



May 12, 2004

Julie Louise Gerberding, MD, MPH  
Director  
Centers for Disease Control and Prevention  
Office of the Director/Administrator  
1600 Clifton Road  
Atlanta, GA 30333

**Dear Dr. Gerberding,**

Following, please find our topics of concern for your attention, review and response.

**Conflict of Interest Concerns**

I am sure you personally share the same concerns I do about preserving the public trust in the vaccine approval and recommendation process. Because vaccines are the only medications administered to a majority of American children, based on Federal recommendations, every individual involved in any vaccine program within HHS must be free of any conflicts of interest as well as the appearance of a conflict.

In June 2000, the House Committee on Government Reform, conducted a hearing as part of an investigation into possible conflicts of interest on vaccine-related advisory committees at both the Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC). It was discovered during this investigation that members of the FDA's Vaccines and Related Biologicals Advisory Committee had direct financial ties to vaccine manufacturers that had been waived to allow their participation in reviewing and approving vaccines. The CDC's Advisory Committee on Immunization Practices granted waivers to all of its members almost automatically. A number of individuals continue to participate on this Committee while acting as advisors and investigators for vaccine manufacturers. The staff report that was the product of this investigation offered several important recommendations that as yet have not been implemented by HHS. These ongoing conflicts of interest in vaccine-related advisory committee's undermines the public's confidence in the decisions and opinions of these Committees. While some within HHS would proffer that the agencies are not required to follow the advice of the Committees, seldom if ever has either the FDA or CDC taken a different course than suggested by these vaccine advisors.

Of even greater concern are conflicts of interest and outside activities of full-time government employees and other individuals working within HHS on vaccine related matters. I have recently learned about the Brighton Collaboration. On their website, the following information is provided about the organization:

***Mission:*** *The Brighton Collaboration is an international voluntary collaboration to facilitate the development, evaluation, and dissemination of high quality information about the safety of human vaccines.*

**Primary Aim:** *To develop globally accepted and implemented standardized case definitions of Adverse Events Following Immunization. (AEFI)*

**The Brighton Collaboration:** *The Brighton Collaboration is committed to develop standardized, widely disseminated and globally accepted Case Definitions for an exhaustive number of adverse events following immunizations (AEFI) as well as guidelines for data collection, analysis, and presentation.*

*The Brighton Collaboration was founded by Robert Chen (of the CDC), Harald Heijbel, Tom Jefferson, Ulrich Heininger, and Elisabeth Loupi in 1999 at a meeting in Brighton, England. It was officially launched in autumn 2000. The Collaboration consists of members from patient care, public health, scientific, pharmaceutical, regulatory and professional organizations coming from developed and developing countries.*

*Our target groups are health care providers, health officials, scientists, regulators, and all others who carry out immunization studies, who make clinical decisions about immunizations, and who need to get, interpret, provide, and report information on immunization safety.*

**Sources of Support:** *The work of the Brighton Collaboration is based on a large number of volunteers worldwide. It obtained its first funding in 1999 (from the CDC). The Brighton Collaboration is presently supported by the Centers for Disease Control and Prevention (CDC), the European Research Program for Improved Vaccine Safety Surveillance (EUSAFEVAC), and the World Health Organization (WHO).*

## **Brighton Collaboration Membership**

The following 81 individuals are listed on the Brighton Collaboration website as active participants in the Collaboration's activities. These individuals are HHS employees, other US or state government employees involved in vaccine issues, US Academic researchers or clinicians (many of whom have been advisers to both industry and HHS and/or are part of the Vaccine Safety Datalink project); and vaccine manufacturer representatives.

