## Public Comment on Fast Tracking Unlicensed Adjuvants for H1N1 Pandemic Influenza Vaccines Barbara Loe Fisher Co-founder & President National Vaccine Information Center FDA Vaccines & Related Biological Products Advisory Committee July 23, 2009

I am co-founder and president of the National Vaccine Information Center, which is a nonprofit vaccine safety and advocacy organization founded in 1982. I have no conflicts of interest.

Although there was a preempted declaration of a national public health emergency on April 26 which allows the accelerated development of H1N1 swine flu vaccines using unlicensed oil in water adjuvants under the emergency use authorization, as Dr. Cox indicated this morning, there is no signal that the novel H1N1 virus is mutating to cause more severe complications or excess mortality that surpasses that of influenza circulating in most years.

The National Vaccine Information Center does not support the fast tracking of unlicensed adjuvants under a EUA for flu vaccines that are going to be given to millions of children, especially when there are no published biological mechanism studies identifying which children may be at high risk for developing immune mediated brain and immune system dysfunction after use of adjuvanted flu vaccines.

The FDA needs to know more, and parents deserve to know more about oil in water adjuvants before agreeing to get their children vaccinated, especially the millions of parents who have children who are already suffering from chronic inflammation and brain and immune system dysfunction.