



Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

JUL 9 2004

Lyn Redwood, R.N., M.S.N., N.P.
President
Safe Minds
14 Commerce Drive, 3rd Floor
Cranford, New Jersey 07016

Dear Ms. Redwood:

Thank you for sharing your concerns about the Centers for Disease Control and Prevention's (CDC) immunization program. CDC takes the issue of vaccine safety and the integrity of its immunization program very seriously. It is in the interest of preserving public trust in immunization programs that the Brighton Collaboration was formed in 2000 to support and enhance vaccine safety activities.

The Brighton Collaboration is a global network of individuals and organizations concerned with immunization, including CDC and many of its immunization partners. They are committed to strengthening vaccine safety through development and implementation of standard case definitions for vaccine adverse events.

Uniformly accepted case definitions greatly facilitate the meaningful assessment of surveillance data. This standardization is especially important when comparing the numbers of affected patients across different surveillance systems (or clinical trials) in different countries, and is critical to the vaccine safety research conducted in the United States and internationally.

The case definitions and guidelines developed by the Brighton Collaboration cannot and are not intended to establish any causality of the occurrence of the adverse event with a given vaccine. The case definitions are a tool to provide a uniform understanding of the diagnostic certainty of an observed or reported adverse event. Therefore, the Brighton Collaboration aims to define what an adverse event is, but does not aim to study what causes the adverse event.

In your letter, you raised several questions regarding the funding of the Brighton Collaboration. CDC does not award funds directly to the Brighton Collaboration; however, CDC does support staff at the National Immunization Program (NIP) whose responsibilities include providing technical and programmatic assistance for the Brighton Collaboration. In addition, the NIP provides partial funding for one staff person located at the University Children's Hospital in Switzerland, whose duties include coordination and support for work associated with the Brighton Collaboration.

References to grant funding on the Brighton Collaboration website are somewhat misleading and warrant clarification. The funding referred to was not a direct grant to the Brighton Collaboration. It was, instead, funding received by the NIP to support a proposal to "evaluate the applicability, reliability, sensitivity, and specificity of the case definitions in CDC's Vaccine Adverse Event Reporting System." This proposal was submitted by NIP and competed among other CDC proposals for unmet needs funding awarded by the National Vaccine Program Office (NVPO). Funds supporting this proposal were used to review case reports in VAERS and to compare them with proposed standard case definitions.

The Brighton Collaboration Foundation is an independent, not-for-profit organization under the direct supervision of the Swiss government. The Foundation was established in December 2003 to connect partners and resources to support and enhance the efforts of the Brighton Collaboration. CDC does not provide funding to support the developed Brighton Collaboration Foundation.

Again, I appreciate your interest in CDC's immunization program and the Brighton Collaboration. I hope this information is helpful. If you have any other questions, please call Lorine Spencer at 404-639-7000, the CDC Community Outreach Liaison. I also will provide this response to Ms. Sallie Bernard.

Sincerely,


Julie Louise Gerberding, M.D., M.P.H.
Director