- |                             |   |
|-----------------------------|---|
| 1. Ball, Leslie             | Center for Drug Evaluation and Research, FDA  |
| 2. Ball, Robert             | Medical Officer IV, Division of Epidemiology, Office of Biostatistics and Epidemiology, CBER/FDA                            |
| 3. Bass, Dorsey             | Stanford University   |
| 4. Beeler, Judy             | Medical Officer Division of Vaccines & Related Products and Applications, Office of Vaccines Research and Review, CBER, FDA |
| 5. Bilinsky, Lt. Col. Roman | US Army   |
| 6. Black, Steve             | Kaiser Permanente Vaccine Study Center, NCK Permanente  |
| 7. Blum, Michael D.         | Wyeth, Wyeth-Ayerst Research  |
| 8. Blumberg, Dean A.        | UC Davis Medical Center   |
| 10. Braun, Miles            | Director, Division of Epidemiology, CBER, FDA   |
| 11. Buckwald, Dedra         | University of Washington, Harborview Medical Center   |
| 12. Carbone, Kathryn        | Associate Director for Research Supervisor Medical Officer Division of Vaccines and Related Products, CBER/FDA              |
| 13. Chen, Robert            | Chief, Immunization Safety Branch National Immunization Program, CDC  |

14. Connell, Jones Marcy
  15. Cvetkovich, Therese
  16. Davis, Robert L.
  17. Delattre, Dominique
  18. Drammeh, Bakary
  19. Engel, Charles
  20. Engler, JM Renata
  21. Evans, Geoffrey
  22. Feigin , Ralph
  23. Fischer, Margaret (Meg)
  24. Fischer, Thea
  25. Forrat, Marrie Christine
  26. France, Eric
  27. Friedlander, Sheila
  28. Gale, Arnie
  29. Graham, Philip
  30. Gralnz, Jason
  31. Guenaneche, Fouzia
  32. Gurtman, Alejandra
  33. Halsey, Neal
  34. Hansen, John
  35. Hartmann, Katharina
  36. Hoet, Bernard
  37. Hummer, Sandra Jo
  38. Jacobson , Robert
  39. Jason, Lenny
  40. Jones, James (Jim F)
  41. Katikaneni , Lakshmi
  42. Kenney, Kimberly
  43. Kleppinger , Cynthia
  44. Klimas, Nancy
  45. Kohl, Katrin
  46. Kumar, Mudra
  47. LaRussa, Phillip
  48. Laufer, Dagna
  49. Lee, Lucia
  50. Lewis, Edwin
  51. Loupi Elisabeth
  52. Love, Suzanne
  53. Marcy, Mike
- California DHS Immunization Branch  
Non-government, Medical Officer Division of Vaccines  
and Related Products, CBER, FDA  
Department of Pediatrics University of Washington;  
Group Health Cooperative  
Aventis Pasteur  
(He list himself as part of the Immunization Safety  
Branch National Immunization Program, CDC) the HHS  
site lists him as an Orise Contractor non-government  
CDC/NIP/ESD  
USUHS/Walter Reed  
DOD Walter Reed National Vaccine Healthcare Center  
Medical Director, Division of Vaccine Injury  
Compensation Program, HRSA  
Texas Children's Hospital  
Committee on Infectious Disease Monmouth Medical  
Center American Academy of Pediatrics  
EIS Officer Class of 2003, NCID/VR/CDC  
Aventis Pasteur  
Clinical Research Unit, Kaiser Permanente Colorado  
USCD Pediatrics  
Johns Hopkins University (Expert Witness for the  
Government for the VICP)  
Columbia University  
Clinical Research Unit Kaiser Permanente Colorado  
Aventis Pasteur  
Mount Sinai School of Medicine  
Johns Hopkins University  
NCK Kaiser Permanente  
Berna Biotech AG  
Glaxo Smithkline Beecham  
Immunization Branch California Department of Health  
Mayo Clinic  
Depaul University  
Research Medical Officer VR/NCID/CDC  
University of South Carolina  
CFIDS Association of America  
F. CBER/FDA Or NIDA/NIH  
University of Miami  
Fellow Immunization Safety Branch National  
Immunization Program, CDC  
UCSF  
Pediatrics, University of Columbia  
Wyeth  
Medical Officer DVRPA, OFFICE OF VACCINES  
RESEARCH AND REVIEW CBER/ FDA  
NCK Kaiser Permanente  
Aventis Pasteur  
US Navy Medical  
VSD Co-investigator, Clinical Professor of Pediatrics,  
Center for Vaccine Research, Harbor-University of

