



STATE OF HAWAII
DEPARTMENT OF HEALTH
P.O Box 3378
Honolulu, Hawaii 96801-3378

November 2, 2009

TO: Chiyome Leinaala Fukino, M.D.
Director of Health

A handwritten signature in black ink, appearing to read "Chiyome", written over the name in the TO field.

THROUGH: Health Resources Administration

FROM: Sarah Y. Park, M.D., F.A.A.P., Chief
Disease Outbreak Control Division

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SUBJECT: County of Hawai'i, State of Hawai'i Resolution Number 237-09 (Draft 2):

“A RESOLUTION URGING HAWAII STATE AND FEDERAL LEGISLATORS TO AMEND VACCINE LAWS TO INCLUDE THE RIGHT OF MEDICAL, RELIGIOUS, AND PHILOSOPHICAL EXEMPTION FROM MANDATED VACCINATION PROGRAMS”

The only mandatory immunizations in the State of Hawai'i are those specified by the Hawai'i Administrative Rules, Title 11, Chapter 157 “Examination and Immunization” for preschool, school, and post-secondary school entry and attendance. Required immunizations include diphtheria, tetanus, and pertussis (whooping cough), polio, *Haemophilus influenzae* type b, hepatitis B, measles, mumps, rubella, and varicella (chicken pox) vaccinations. Influenza vaccinations (seasonal and 2009 H1N1) are **NOT** required for preschool, school, and post-secondary school entry and attendance in the State of Hawai'i.

The initial target groups for 2009 H1N1 influenza vaccination include:

- Pregnant women;
- People who live with or provide care for infants younger than age 6 months;
- Health care and emergency medical services personnel, who provide direct patient care;
- People ages 6 months through 24 years;
- People ages 25 years through 64 years who have certain medical conditions that put them at higher risk for influenza-related complications.

Young children are at high risk of serious complications from 2009 H1N1 influenza, just as they are from seasonal flu. To reach this population, specifically children ages 5-13 years, the Hawai'i Department of Health is conducting school-based clinics in public and private elementary and middle schools statewide. School and student participation in the influenza clinics is voluntary, and a parent or guardian must provide written consent before their child may be vaccinated.

A great deal of information about vaccinations is available to parents and individuals. People should have access to information, such as that published by the National Network for Immunization Information (www.immunizationinfo.org) that will help them make informed

AMEND VACCINE LAWS

Page 2

November 2, 2009

decisions about vaccination. However, some published information is inaccurate or can be misleading, especially when taken out of context. A number of these inaccuracies pertaining to immunization were cited in Resolution Number 237-09, Draft 2. In response:

School Immunization Requirements

School immunization requirements serve to ensure that thresholds for maintaining community-wide protection from the spread of infectious diseases are maintained and seek to balance the rights of individuals with the need to protect the health of the public. In Hawai'i, medical exemptions to vaccination are allowed if the vaccination required for school or post-secondary school entry/attendance would endanger the life or health of the individual (for example, those who have severe immune system problems). In addition, religious exemptions are also allowed for persons who certify that their religious beliefs prohibit the practice of immunization (Hawai'i Revised Statutes §302A-1156).

If a vaccine-preventable disease epidemic were to occur for which vaccination is a requirement for preschool, school, or post-secondary school attendance, exempted students would not be forced to receive the vaccinations for which they have been exempted. Rather, to protect the health of all students, including the unimmunized students who would be at much greater risk for contracting and spreading the disease, the school would be directed to exclude students without evidence of immunity to the disease (i.e., proof of vaccination or evidence of immunity through special blood tests if available).

Unvaccinated children are not only at greater risk of catching vaccine-preventable diseases, but they can affect community-wide immunity. For instance, various studies have looked at the health consequences of exemptions from immunization laws.^{1,2} These studies have found that individuals claiming religious and/or philosophical exemptions from immunization (exemptors) are at a greater risk of contracting the diseases and thus put the rest of the population at risk by spreading infection. For those reasons, the Department would not recommend expanding these exemptions to include philosophical exemptions based on personal convictions because of the increased risk of disease that would then need to be borne by the rest of the community.

