

Public Comment
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Licensure Pathways for Pandemic Influenza Vaccines

My name is Barbara Loe Fisher. I am co-founder and president of the nonprofit National Vaccine Information Center, founded in 1982 to promote vaccine safety and protect informed consent rights. NVIC does not receive any money from vaccine manufacturers or government agencies and I have no financial conflicts of interest regarding the topic under discussion.

If past is prologue, today's VRBPAC Committee deliberations may be the only opportunity this Committee or the public will have to comment on licensing standards being developed by FDA for future pandemic influenza vaccines marketed by multi-national pharmaceutical corporations and likely mandated for use by Americans. I tried to listen to part of yesterday's meeting via the webcast but the microphones and audio was so poor that most of your comments were inaudible and transcriptionally indecipherable to the web viewing public. This interferes with the transparency of this FDA Committee's work and limits public participation.

The informed American health care consumer expects FDA vaccine licensing standards demonstrating the safety and effectiveness of new vaccines, including those developed for pandemic influenza, to be very high. If the regulatory standards are too low and the pre-licensure scientific data is limited because everything is put on an accelerated "fast track," the informed public will question and resist using those newly licensed vaccines – even if the heel of the boot of the state is used to try to force compliance with federal recommendations and state mandatory vaccination laws.

It is a fact that the H1N1 influenza pandemic turned out to be much milder than originally predicted following the declaration of an international and national health emergency by the WHO and the U.S. Secretaries of Health and Human Services and Homeland Security in the spring of 2009. Questions began to be asked about the safety, effectiveness and necessity of the pandemic vaccine, as the numbers of pandemic influenza-associated deaths in the U.S. were less than half of the estimated annual deaths from seasonal influenza.

One question that remains is: Where are the published results of the post-licensure studies that NIH, FDA and CDC were supposed to conduct in 2009 to evaluate pandemic H1N1 vaccine safety for children and pregnant women? The informed public is aware of the reported increased risk for seizures in young

children with an Australian-made pandemic vaccine; the increased risk for narcolepsy in children with a squalene-adjuvanted pandemic vaccine used in Europe; and the elevated risk for Guillain Barre Syndrome in U.S. pandemic vaccines. Americans are also aware of the well-publicized apocalyptic movie, *Contagion*, and are worried about NIH funded research that created a genetically engineered, lethal pandemic H5N1 bird flu virus in U.S. and European labs.

The informed public will be carefully evaluating future pandemic vaccines, including genetically engineered influenza vaccines that contain novel adjuvants, like squalene, which ramp up the immune response. The growing numbers of children and adults with biological vulnerability to suffering immune-mediated brain and immune system dysfunction because they mount atypical inflammatory responses, are particularly wary of novel adjuvants. The informed public will also be closely monitoring future seasonal flu vaccines that contain four or more strains of genetically engineered influenza virus using novel cell substrates, such as insect cells.

The August 2011 Institute of Medicine report on *Adverse Effects of Vaccines: Evidence and Causality* importantly acknowledged biodiversity and increased individual biological susceptibility to vaccine injury. This places a special responsibility on the FDA to ensure that candidate pandemic influenza vaccines, as well as new vaccine adjuvants not yet licensed in the U.S., are separately tested pre-licensure in animal and human trials. At a minimum, pre-licensure trials should include (1) inactive placebos and participants, who remain unvaccinated or not exposed to the novel adjuvant, as controls; (2) study populations, which reflect all populations to be targeted for vaccine or new adjuvant use post-licensure; (3) at least 60 days follow-up to evaluate safety; 4) administration of the experimental influenza vaccine simultaneously with other vaccines routinely given to children and adults and (5) robust post-licensure evaluation.

Informed consumers in America are watching what you do. They do not want the FDA to allow assumptions or inferences or take shortcuts using an accelerated vaccine approval process in the absence of a true emergency. They want you to adopt rigorous scientific licensing standards for proof of safety and effectiveness of all new vaccines, including pandemic influenza vaccines. If you do not do this, future seasonal and pandemic influenza vaccines will be viewed with skepticism by the informed public.