

From: Sylvester, Gregg C
Sent: Mon, 4 Jun 2012 13:52:14 +0000
To: Vellozzi, Claudia (CDC/OID/NCEZID)
Cc: Destefano, Frank (CDC/OID/NCEZID);Slavin, Dorothy
Subject: RE: Pfizer (PCV13) Safety

Claudia:

I hope you are doing well. I'm just checking in with you because, I will be traveling for most of the month of June. No worries, I have copied Dorrie Slavin on this e-mail. She is a medical colleague of mine and can be your contact person when you (CDC) are prepared to share the data with us (Pfizer). Dorrie has taken the lead on drafting our response back to the FDA, so she is intimately involved in the issue.

You have her e-mail address (up above) and her office phone is (b)(6). Please don't hesitate to call her.

It is our hope that we can pull a few of our medical folks together to hear your findings.

**Thanks again,
Gregg**

Gregg C. Sylvester, MD, MPH
Medical Lead for Prevenar & Prevenar 13
Pediatric Vaccines
Medicines Development Group
Pfizer Inc.

From: Vellozzi, Claudia (CDC/OID/NCEZID) [mailto:bno1@cdc.gov]
Sent: Wednesday, May 16, 2012 9:34 AM
To: Sylvester, Gregg C
Cc: Destefano, Frank (CDC/OID/NCEZID)
Subject: RE: Pfizer (PCV13) Safety

Gregg

The analysis should be completed the first week of June and I suspect we will be sharing with a variety folks shortly after, including you.

Claudia Vellozzi, MD, MPH
404-639-6175
404-944-2737

From: Sylvester, Gregg C [mailto:Gregg.C.Sylvester@pfizer.com]
Sent: Tuesday, May 15, 2012 5:58 PM
To: Vellozzi, Claudia (CDC/OID/NCEZID)
Subject: RE: Pfizer (PCV13) Safety

Claudia:

How are you? Have you finished that wonderful Spring that Atlanta is famous for? Has Summer started? ;-)

I was wondering if your team (internal/external) has finished the VSD study on KD after PCV13 vaccination?

If so.....would you share the results with us (Pfizer)? If not.....do you know when it might be finished?

**Thanks,
Gregg**

Gregg C. Sylvester, MD, MPH
Global Medical Lead for Prevenar & Prevenar 13
Pediatric Vaccines
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Pfizer Inc.

From: Vellozzi, Claudia (CDC/OID/NCEZID) [<mailto:bno1@cdc.gov>]
Sent: Wednesday, April 18, 2012 6:23 PM
To: Sylvester, Gregg C
Cc: Destefano, Frank (CDC/OID/NCEZID); Shimabukuro, Tom (CDC/OID/NCEZID)
Subject: RE: Pfizer (PCV13) Safety

That shouldn't be problem
Claudia

From: Sylvester, Gregg C (b)(6)
Sent: Wednesday, April 18, 2012 5:41 PM
To: Vellozzi, Claudia (CDC/OID/NCEZID)
Cc: Destefano, Frank (CDC/OID/NCEZID); Shimabukuro, Tom (CDC/OID/NCEZID)
Subject: RE: Pfizer (PCV13) Safety

Claudia:

Thank you for updating me. I think that seems like a fair and prudent approach. We are reviewing all of our internal data also.

Would it be possible for your team to share the results with us (Pfizer) when you complete your analysis?

**Thanks again,
Gregg**

From: Vellozzi, Claudia (CDC/OID/NCEZID) [<mailto:bno1@cdc.gov>]
Sent: Wednesday, April 18, 2012 8:30 AM
To: Sylvester, Gregg C
Cc: Destefano, Frank (CDC/OID/NCEZID); Shimabukuro, Tom (CDC/OID/NCEZID)
Subject: RE: Pfizer (PCV13) Safety

Hi Gregg,
I just wanted you to know that I did discuss this with our counterparts at the FDA (so not Holly below) and they will share our update regarding the timeline for a final analysis for Kawasaki with Holly's group. I hope this helps.
Thanks,
Claudia

From: Sylvester, Gregg C (b)(6)
Sent: Wednesday, April 11, 2012 9:59 AM

To: Vellozzi, Claudia (CDC/OID/NCEZID); Shimabukuro, Tom (CDC/OID/NCEZID)
Subject: RE: Pfizer (PCV13) Safety

Claudia & Tom:

Holly Wieland (b)(6) is the person that we had spoken to at CBER within the FDA. Please don't hesitate to tell her that you have spoken with us. We are not trying to hide anything.