Vaccine Safety

People have a right to expect that the vaccines they receive are safe and effective. The United States Centers for Disease Control and Prevention (CDC) and the Federal Drug Administration (FDA) also hold vaccines to the highest standards of safety. Vaccines must be licensed by the FDA before they can be used in the United States. Before the FDA approves a license, vaccines are tested extensively to ensure they are safe. Pre-licensure computer models, animal testing, and clinical trials are all necessary before a vaccine manufacturer can seek FDA licensure of a new vaccine. Before a vaccine is licensed, the FDA reviews the clinical trial results and the proposed label for the vaccine. The FDA also inspects the plant where the vaccine will be made and reviews the process for making the vaccine. When the FDA is satisfied it is safe, the vaccine

¹ Salmon DA, Haber M, Gangarosa EJ, Phillips L, Smith NJ, and Chen RT (1999). Health consequences of religious and philosophical exemptions from immunization laws: Individual and societal risk of measles. *JAMA* 282:47-53.

² Feikin DR, Lezotte DC, Hamman RF, Salmon DA, Chen RT, and Hoffman RE (2000). Individual and community risks of measles and pertussis associated with personal exemptions to immunization. *JAMA* 284:3145-3150.

AMEND VACCINE LAWS

Page 3

November 2, 2009

is licensed for public use. The licensing process can take 10 years or longer. Note, that the 2009 H1N1 vaccine is manufactured using the same processes and facilities that are used to make the currently licensed seasonal influenza vaccines. Therefore, FDA has assessed this vaccine as a strain change in the regular flu vaccine, just as there are yearly strain changes in the seasonal flu vaccines. As such, the 2009 H1N1 vaccine can be licensed immediately assuming manufacturing plants pass FDA inspection, which they have.

After a vaccine is licensed for public use, the vaccine continues to be monitored for safety. The FDA requires all manufacturers to submit samples from each vaccine lot before its release. Manufacturers must give the FDA their test results for vaccine safety, potency, and purity. Post-licensure surveillance is also conducted via the CDC's Vaccine Adverse Event Reporting System, Vaccine Safety Datalink, and the Emerging Infections Program. CDC expects that the 2009 H1N1 vaccine will have a similar safety profile as seasonal flu vaccines, which have very good safety track records.

Thimerosal (Mercury) in Vaccines

Since 2001, no new vaccine licensed by the FDA for use in children has contained thimerosal as a preservative, and all vaccines routinely recommended by CDC for children under age six years have been thimerosal-free, or contain only trace amounts, except for multi-dose formulations of influenza vaccine. This was done as a precautionary step and not because there was evidence confirming that thimerosal-containing vaccines were causing health problems. The most recent and rigorous scientific research does not support the hypothesis that thimerosal-containing vaccines are harmful.

Thimerosal is an important preservative that protects vaccines against potential microbial contamination, which may occur in opened multi-dose vials of vaccine. Such contamination could cause serious illness or death. Since seasonal and H1N1 influenza vaccines are produced in large quantities for mass immunization campaigns, some of the vaccine is produced in multi-dose vials, and contains thimerosal to safeguard against possible microbial contamination of the vial once it is opened.

Three leading federal agencies (CDC, FDA, and the National Institutes of Health [NIH]) have reviewed the published research on thimerosal and found it to be a safe product to use in vaccines. Three independent organizations (the National Academy of Sciences' Institute of Medicine, the Advisory Committee on Immunization Practices [ACIP], and the American Academy of Pediatrics [AAP]) reviewed the published research and also found thimerosal to be a safe product to use in vaccines. The scientific community supports the use of thimerosal in influenza vaccines.

Thank you for allowing the Disease Outbreak Control Division to comment on this measure. If you have any questions please contact me at (808) 586-6845 or my Immunization Branch at (808) 586-8300.

C: Aaron Ueno, District Health Officer
Hawaii District Health Office

AMEND VACCINE LAWS

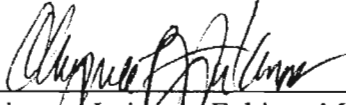
Page 4

November 5, 2009

RECOMMEND:

APPROVAL

DISAPPROVAL



Chiyome Leiraala Fukino, M.D.
Director of Health

NOV - 5 2009

Date