4643 Teller Street Columbus, OH 43228 June 5, 2017

The Ohio House of Representatives
Economic Development, Commerce and Labor Committee
77 S. High St
13th Floor
Columbus, OH 43215

Dear Chair Young, Vice Chair DeVitis, and Distinguished Committee Members:

I support Representative Hagan's efforts via House Bill 193to keep employers from taking adverse actions on employees who decline flu vaccines. Flu vaccine carries inherent risks, some of which I have experienced personally.

I was the first in my family to receive a flu shot in 1987 at age 17. Our rural family doctor believed because of my disability that I was in the category most at benefit from added influenza protection. However, within minutes, I literally hit the floor with anaphylaxis. While I was still lucid, I could feel my heart pounding in my chest to the point that it felt like it would explode. I couldn't take a breath. And then I lost consciousness. I remember thinking that I was going to die, having been fine moments before. Wisely, after stabilizing me, the doctor recommended I never get another flu shot, and I have avoided them since.

It is believed that many reactions are related to allergies to vaccine components. The problem is that there is no universal screening process for any of these vaccines. You get them at your own risk, and unfortunately for myself and my children, the risk is great. The flu shot itself has the highest incidence of Vaccine Adverse Event Reporting System claims. ¹

In my case and many others, the best guess for why I had anaphylaxis was egg allergy. However, I have eaten eggs my entire life and never tested allergic to them. It is interesting to note that until recently, severe chicken egg allergy was a contraindication to receive influenza vaccine. Working off the safety principle, in 1986 and many years following, it was advised:

Inactivated influenza vaccine should not be given to persons who have an anaphylactic sensitivity to eggs.²

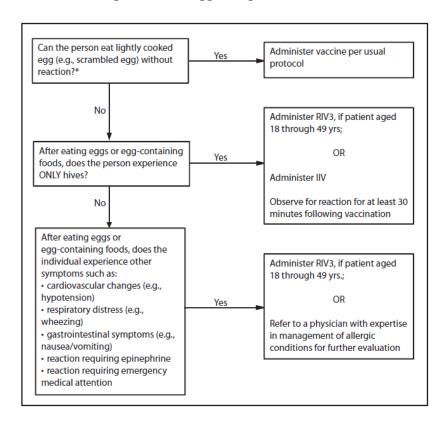
In 2004, the recommendation was similar but added:

¹ https://www.hrsa.gov/vaccinecompensation/data/vicpmonthlyreporttemplate5 1 17.pdf

² https://www.cdc.gov/mmwr/preview/mmwrhtml/00022941.htm

Persons who have a history of anaphylactic hypersensitivity to vaccine components but who are also at high risk for complications from influenza can benefit from vaccine after appropriate allergy evaluation and desensitization.³

In 2014, the algorithm for egg-allergic individuals⁴ looked like this:



In 2016, based on a study of 367 patients with egg allergies and some analysis of allergic individuals who had received influenza vaccine, the recommendation changed significantly:

- Removal of the recommendation that egg-allergic recipients should be observed for 30 minutes postvaccination for signs and symptoms of an allergic reaction. Providers should consider observing all patients for 15 minutes after vaccination to decrease the risk for injury should they experience syncope, per the ACIP General Recommendations on Immunization.
- A recommendation that persons with a history of severe allergic reaction to egg (i.e., any symptom other than hives) should be vaccinated in an inpatient or outpatient medical setting (including but not necessarily limited to hospitals, clinics, health

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https://www.researchgate.net/profile/Carolyn Bridges2/publication/10753336 Bridges CB Harper SA Fukuda K et al Prevention and control of influenza Recommendations of the Advisory Committee on Immunization Practices ACIP MMWR Recomm Rep 52 1-34 guiz CE1-4/links/00b7d529dd54d69f72000000.pdf

