(most recently, Dynavax asked if we could make a stronger reference to a 2-dose hepB series because providers were asking for it after the licensure of Heplisav-B).

Skip

From: Stanley Plotkin <stanley.plotkin@vaxconsult.com>
Sent: Tuesday, March 12, 2019 2:35 PM
To: Wolfe, Skip (CDC/DDID/NCIRD/ISD) <crw4@cdc.gov>
Subject: RE: MMR VIS Update

Dear Skip:

It appears to me that the VISs are generally acceptable, but I am still concerned about the MMR one and its listing of serious reactions. Can you determine who framed that section? Also, what role if any do manufacturers play in constructing a VIS?

Thanks,

Stanley

From: Wolfe, Skip (CDC/DDID/NCIRD/ISD) [mailto:crw4@cdc.gov]
Sent: Friday, March 08, 2019 12:24 PM
To: Stanley Plotkin
Subject: MMR VIS Update

Dear Dr. Plotkin,

I've shared your specific questions with Frank DeStefano and others at CDC's Immunization Safety Office, and while I'm awaiting their response, here are some results of my own quick research, assumptions, and thoughts:

"Long term seizures, coma or lowered consciousness" has appeared in VISs since the first MMR VIS in 1994, and deafness and brain damage since the second in 1998.

Sensorineural deafness was mentioned under "neurological events" in the 1998 MMR ACIP statement, and is mentioned in passing (as "hearing loss") in the current statement. My assumption is that "encephalopathy/encephalitis" (which also appears in both the 1998 and current ACIP statements) may account for both "long term seizures . . ." and "brain damage." The current ACIP statement also mentions measles inclusion body encephalitis. As I suggested during our phone conversation, we sometimes have lengthy discussions regarding how to paraphrase medical terms in ways that make them comprehensible by patients with limited literacy.

One relevant fact is that, regardless of the original rationale for including these adverse events on the VIS, reviewers in the 20 years since then have not suggested removing them.

Other considerations: During the various VIS reviews (i.e., FDA, ACCV, "consultation meetings" and reviews by CDC's epidemiologists) we often agree to include a rare adverse event for which there is "inadequate evidence to accept or reject" a causal relationship, simply out of a perceived ethical responsibility to advise patients of the possibility of its occurrence, no matter how rare. There is also a