

HB1135-Health Occupations- Pharmacists- Vaccination Orders

Unfavorable

Alliance for Science Based Policy

Dear Chair Bagnall, Vice Chair Cullison and members of the Health Committee,

My name is Megan Montgomery, and I am submitting this testimony on behalf of the Alliance for Science Based Policy.

The Alliance for Science Based Policy opposes this bill for several reasons. First, the administration of any vaccination is serious medical business and should be done by a qualified professional. Second, medical decision-making lays clearly in the hands of parents and guardians, not caregivers. Third, administration of this medical product in a non-clinical setting appears to fall outside of the parameters of legal liability for vaccine administrators.

Non-professional Administration of the flu-mist vaccine

The flu mist vaccine is a product that has a checkered at best medical history. Nasal flu mist is a live virus vaccine that has been on and off the market for over a decade due to losing its FDA authorization- a serious event which has only happened a small number of times in the US. This product does not have a long-standing record of safety and efficacy and should only be administered by a licensed professional given the repeated safety failures it has experienced over the past decade.

This product has a vaccine insert that is more than 30 pages:

<https://www.fda.gov/media/180697/download> **If you do nothing else before voting on this bill, I implore you to read the vaccine insert from beginning to end and imagine that you as a lay parent are now responsible for everything in the insert. All 30 pages.**

Please especially focus on the Contraindication, Warnings and Precautions, Adverse Reactions, Patient Counseling (intended to be done by a medical professional), Drug

Interactions and disposal sections. This is a tremendous amount of information to take in, and needs to be done in a proper medical facility under professional medical care. Contraindications include age, immunocompromised status, current anti-viral exposure, aspirin therapy, egg and other vaccine ingredient allergies, prior bad reactions to flu vaccines and more.

Disposal alone is inappropriate to be done at home, unless the family happens to have access to a biohazard or sharps container. Flu mist is a LIVE VIRUS VACCINE and absolutely needs proper disposal to ensure that the virus is not inadvertently spread and that non-eligible populations (children under 24 months of age, persons over 65, anyone for whom the vaccine is contra-indicated) are not accidentally exposed during improper disposal.

The fact that this is a live virus vaccine also means that improper storage leading up to the administration may render the vaccine ineffective. There is no way to ensure that any live virus vaccine shipped through traditional shipping channels is going to be properly temperature regulated through delivery and administration.

Contraindication includes age- what is to stop a parent from deciding that a baby under 24 months could be ok with half a dose? Or that to save money they can take one full dose and spilt it amongst several children in the household? Or that the child that does have a contraindication will probably be “fine” to be in the same vicinity as the child getting the flu mist vaccine, and is therefore accidentally exposed to the very vaccine that is a known harm for them?

Imagine that you are an overworked and overwhelmed parent working multiple jobs to keep your household financially afloat in these very hard economic times. Under what circumstances will those busy parents have time to read *and digest* this 30-page insert? To properly receive and store the vaccine, to properly screen for contraindications? To properly administer the vaccine taking great care not to expose anyone else in the household to the live virus vaccine? To properly dispose of the vaccine medical waste in a biohazard or closed sharps container? To properly watch for adverse reactions to the vaccination?

Vaccines are intended to be administered ONLY after a thorough and professional medical evaluation by a physician (ideally) or other professionally trained vaccine administrator. They are not candy to be handed out at pharmacies like a free frisbee for signing up for a credit card the first week of college. Taking any vaccine out of that vital clinical setting is asking for the most vulnerable populations to be put in danger.

Please see these recent articles from Pharmacy Times:

<https://www.pharmacytimes.com/view/concerns-of-the-at-home-flumist-emphasize-need-for-patient-safety-proper-administration> and The Children's Hospital of Philadelphia: <https://www.chop.edu/vaccine-update-healthcare-professionals/newsletter/technically-speaking-flumist-home> in conjunction with the concerns raised above.

Immunet

How will these doses be entered into Immunet? Immunet has been a central component of the state health authority's management of vaccinations and vaccine tracking in the state of Maryland- how is that being factored into this bill? Will the vaccines be reported at the time of prescription? That dose may never in fact make it to the patient. Self-reporting? What will be the mechanism for that? Reporting after the fact? What safeguards will be in place to determine that the vaccine was properly stored to preserve efficacy and was properly administered to ensure that the clinical benefits were actually achieved?

Non-coordinated Administration Risks

Anytime a vaccination moves outside of the domain of a single, partnered medical provider (ideally a family physician or pediatrician) you run the risk of non-coordinated administration. We have noted this in our recurring testimony regarding children getting vaccinated at the pharmacy instead of in their doctor's office. At home administration will substantially increase the risk of an accidental double or triple dose of a vaccine. Imagine a high conflict divorce with shared medical decision-making authority. There is NOTHING to prevent that child from getting vaccinated multiple times. And adding in the 'caregiver' language, we could also see a scenario where a child could be dangerously vaccinated even 3 times before anyone catches the mistake. Multiple doses of the vaccine for any age

group over 24 months, and vaccine doses given less than a month apart for younger patients is a clear contraindication to vaccination outlined in the vaccine insert.

Liability

Who will be liable for vaccine injury that comes from an at home administration that is either improperly done or results in a reaction that could have been addressed in a medical setting but is unable to be properly addressed at a private residence? Improper storage? Improper administration? Severe adverse reaction including anaphylaxis that may result in lifelong disability or death? Where will these parents turn for help with medical bills, financial relief for a life-altering disability or other adverse event that results from an at home vaccination without proper medical assessment and administration? Will it be the prescribing pharmacy? It will not be the manufacturer- they are shielded from all liability under the federal 1986 act. Will it be the delivery service that delivered the vaccine to the home?

Conclusion

Vaccination is a serious medical event and can result in injury. Surely these parents need a clear path to relief. We hope that these questions will be addressed prior to the passage of this bill. Thank you for your time and consideration.