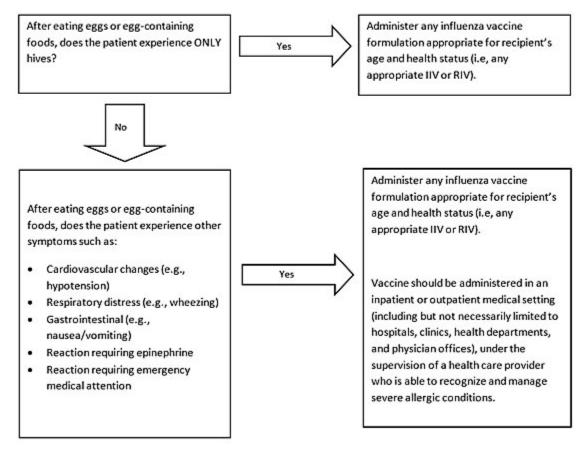
⁴ https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6207a1.htm

departments, and physician offices), under the supervision of a health care provider who is able to recognize and manage severe allergic conditions.⁵

The algorithm was simplified to this one, in which no matter the prior overserved allergic symptoms, the vaccine is given.

Recommendations regarding influenza vaccination of persons who report allergy to eggs: Advisory Committee on Immunization Practices, United States, 2016-17 Influenza season.

NOTE: Regardless of a recipient's allergy history, all vaccination providers should be familiar with the office emergency plan and be currently certified in cardiopulmonary resuscitation. Epinephrine and equipment for maintaining an airway should be available for immediate use. (CDC. General recommendations on immunization—recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR Recomm Rep 2011;60(No. RR-2)



IIV=Inactivated Influenza Vaccine; RIV=Recombinant Influenza Vaccine.

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⁵ https://www.cdc.gov/flu/professionals/acip/

What was the robust body of evidence supporting the changes? Mostly analysis of cases where flu vaccine had been given to egg-allergic individuals and one study of 367 egg-allergic people (with various criteria for allergy status), given a total of given a total of 457 vaccines over 5 seasons, with only 132 having history of severe egg allergy. Several concerns with this should be noted:

- Some people got consecutive (serial) doses but most did not, so we don't know about phenomena like multiple-exposure risks. This is especially pertinent since workers who are mandated to receive influenza shots will receive them annually.
- 36 of the severe allergy cases had tolerated baked goods well and, therefore, might be more aptly labeled mild allergy.
- Patients were followed for 24 hours. We do not know if in the days following, as is
 possible in allergic reactions, that these individuals were sensitized further to egg
 protein.
- Ovalbumin content for the lots used varied: 0.09 μ g/mL in 2007-2008, 0.03 μ g/mL in 2008-2009, 0.31 μ g/mL in 2009-2010, up to 0.2 μ g/mL in 2010-2011, and up to 0.06 μ g/mL for 2011-2012.

As the parent of two egg-allergic children, these recommendations are not reassuring. But further investigation shows that scientists think it might not be egg protein that is the worry, but gelatin instead. After a boy who had been given influenza vaccine without incident in the past developed anaphylaxis, a gelatin warning may replace the egg allergy precautions.⁷

What this tells us is that, even if an individual has successfully received influenza vaccine many times, life-threatening allergy symptoms could still happen. This would negate the notion in the egg-allergy paper that evidence of no reactions means the vaccine can be given safely. To me it indicates a reckless disregard for what I and others know about allergies, reactions, and risk.

Further, the multidose vials of flu vaccine still contain thimerosal, ⁸ the safety status of which is controversial. Being a biomedical engineer, I find it questionable to include any mercury derivatives as preservatives in injectable drugs because allergy/toxicity has been reported in topical applications. In fact, thimerosal is the fifth most common allergen. ⁹

It is perfectly fine for individuals to choose influenza vaccine. It is unacceptable for this to be mandatory or the basis for employment, as it is an invasive medical procedure with many inherent risks being performed on ostensibly healthy people for the purpose of (imperfectly) protecting against a disease which they may or may not have otherwise gotten.

⁶ http://www.jacionline.org/article/S0091-6749(12)01293-6/fulltext

⁷ http://www.medscape.com/viewarticle/814826#vp 2

⁸ https://www.cdc.gov/flu/protect/vaccine/thimerosal.htm

⁹ http://www.medscape.com/viewarticle/516045 3

Please keep flu vaccine status out of employment entirely. The decision to get a flu shot should
be a personal one under the guidance and oversight of one's own physician ideally. Flu
vaccination may be encouraged and offered, but because of the risks, should never become a
condition of employment.

Sincerely,

Donna Jo Kazee