- California Los Angeles Medical Center , University of Southern California and Kaiser Foundation Hospital  
Torrance
54. Martin, Bryan Allergy Immunology Department Walter Reed Army Medical Center
55. Matthews, Dana University of Washington-Children's Hospital and Regional Medical Center/Fred Hutchinson Cancer Research Center
56. Menkes, John H. Pediatric, Neurology Cedar Mt. Sinai Medical Center
57. Murphy, Trudy Medical Officer, ESD/NIP/CDC Child Vaccines/ESD CDC
58. Monath, Thomas Acambis, Inc.
59. Music, Stanley Merck
60. Nalin, David Merck Vaccine Division
61. Niu, Manette Medical Officer DBA/OBRR/CBER, FDA
62. O'Brien, Katherine L. Center for American Indian and Alaskan Native Health/NIH (her affiliation at BC is listed as NIH, but her email is JHU)
63. Oleske , James University Hospital NJ Medical School
64. Papanicolaou ,Dimitris Emory University
65. Pool, Vitali Visiting Scientist ESD/NIP/CDC
66. Pustilnik, Stephen Galveston County Medical Examiner Office University of Texas Medical Branch
67. Reeves, William C (Bill) Supervisory Medical Officer, VR/NCID/CDC
68. Rothstein, Edward Pennridge Pediatrics Associate, Temple University
69. Schechter , Robert California Department of Health
70. Schuind, Ann GLAXOSMITHKLINE
71. Schwartz, Ann Medical Officer, DVRPA OFFICE OF VACCINES RESEARCH AND REVIEW/CBER/FDA
72. Sejvar , James Medical Officer, Epidemiologist, VR/NCID/CDC
73. Slater, Jay Supervisory Medical Officer DBPAP/OFFICE OF VACCINES RESEARCH AND REVIEW/CBER/FDA
74. Varricchio, Frederic Medical Officer DIVISION OF EPIDEMIOLOGY/OFFICE OF BIOSTATISTICS AND EPIDEMIOLOGY/CBER/FDA
75. Vernon, Suzanne Research Microbiologist, VR/NCID/CDC
76. Whitley, Richard Professor, Department of Medicine University of Alabama at Birmingham
77. Wise, Robert Medical Officer DIVISION OF EPIDEMIOLOGY/OFFICE OF BIOSTATISTICS AND EPIDEMIOLOGY/CBER/FDA
78. Wiznitzer, Max University Hospitals of Cleveland
79. Wolter, Joanne GLAXOSMITHKLINE
80. Zahorodny Walter Department of Pediatrics New Jersey Medical School
81. Zanardi, Lynn Epidemiologist, DAPHT/EPO/CDC, Burlington, VT

**Please provide answers to the following questions:**

1. Prior to receiving this letter, were you personally aware that HHS employees are actively involved with the Brighton Collaboration and that HHS is funding this project?
2. Do these employees, contractors, visiting scientists, and fellows have approved outside activities to participate in the Brighton Collaboration? If so, please provide a copy of each of these forms as well as a list of the individuals who approved these activities. If these outside activities were not approved, how will you address these unapproved outside activities?
3. Many of the academic researchers and clinicians involved in Brighton are recipients of HHS funding to conduct research on vaccines, act as special government employees, act as expert witnesses in vaccine injury compensation program hearings, and to participate in the Vaccine Safety Datalink Project. It appears that a significant portion of senior leadership in vaccine-related activities at HHS have compromised their ability to perform their duties as they would be required to recuse themselves from any actions with individuals listed above or their institutions, as well as their international negotiations and funding with the international participants of the Brighton Collaborations and their institutions. Please provide copies of all written recusals from these individuals for all grants, contracts, policy and funding issues, or other activities involving individuals listed above or their institutions?
4. Is it not outside the realms of ethical behavior for Federal employees to be actively involved with an organization with activities directly related to their government position?
5. Because of the reliance of other nations, especially developing countries on HHS on vaccine-related activities, I am also concerned that international researchers and government officials will feel forced into participation with the Brighton Collaboration for fear they will be excluded from future funding opportunities by CDC or be viewed in disfavor in the development of international collaborations.