It is not our intent or desire for you to get involved with their regulatory decision process. We are only asking that you make Holly (CBER) aware that your VSD study is still ongoing and when you believe your analysis will be finished.

Pfizer is asking for more time to gather internal data and hopefully review the VSD before we commit to a language change in our label. We are hoping that good science and reliable data will shape our PCV13 label.

Please let me know if I can provide you any other further information.

Thanks you,
Gregg

Gregg C. Sylvester, MD, MPH
Medical Lead for Prevenar & Prevenar 13
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From: Vellozzi, Claudia (CDC/OID/NCEZID) [<mailto:bno1@cdc.gov>]
Sent: Monday, April 09, 2012 4:25 PM
To: Shimabukuro, Tom (CDC/OID/NCEZID); Sylvester, Gregg C
Subject: RE: Pfizer (PCV13) Safety

Gregg,

Just to clarify—we can give the FDA our timeline for final results, etc but we do not provide advice for their regulatory decisions. We are happy to discuss our current findings and timeline for final analysis with the FDA.

Thanks.

Claudia Vellozzi, MD, MPH
Deputy Director, Immunization Safety Office, CDC
404-639-6175
cell: 404-944-2737

From: Shimabukuro, Tom (CDC/OID/NCEZID)
Sent: Monday, April 09, 2012 4:00 PM
To: Sylvester, Gregg C
Cc: Vellozzi, Claudia (CDC/OID/NCEZID)
Subject: RE: Pfizer (PCV13) Safety

Okay, thanks.
Tom

From: Sylvester, Gregg C (b)(6)
Sent: Monday, April 09, 2012 3:00 PM

To: Shimabukuro, Tom (CDC/OID/NCEZID)
Subject: RE: Pfizer (PCV13) Safety

Tom & Claudia:

Thanks again for speaking with me last week. I understand that it's too soon to sit down and share with us the results from SCKP, however, I do want to accept your offer of talking with the FDA.

I have discussed it with my colleagues at Pfizer and we would appreciate it if you would be willing to follow up with the FDA and suggest that it is premature to add KD to our label. We are reexamining our internal data and would like to see the results of the VSD (SCKP) prior to further discussion.

I will get you the name of our contact at the FDA. It might very well be the same person you are sharing information with.

Thanks again,
Gregg

P.S. I don't have Claudia's e-mail. Can you please forward or discuss with her. Thx

Gregg C. Sylvester, MD, MPH
Medical Lead for Prevenar & Prevenar 13
Pediatric Vaccines
Medicines Development Group
Pfizer Inc.

From: Shimabukuro, Tom (CDC/OID/NCEZID) [<mailto:ayv6@cdc.gov>]
Sent: Thursday, April 05, 2012 2:10 PM
To: Sylvester, Gregg C
Subject: RE: Pfizer (PCV13) Safety

Gregg,

I'll set up a call for next week. Maybe Tuesday morning, but we need to get S. California Kaiser on the line, so that may take a little time to organize. Is Tuesday morning good for you?

Tom

From: Sylvester, Gregg C (b)(6)
Sent: Thursday, April 05, 2012 1:52 PM
To: Shimabukuro, Tom (CDC/OID/NCEZID)
Subject: RE: Pfizer (PCV13) Safety

Tom:

Thanks for the information. It seems from my internal discussions that the FDA has a shorter timeframe. I am under the impression that they are looking for something from us sooner. Is it possible to have a preliminary meeting in the next week or two and meet again in a month when the data is final?

