From: Stanley Plotkin
Sent: 7 Jul 2018 12:29:45 -0400
To: 'Paul Offit';Destefano, Frank (CDC/OID/NCEZID);'Amy Pisani';'Dorit Reiss'
Subject: email from Ed Marcuse

Dear All:

Ed Marcuse wrote the email below to a member of the AAP Executive Board. I think it expresses very well the Package Insert Problem, and I will pursue further with the AAP. If you know anyone on the Board, please copy.

Stan

FDA package inserts for childhood vaccines do not accurately reflect what is now known about the safety of these vaccines.
I write to you to bring this to your attention and seek your guidance on how the AAP might partner with other organizations to request that the FDA review the package inserts for these products and revise them to state the current duration of follow-up and clarify the attribution of adverse events.
The Pediatric Infectious Disease Society is formally requesting the FDA to review these package inserts. Addition of the AAP's voice would be an enormous help.

Why is this import to AAP membership? Out of date, incomplete or misleading information in package inserts is cited to create doubt about the safety of these products thereby contributing to loss of confidence in universally recommended childhood vaccines and is also cited by plaintiffs in immunization litigation. Primary care pediatricians struggle daily to overcome parents doubts vaccines at least some of which are unfortunately based in part on information in these FDA documents.

Examples:
IPV package insert states vaccines followed fore 48 hours.
ActHib insert states there were serious adverse events in 3.4% of vaccines without defining serious adverse events.
Gardisil mentions a 2.3% rate of autoimmune disease Recombivax Hepatitis B package insert states safety was monitored for 5 days, no mention of use of a control group in licensing studies, multiple sclerosis and autoimmune diseases are mentioned as reported adverse events following vaccination which was reported in data from France but there is no mention of the subsequent negative studies about these events.
Engerix states vaccines were followed for 4 days

These inserts reflect some of the data initially submitted to the FDA at the time licensing but do not include information collected in much longer clinical trials or the information amassed from post marketing surveillance.

Package inserts also fail to distinguish between temporal versus causal association of adverse events with vaccination.

This issue was brought to my attention and to that of the Pediatric Infectious Disease Society by Dr. Stan Plotkin whose enormous contributions to modern vaccinology include the development of rubella vaccine and serving as chair of