**Approval of the Establishment of the Brighton Collaboration Within the CDC**

According to the Brighton Collaboration website, the organization received its first funding from the CDC in 1999, prior to its formal establishment.

- How much funding has been provided to the organization since 1999?
- Who authorized the funding each year? Please provide a list of all individuals in the decision chain on these fundings, as well as their titles at the time of the decision. Did anyone within the Office of the Secretary, HHS approve or clear participation of these activities and funding, or was this solely a CDC funding decision?
- Under what mechanism was this funding provided? Did any other organization compete for this funding or was it a sole source?

Also according to the website, the Brighton Collaboration has offices within the CDC. It appears that not only are HHS employees participating in an outside activity, but they are doing so during official hours and at government expense. Are these employees double dipping, i.e., receiving salaries from both the CDC and the Brighton Collaboration? Who approved the running of a non-government organization registered in Switzerland in a US Government facility? I find this very troubling and request clarification on how this activity has been entrenched within the CDC organization and facilities as well as how much HHS staff time and resources are being diverted from official duties to participating in this outside activity.

One example outlined on the Brighton Collaboration of this entrenchment and diversion from official duties includes the welcoming of the new member of the Brighton Secretariat in the January 2002 newsletter, "Bakary S. Drammeh, PhD, MPH as a new member of the secretariat. He will serve as the

Project Manager for the Brighton Collaboration as of 1/1/2002.” While he lists himself on their site as part of the Immunization Safety Branch National Immunization Program, CDC, the HHS employee directory lists him as an “Orise Contractor – non government CDC/NIP/ESD”. Dr. Drammeh works out of the CDC offices managing the Brighton Collaboration.

### **Consequences to Vaccine Injury Policy and Compensation**

I am very concerned that the activities of the Brighton Collaboration are intentionally or otherwise undermining the vaccine-insured’s ability to seek compensation through the Vaccine Injury Compensation Program.

For example:

In the January 2002 Brighton Collaboration Newsletter, the following statement illuminates this issue: “The Brighton Collaboration is about to set up a formal group looking at methodological problems of standardization of case definitions, which came in all working groups developing case definitions of ‘AEFI’ (e.g., how to prevent ‘post hoc ergo propter hoc’ assumptions in users, how to define a time frame following immunization- if at all, etc.). One outcome of this group should be an overall guideline document for case determination, recording, and presentation of immunization safety data.... We envision to define Allergic Reaction, Rash, Asthenia, Paresthesia, Sudden Infant Death Syndrome, Myalgia, Idiopathic Thrombocytopenia.”

**In May 2001**, the Seizure Working Group conducted a conference call (Participants: De Souza Brito, Glaucus, Fisher Meg, Gold Mike, Jan Bonhoeffer). The following statement was included in the minutes of the call:

*“Use of Brighton definitions Jan highlighted, that the definition we are aiming for is a single definition for all vaccine safety purposes including passive surveillance as well as pre- and post licensure trials. Further, the definition should be applicable in countries with more and less financial resources. This should be achieved by framing the definition in two to three levels. The first level should provide criteria being sensitive for convulsion, less cost intensive, and allowing for suboptimal data completeness. Hence, suitable for surveillance and settings with less financial possibilities. The second level should provide criteria being specific for the event, requiring a more detailed set of data available and possibly more financial resources. Hence, suitable for pre and post licensure trials. It was discussed, that we might not be able to come up with a two level definition as in another working group the need for a three level definition arose. In this group the terms ‘definite’, ‘probable’, ‘possible’ are used at this stage to grade the level of certainty that the reported event is actually what it was reported as. Mike pointed out, that these terms are otherwise used in the context of causality assessment of adverse drug events and might be misleading in our context. As we are aiming to use one format for all case definitions this is relevant to the members of all WGs. An email discussion involving the members of all WGs will be initiated by the coordinators.”*

The development of these guidelines will undermine the vaccine injury table and the ability for families to be compensated in the Vaccine Injury Compensation Program. Conclusions regarding adverse events related to immunization in these working groups included,

