



NATIONAL VACCINE INFORMATION CENTER

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August 14, 2007

Dale L. Morse, M.D.
Chair, Advisory Committee on Immunization Practices (ACIP)
Centers for Disease Control and Prevention
Director, Office of Science and Public Health
New York State Department of Health
1483 Corning Tower, ESP, Room 1420
Albany, New York 12237

Dear Dr. Morse:

Enclosed is a report, "Human Papillomavirus Virus Vaccine Safety: Analysis of Vaccine Adverse Events Reporting System Reports: Part III," authored by the National Vaccine Information Center (NVIC).

This new analysis gives evidence for a reported association in VAERS between Gardasil and Guillain- Barre Syndrome, with a statistically significant increased risk of GBS and other serious adverse event reports when Gardasil is co-administered with other vaccines, especially meningococcal vaccine (Menactra). This analysis of Gardasil reports to VAERS indicates that there was a two to 12 times greater likelihood that serious adverse events, such as GBS, were reported when Gardasil was given simultaneously with Menactra rather than given alone. Accepted scientific standards indicate that these findings are statistically significant and cannot be dismissed as coincidence.

On March 12, 2007, the MMWR published "Quadrivalent Human Papillomavirus Vaccine: Recommendations of the Advisory Committee on Immunization Practices (ACIP), which stated *"Although no data exist on administration of quadrivalent HPV vaccine with vaccines other than hepatitis B vaccine, quadrivalent HPV vaccine is not a live vaccine and has no components that adversely impact safety or efficacy of other vaccinations. Quadrivalent HPV vaccine can be administered at the same visit as other age appropriate vaccines, such as the Tdap and quadrivalent meningococcal conjugate (MCV4) vaccines. Administering all indicated vaccines together at a single visit increases the likelihood that adolescents and young adults will receive each of the vaccines on schedule. Each vaccine should be administered using a separate syringe at a different anatomic site."*

Dismissing the importance of implementing evidence-based policies by making assumptions of safety in the absence of scientific certainty is not the standard of care American health care consumers expect from federal health officials. Federal vaccine policy recommendations are carried out by pediatricians and other vaccine providers, who do not question the scientific evidence upon which federal health officials made the recommendation. The burden should not be on consumers to prove recommended use of

a new drug or vaccine is unsafe; the legal and ethical burden is properly on federal health officials to prove to consumers and prescribing physicians that recommended use of a new drug or vaccine is safe.

The precautionary principle dictates that good science should precede CDC vaccine policy recommendations. ACIP should immediately issue a public Advisory and amend the March 12, 2007 HPV Vaccine Recommendations alerting vaccine providers and the public that Gardasil has been associated with 15 cases of GBS and an increased risk of GBS and other serious adverse event reports to VAERS when Gardasil is administered with Menactra and other vaccines.

Please advise us of what you plan to do to minimize the risk of Gardasil vaccine associated injuries and deaths for girls for whom ACIP has recommended the vaccine.

Sincerely,

A handwritten signature in black ink that reads "Barbara Loe Fisher". The signature is written in a cursive style with a large initial 'B'.

Barbara Loe Fisher
Co-founder & President

cc: Julie Gerberding, M.D.