administration of that number of antigens at once is appropriate for each individual child. There are many Pennsylvanians, and people around the globe, who are strong advocates for safer vaccines through elimination of the combination shot. In many countries the combination shots are not required due to safety concerns.

The PA Joint State Government Commission recently released a report on Youth Vaccinations (May 2016). They indicate combination shots are safe, and cite a CDC web page claiming the same. I would urge lawmakers to follow up on the summary claims cited by the CDC on their web page that combination shots are found safe. No studies are cited to back up this summary claim.

3. PA Legislators recently declined to add an additional meningitis booster for high school seniors, yet the Departments are proposing to add it anyway, with potential harm to Pennsylvanians.

PA lawmakers had an opportunity to add a meningitis booster to the vaccination requirements, with the introduction of SB797 one year ago in May 2015, but declined to take any action to do so. It is totally inappropriate for the Departments to attempt to circumvent the legislative process by adding a provision that was rejected by legislators in this current legislative session. Pennsylvanians could be harmed by unnecessary medical treatments.

4. There is no proof that an additional pertussis booster should be added to the regulations for Kindergarten admission.

It has been acknowledged in this proposal, and the recent Joint State Government Commission report on Youth Vaccinations in Pennsylvania (May 2016) that data is Pennsylvania is inaccurate. The Departments should not be making recommendations to change the vaccine requirements based on inaccurate data.

Specific to pertussis, many recent outbreaks have been found in vaccinated populations. I disagree that Pennsylvania, or any state, should require additional boosters for a vaccine that is exhibiting vaccine failure and/or contributing to the spread of disease through shedding.

5. Allowing only a Physician, NP or PA to provide verification of immunity of any disease is inefficient, untenable and sows mistrust amongst Pennsylvanians.

Requiring a parent to bring their child to a doctor's office for verification could cause spread of the disease. Further, it may prove impossible if the disease is in the child's medical history, but the parent did not bring their child to an office for diagnosis, which can be common for diseases like varicella, in order to prevent the spread of disease.

Further, choosing not to trust the word of parents sows discord, and creates a break down in the integrity of the relationship between Pennsylvania lawmakers, and the school entities enforcing their edicts, and the parents subject to the laws.

6. More than five days are necessary for provisional enrollment requirements to be fulfilled.

Many have already commented on this, and I will simply add my voice to that chorus that five days is potentially dangerous and is monumentally too short for parents or guardians, and school officials to process provisional enrollment requirements. The result of such a short period could mean that a child is receiving up to 10 vaccines within 5 days—10 medical treatments in such a short period of time could cause an adverse reaction.

7. I support changing the reporting deadline from October 15 to December 31.

More time should equate to more accurate records, which is important for lawmakers trying to base policy on these numbers, as well as Pennsylvanians concerned about accurate information in order to make their individual medical decisions.

CLARIFICATIONS--The Departments have not shown a change in regulations (beyond increasing the reporting deadline) is merited or necessary

Summarily stating "the number of children provisionally admitted to and attending school might at some future point contribute to a lessening of herd immunity" does not meet the standard of a compelling public interest. See Department response to IRRC Question #10. At no point does the Department define or quantify the targeted herd immunity, and throughout the proposal it is indicated that data is inaccurate. However, the Department is proposing to require potentially harmful medical treatment be mandated for Pennsylvania children based on inaccurate data to achieve an unquantified and undefined end. The Department makes this recommendation, weighing against a cost analysis not done with Pennsylvania data, but instead by borrowing information from California. I will also request, as other commenters have, that the Department use data for Pennsylvania with respect to economic analysis, rather than relying second-hand on information from the recent California measles outbreak. I would further request the Departments be careful with their use of the term non-vaccinated, which is used interchangeably throughout the proposal to describe children who have received some but not all required vaccines.

SUGGESTION—PA Schools need standardized language from the state to inform parents about vaccine requirements and exemptions.

I also add my voice to the Pennsylvania citizens calling for standardized language from schools informing parents about vaccination requirements for attendance. There has been much misinformation sent to parents by school districts indicating certain vaccination requirements that are not legally accurate. I would request a penalty be added to schools that willfully mislead parents with respect to vaccine requirements, or by failure to notify parents of their rights to exemptions.

Sincerely,

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