*“We agreed that a seizure following immunization with a killed vaccine is unlikely beyond 72 hours following immunization.” (Participants: John Menkes, Mike Gold, Meg Fisher, Jan Bonhoeffer) and “The ‘Brighton’ steering committee and the EUSAFEVAC steering committee have proposed to use a 3 level format for all definitions. For some definitions, particularly those*

*of symptoms and symptom complexes a one level format might be sufficient. In these cases the 'probable' and 'possible' level should be marked 'Not applicable'. We discussed that it might be difficult to develop three levels of certainty for the diagnosis 'seizure' as events are paroxysmal and usually of short duration. Hence the diagnosis is based on the history alone and timely performance of more specific tests such as EEG or Video-EEG are frequently not possible. A concern was also that we would 'loose' definite cases if the highest level of certainty was too exclusive by only allowing neurophysiological testing. Thus we confirmed our previous position to allow cases to be 'definite' on the basis of clinical criteria alone. But those should be rather strict. Glacus questioned the introduction of three levels in our definition in general as he felt it was not helpful to know the difference, between a probable and a possible seizure. Patricia pointed out, that a three level format would be helpful for causality assessment e.g. if in a study with two arms, the distribution of cases in one arm was in favour of definite seizures and in the other in favour of the possible seizures. This was agreed on, but we pointed out, that main reason for several levels is to classify individual cases on the bases of available clinical criteria of different specificity. Patricia pointed out, that a three level definition would be also helpful in passive surveillance to classify cases on the level of information missing. Jan highlighted, that cases with insufficient evidence, i.e. either missing information or a scientifically unacceptable test, should be listed as such in a separate category called 'Suspected case, with insufficient evidence' regardless of the amount of evidence missing. In these cases there is less evidence then for a 'possible case' which is defined by a particular set of predefined criteria specific for the event. Therefore, events should NOT be classified on the basis of missing information (i.e. the more information is missing, the less certain the event)." (Participants: Margaret Fisher, Patricia Vermeer, Mike Gold, Jan Bonhoeffer)*

**In June 2002**, the Brighton Collaboration Newsletter stated, "*Ad hoc Working Groups may be formed to take up new emerging AEFI /hot case definitions if additional Working Group Coordinators are available...Currently the Oxford Vaccine Group, VAERS, VSD, CISA and GSK have begun to use and/or evaluate the applicability of definitions.*"

**In July 2002**, the Brighton Collaboration announced that they were "*waiting for CDC clearance of a first paper to be submitted to the Journal "Vaccine" on the work of the Collaboration. We are also preparing publication of case definitions. We continue to spread the word at various Vaccine meetings in the US and Europe.*"

**In August 2002** the Brighton Collaboration lists its accomplishments for the previous year:

1. Secured funding from the World Health Organization (WHO) for computer/website programming and travel, the European Research Grant for Improved Vaccine Safety Surveillance (EUSAFEVAC) for 50% of one coordinator position, and in kind from the Centers for Disease Control and Prevention (CDC) for two full time staff members (U.S. coordinator Katrin Kohl and project manager Bakary Drammeh) and 50% of the EU coordinator position (Jan Bonhoeffer).
2. Developed a strategic document outlining the overall structure, policies and processes for the Collaboration.
3. Developed a 5 year strategic plan and a funding document.
4. Created a 'Brighton' Internet site (<http://Brightoncollaboration.org>), and a 'Brighton' e-mail ListServer.
5. Organized four in-person steering committee meetings.
6. Enlisted 56 volunteers in seven active working groups, and so far 16 additional volunteers for our next round of working groups.
7. Created a global network of ~300 participants coming from 34 countries.