Gregg

Gregg C. Sylvester, MD, MPH
Medical Lead for Prevenar & Prevenar 13
Pediatric Vaccines
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From: Shimabukuro, Tom (CDC/OID/NCEZID) [<mailto:ayv6@cdc.gov>]
Sent: Thursday, April 05, 2012 1:44 PM
To: Sylvester, Gregg C
Subject: RE: Pfizer (PCV13) Safety

Gregg,

The VSD evaluation of the association between PCV13 and Kawasaki disease is ongoing, but close to completion and we should have final results either later this month or in May. We can do a briefing for the Pfizer staff to present the final data. Maybe we can tentatively schedule something for early May. Will that work for you? Let me know.

Tom

From: Sylvester, Gregg C (b)(6)
Sent: Thursday, April 05, 2012 9:55 AM
To: Shimabukuro, Tom (CDC/OID/NCEZID)
Subject: RE: Pfizer (PCV13) Safety

Thank you very much.....

Gregg C. Sylvester, MD, MPH
Medical Lead for Prevenar & Prevenar 13
Pediatric Vaccines
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Pfizer Inc.

From: Shimabukuro, Tom (CDC/OID/NCEZID) [<mailto:ayv6@cdc.gov>]
Sent: Thursday, April 05, 2012 9:54 AM
To: Sylvester, Gregg C
Subject: RE: Pfizer (PCV13) Safety

Gregg,

I am aware of the ongoing PCV13 surveillance in VSD, but not familiar with the details for Kawasaki. Let me check with the VSD team and get back to you on that.

Tom

From: Sylvester, Gregg C (b)(6)
Sent: Thursday, April 05, 2012 7:54 AM
To: Shimabukuro, Tom (CDC/OID/NCEZID)
Subject: RE: Pfizer (PCV13) Safety

Tom:

Thank you for the follow up. I will share this analysis with my colleagues here.

I was actually calling you about another issue. FDA mentioned that the CDC saw a transient signal with PCV13 for Kawasaki Disease in VSD. We have not seen any type of signal and would like to learn more. Can you direct me to the right person to discuss this matter?

Gregg

Gregg C. Sylvester, MD, MPH
Medical Lead for Prevenar & Prevenar 13
Pediatric Vaccines
Medicines Development Group
Pfizer Inc.

From: Shimabukuro, Tom (CDC/OID/NCEZID) [<mailto:ayv6@cdc.gov>]
Sent: Wednesday, April 04, 2012 4:43 PM
To: Sylvester, Gregg C
Subject: RE: Pfizer (PCV13) Safety

Gregg,

Attached is the final VSD analysis of the 2010-11 febrile seizure signal. This really summarizes the data that was presented to ACIP and CDC leadership and was the basis for our public communications on febrile seizure risk and the determining factor for not recommending any changes in the schedule. It is the same data that was presented to Pfizer and Sanofi back in the fall of 2011, so I think you have seen the relevant data.

We have been monitoring for seizures for this influenza season in VSD, but not with the same intensity as last season because TIV didn't change from 2010-11 and recommendations didn't change and we already consider the signal to be assessed and quantified. The findings for this influenza season are consistent with what we saw in 2010-11 and this is not unexpected. This information was communicated to ACIP at the last meeting.

Let me know if you still want to discuss this. Thanks.

Tom

Tom Shimabukuro, MD, MPH, MBA
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From: Sylvester, Gregg C [<mailto:Gregg.C.Sylvester@pfizer.com>]
Sent: Wednesday, April 04, 2012 11:22 AM
To: Shimabukuro, Tom (CDC/OID/NCEZID)
Subject: Pfizer (PCV13) Safety

Tom:

Remember me? We spoke last year, regarding TIV/PCV13 and febrile seizures.

I have a new question with regards to the FDA and our PCV13 label. The FDA is telling us that they have seen some VSD data that has not been shared with us.

Could we chat for a few minutes today?

**Thanks,
Gregg**

P.S. I know the world of Public Health is a small world.....but I didn't put 2 + 2 together. We have met before.....through your (b)(6)

Gregg C. Sylvester, MD, MPH
Medical Lead for Prevenar & Prevenar 13
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