8. Established collaboration with more than 30 organizations participating in the Reference Group (including WHO, FDA, CDC, GSK, INCLEN, AAP, AAFP, PhARMA, MedDRA/IFPMA, and many more), in addition to numerous individual experts in their field.
9. Developed case definitions and guidelines for 'intussusception', 'fever', 'prolonged crying', 'seizure', 'hypotonic-hyporesponsive episode', and for local reactions: 'nodule', 'swelling', 'cellulitis', 'abscess'.
10. Administered and evaluated web-based surveys for six definition documents.
11. Collaborated with several groups for the development, evaluation and implementation of case definitions, including the Oxford Vaccine Group for a needle size study, GlaxoSmithKline for intussusception in Singapore, CDC centers for yellow fever AEFI and DTaP trials, FDA for encephalopathy, and several more."

**In September 2002** the Brighton Collaboration announced they were "*progressing towards incorporation as an NGO/NPO Incorporation as an NGO/NPO in Switzerland by December 2002 seems probable while that in the USA is still uncertain. Incorporation is necessary (for the growth of the Collaboration) in order to solicit extra funds to supplement CDC, EUSAFEVAC, and WHO funds. These funds are essential if we are to fulfill our objectives of establishing a growing global network, develop 10 case definition documents per year, and evaluate and implement them....We want your input about advocacy. Largely due to your efforts and input, six case definition documents will soon be developed. Now it's time to start thinking about getting these case definitions off Brighton's shelves and into the field. In order to achieve successful implementation, we would appreciate your suggestions as how to advocate for the adoption and implementation of 'Brighton' documents in clinical trials and surveillance systems.... Development of Brighton standardized case definitions and guidelines for data collection, analysis, and presentation" was the topic of an oral presentation by Katrin Kohl to the Epidemiology Program Office (EPO) of the Centers for Disease Control and Prevention (CDC), Atlanta, October 1<sup>st</sup>, 2002. Ways to collaborate will be further explored with other CDC groups developing case definitions.*"

**In November 2002** the Newsletter states, "November was quite a productive month for the finalization of the six Case Definitions documents together with guidelines for data collection, analysis, and presentation of Adverse Event Following Immunization (AEFI) that was coupled with fundraising activities."

**In March 2003** the Collaboration announced: "We are pleased to report that we have received a grant to conduct a study to evaluate the applicability, reliability, sensitivity, and specificity of our case definitions in CDC Vaccine Adverse Event Reporting system (VAERS). One of the study objectives is to develop a generic protocol to evaluate the case definitions in other surveillance systems."

**Question:** Was this grant from HHS? If so, was it competed for, or was it a sole source? Who is managing this grant? Which individuals within HHS were involved in determining that Brighton would receive this grant? Please list their names and positions.

**In April 2003** the Collaboration announced: "So far we know of 21+ users of our case definition and guidelines documents coming from industry, national surveillance systems and various other clinical research settings from 14+ countries. You can assist us in further promoting the use of our documents! After all, only with their use will the elaborate and intense work of the respective working groups truly come to life."

**In May 2003**, the Collaboration announced: "Evaluation of Case Definitions in CDC Vaccine Adverse Event Reporting System (VAERS) We received funding to evaluate the applicability, reliability, sensitivity and specificity of the first six 'Brighton' case definitions in VAERS. We will collaborate with scientists from Tulane School of Public Health and Tropical Medicine for the protocol development and



implementation, and with principal investigators from the CISA (Clinical Immunization Safety Assessment) Network for the clinical review of case reports.”

**In June 2003**, the Collaboration announced: “Brighton Collaboration Foundation has been granted a tax exempt status in Switzerland” to enable the Collaboration to work efficiently at a low cost.”

**In July 2003** the Collaboration announced, “Sources of support: We are pleased to announce that The WHO will continue to fund the Collaboration and anticipate signing a new contract for 49,000 USD in the near future. The CDC Foundation has agreed to conduct fundraising activities for the Collaboration... We presented the work of the Collaboration to the Pharmacovigilance Working Group of the European Agency for the Evaluation of Medical Products (EMA) and look forward to an enhanced partnership.”

**Question:** Were any HHS or US employees involved or on loan to the WHO involved in contracting to provide the Brighton Collaboration funding? Are US taxpayer funds being funneled through the WHO to fund the Brighton Collaboration?

**In August 2003**, the Collaboration newsletter mentions that US taxpayer resources are being utilized for their activities in the form of the computer services (“the Brighton Listserv hosted by CDC Listservices”). They also announce, “Dr. Manya Magnus, professor of epidemiology from George Washington University, visited CDC in her role as contractor for a formal evaluation of six of our case definitions in the U.S. Vaccine Adverse Event Reporting System (VAERS). Preliminary data show usefulness and reasonably easy applicability of the case definition for “fever”, “nodule at injection site”, “persistent crying”, “intussusception”, “hypotonic-hyporesponsive episode”, and “generalized convulsive seizure” in VAERS.... We are aware of 37 different study groups or surveillance systems from 17 countries currently using the first 6 definitions & guideline documents.”

**In October 2003**, the Collaboration newsletters makes the following announcements: “We continue to aim for broad visibility of our work. One strategy includes to write editorials to scientific journals to alert other professionals about our work. In fact, all of you are invited to write a commentary or letter to a journal or newsletter to promote our work, and seek broader participation and implementation of our documents... The formal evaluation of the first six case definitions in VAERS has moved into the phase of selecting reports for a clinical review and for applying the definitions to the VAERS database. Johns Hopkins, University through the Clinical Immunization Safety Assessment Centers, will conduct the clinical review of selected reports... The Collaboration is intensifying its efforts to promote the implementation of our case definitions and guidelines by stimulating discussions between regulatory organizations and industry. A reference to the Brighton Collaboration is being considered in ICH and FDA technical and guidance documents... The case definition and guideline documents are being translated into other languages to maximize their impact and availability worldwide. The World Health Organization kindly offered their support in the process.”

**In November 2003** the Collaboration announces: “We are currently very active in promoting the recognition of Brighton case definitions and guidelines as a global standard. Several national and international regulatory authorities and vaccine manufacturers are considering recommendation of finalized documents in their respective settings. We encourage all of you to think of the different ways to use the Brighton documents in your respective organization.”

**In December 2003** the Collaboration makes the following announcements: “We are pleased to announce that the Brighton Collaboration Foundation has incorporated in Switzerland (CH-270.7.002.873-2). The Foundation is dedicated to fostering the attainment of The Brighton Collaboration’s vision. It was established to connect outside partners and resources with the Brighton Collaboration scientists to build strategies that can substantially enhance the Brighton Collaboration’s impact. The Foundation is an

independent, not-for-profit organization, under the direct supervision of the Swiss government. It can accept funding and responsibly create strategies that help donors and The Brighton Collaboration scientists achieve their common goals. The founder is the University Children's Hospital, Basel Switzerland. The founder has appointed the first Board consisting of Dr. Jan Bonhoeffer, University Children's Hospital Basel, Switzerland, President, Prof. Margaret Fisher, Monmouth Medical Center, New Jersey, U.S.A, Stephan Graus, Communication Specialist, Basel, Switzerland, Dr. Thomas Mayer, Attourney, Basel, Switzerland, Vice-President, Dr. David Nalin, Consultant in Vaccinology, Pennsylvania, U.S.A, Prof. Ray Spier, Editor: Vaccine, London, England."

Each of these announcements and activities outline an undermining of HHS vaccine-related authorities, policies, and programs. Most disturbing in that this organization was created by Dr. Robert Chen, a long-time HHS employee who takes credit for the creation of both the VAERS and VSD programs. It appears that just as Congress began an intense scrutiny of vaccine safety issues - 1991, Dr. Chen and other HHS employees sought to circumvent the roles and responsibilities of Congress, VRBAC and ACIP, as well as that of the Special Masters for the Vaccine Injury Compensation Program in the US Federal Court of Claims in matters concerning vaccine injury. They have done so while maintaining their status of HHS employees.

The Bright Collaboration has a tiered system of leadership. The top tier is the Steering Committee which oversees the overall mission, sets policies, determines the process, strategic goals and objectives, and monitors the growth of the Collaboration. Steering Committee members serve unlimited terms. Miles Braun, Director, Division of Epidemiology Center for Biologics and Evaluation, Food and Drug Administration and Robert Chen Chief, Immunization Safety Branch, National Immunization Program, Centers for Disease Control & Prevention both serve as Steering Committee Members. Other Members include a WHO official, an Aventis Pasteur Official, and a member of the VSD project.

The second tier of leadership/management is that of the Secretariat. Katrin Kohl, Brighton Collaboration and Working Group Coordinator Immunization Safety Branch, National Immunization Program, CDC and Bakary Drammeh, Project Manager Immunization Safety Branch, National Immunization Program, Centers for Disease Control (CDC) both serve in the Secretariat and are housed at the CDC.

### **IOM Immunization Safety Review**

On February 9, 2004 the IOM's Immunization Safety Reviewed continued its inquiry into vaccine safety data relevant to a potential link between vaccine injury and autism spectrum disorders. I was most disturbed that the research funded to date by HHS and presented to the IOM consisted almost entirely of epidemiological evaluations of vaccine databases both in the US and internationally. Several of the international studies presented were funded by HHS and included members of the Brighton Collaboration.

For more than five years Congress has been asking HHS to replicate the Wakefield research which found measles DNA in the bowels of 200 children who developed autism and chronic inflammatory bowel conditions after vaccination with the MMR vaccine. While HHS has not managed to finish a replication, others have been doing so and finding similar correlations. None of these individuals were invited to present their findings to the IOM, nor did any of the HHS presenters discuss these new clinical findings.

In the five years since the FDA discovered they had allowed children to receive vaccines containing levels of ethylmercury in excess of the EPA's scientifically-validated level for ingested methylmercury, there has been an inadequate response in conducting laboratory and clinical evaluations of the actual pharmacokinetics of IM injection of thimerosal and ethylmercury and their metabolization on the approximately 17 percent of the population allergic to one or more of the contents of thimerosal or the 15 percent of the population with a mercury and/or heavy metal efflux condition. To date, the HHS-funded

studies have not been designed to truly answer the questions. The studies are often too small, or inadequately controlled to garner conclusive information. These flaws have not, however; been readily admitted by HHS personnel, rather their findings have been grossly exaggerated in the media – based on information and statements provided by HHS. HHS employees have gone out of their way to deny any possible connection rather than earnestly and honestly evaluate this issue through well designed laboratory research.

The most recent example of this is of course the VSD study conducted by Thomas Verstraeten. Dr. Verstraeten found a disturbing correlation between the administration of thimerosal-containing vaccines and tics, ADD, speech and learning delays and neurodevelopmental delays. The study went through a number of reiterations and eventually the authors of the study managed to water down the findings to discount any possible vaccine-relation to these conditions. Further, CDC employees who co-authored the story failed to inform the publishing journal that Dr. Verstraeten is now an employee of GlaxoSmithKline in Belgium. These seemingly intentional diversions from the truth are unethical and continue to erode the public's confidence in HHS's desire to learn the level of harm caused by FDA's allowing thimerosal to remain in childhood vaccines decades after it was banned in topical ointments. While many at the FDA and in the public health community continue to say, well we have it out of children's vaccines now, this is not entirely true. One presented at the IOM meeting this past week showed vials of vaccines recommended for children that will not expire until 2005 which still contain thimerosal. Additionally, while FDA and CDC have been saying for more than a year that thimerosal is out of vaccines, the flu vaccine given to children last year and this year likely contained thimerosal. When families learn of these discrepancies, they feel that HHS does not truly have their children's safety and neurological development as the top priority, rather certain individuals, who were asleep at the switch during the decades of allowing thimerosal to remain are likely more concerned with being found negligent in their duties to protect the public health and the public trust.

Rather than truly addressing these legitimate concerns that have arisen in vaccine injury issues, HHS employees have instead focused their desire to create a framework that would discount any potential claim for vaccine-related injury. The Brighton Collaboration is proof of this intention. I believe these issues need your personal review. Much of these activities started prior to your appointment as Secretary; however, they have continued and accelerated on your watch and need to be resolved.

Thank you for your time with this matter. We greatly look forward to your response.

Sincerely,

Lyn Redwood, RN, MSN, NP  
President

Sallie Bernard  
Executive Director