From: Mike Williams
To: 'Blaxill Mark'; Sallie Bernard
CC: tlredwood@mindspring.com
Sent: 10/6/2003 7:29:20 PM
Subject: RE: FW: Autism and thimerosal: questions re Danish Data

Mark, thanks for the kind words and the thoughtful summary of the tensions among interests. I do think we can get everybody working together eventually, at least all the lawers, primarily because with the size and power of our opponents, we cannot afford to be wasting our limited resources by duplicating or pigeonholing work and analyses. At least, I intend to keep trying to get us all in concert.

DOJ lawyers told us today that the thimerosal screening analysis paper (s?) will be published on Nov 1 or shortly thereafter. We may get an early copy of the paper, but won't know for another few days. Through the Geiers, we already have access to the VSD database, plus the CDC is supposed to have a copy of the final dataset from this new paper ready for us to look at next month, too. I have retained a very good biostatistician from Emory who we plan on having independently check the Geiers' VAERS analyses and also help them and us look at the VSD data.

when the three of you get together to brainstorm again, think what questions we might want to pose to the VSD database--for example, questions about the relationship between MMR and autism or other NDD's, and so on. You all have been thinking longer and harder about this stuff than anyone on our side, and your ideas will be welcome.

I will send you the protocol the Geiers have already gotten CDC and IRB approval for,---this must be treated as a confidential document for now as it represents their intellectual property, but if you guys can get Spitzer or perhaps even Sammy Suissa in Montreal to look at it, that would be great. Suissa was the epid on the PPA Yale NEJM stroke study, and I have heard nothing but good things about him. I understand he is one of the experts who filed reports in the UK MMR litigation.

One other thing: when I consult with you folks at Safeminds, the communications should be treated the same as if you were retained expert consultants. That way all of our communications between each other that I am on will almost certainly be privileged and never subject to non voluntary disclosure. Lawyers and parties to lawsuits are always allowed free and confidential consultation with experts of all types, and never have to disclose t o the court or other side that such consultants exist, and have no obligation to disclose communications with them, until and unless that expert consultant agrees to become a testifying expert witness, which is extremely unlikely in this case. Such an understanding does not prevent you from expressing your ideas in any forum, so long as you don't express mine.

-----Original Message-----
From: Blaxill Mark [mailto:Blaxill.Mark@BCG.com]
Sent: Monday, October 06, 2003 3:07 PM
To: Mike Williams; Sallie Bernard
Cc: tlredwood@mindspring.com
Subject: RE: FW: Autism and thimerosal: questions re Danish Data

Mike,
Thanks for the thoughtful note. You point to quite an important issue. Among the parents who are trying to figure out "what happened to my kid", I think there is a bit of a divide between the immune/MMR/viral/GI school and the mercury/toxicity/chelation /developmental people. It's not a large divide, and there is a great deal of common ground, but I do think that different people carry around different beliefs about what is primary and what is secondary and what are the mechanisms and what are the best solutions. Since we all need to simplify our worlds, we tend to choose a primary belief system.

Unfortunately, since the activist side has so many possible divides (this just one of them) and so much passion, we have a very hard time bringing things together. In addition to the immune vs. toxic divide, we also have harder ones
-genes vs environment
-penetrate the science vs. reject the scientists
-compromise on legislation vs hold out
-support litigation vs stay away from it
-anti-corporate vs shaping corporate
-focus on biomedical vs focus on therapy
-"sue the bastards" vs ask the bastards for research money
-alternative medicine vs drug therapy and "by the book" treatments
-etc. etc.

I strongly believe that we need more unity and that will require a greater degree of leadership than anyone has provided up to now in order to bridge more of these divides. I also think Andy Wakefield might have a lot of potential to provide it. He has earned such enormous respect from so many parents. Unfortunately for him, he has placed his chips on a pathway that is not well-supported by the epi data and so he has been on the defensive for too long.

That all said, I think most of us who think about this stuff would admit to a general sense of support for a disease model that reflects an interaction between mercury and viral exposures. None of us are smart enough to be able to specify what that is (and I don't think Sallie is crazy in her cell cycle hypothesis, I'm just not as far down the learning curve as she is and have other pet theories that I understand better). On top of that, selling the notion of the interaction requires a far more diffuse attack on "vaccines" in a general sense, which is a very hard position to defend. It sounds primitive.

The issue I will confess to the most difficulty with is the "sue the bastards" model. I have made some peace with that, in that I believe that anything that gets data into the public domain faster is a good thing and that this whole area needs a great deal more sunlight cast on it. I know you guys are working hard and trying to help a lot of families who need the help desperately. My attitude, therefore, is to try and work in the open too. Please recognize, though, that my firm has clients on the other side and so I cannot--in fairness to my partners--get directly involved in the quest for money. I only am interested in the quest for the truth. To the extent that truth supports the litigation, that's just fine by me. To the extent that the process of litigation shines light on the issues and opens up access to information, that's even better. And these conversations (quality discussions between professional people) are all just fine. I suspect that the insights we're talking about here lend themselves to good legal fact-finding and legwork. And Mike, I really do appreciate your thoughtful perspective and your understanding of the real reasons to do all this. I would say there are a few lawyers I've run into that make my discomfort really sharp. But you have been a class act all along and I appreciate your openness in sharing your insights and experiences with us.

My therapy for the day :)
Mark

-----Original Message-----
From: Mike Williams [mailto:michael_williams@wdolaw.com]
Sent: Sunday, October 05, 2003 9:55 PM
To: Sallie Bernard
Cc: Blaxill Mark; tlredwood@mindspring.com
Subject: RE: FW: Autism and thimerosal: questions re Danish Data

Sallie, Mark and Lyn: my education continued today. I met with Bradstreet for two hours alone at my office. We ran thru several of his slide shows, all excellent. He is good at both big picture and details analysis and convinced me that a synergism with the wounded immune system from thimerosal (especially in those kids with frequent antibiotic use and the susceptibility genes for heavy metal sensitivity) would explain why the kids take an obvious growth and development hit with MMR, and probably with a variety of other viruses many of which we don't even know about. Let me give you all a fresh and surprising recent example in another disease I have been dealing with for 14 years, severe arterial pulmonary hyptertension or primary pulmonary hypertension, a diagnosis more horrible than cancer in the way it inevitably and incurably (except by heart lung transplant) suffocates you: last week in the NEJM a major group of researchers from the U of Colorado published a study showing that 10 of 16 PPH patients had herpes virus 8 in their lung artery lesions. Cool, et al., Expression of Herpesvirus 8 in Primary Pulmonary Hypertension. What a surprise since I have dealt with two pharm disasters with PPH--contaminated L tryptophan also caused it, and clearly a synergistic factor, since three big epi studies have found a relative risk of about six for PPH after fenphen. So I am now a believer on the MMR connection and I understand how it can interact with thimerosal.

In addition, Bradstreet is a genius at visual presentation of complex neurological concepts. His use of digital 3D EEG software is incredibly persuasive, and so is his chart of seven layers of cortex development changes over the first 48 months of life. All this stuff was new to me today, probably not to you.

But I also heard evidence to convcine me that either alone (Thim or MMR) can trigger autism, too. We may well have two different subpopulations that a simple Venn diagram can show the court or jury why some react to either, and some to both. The size of the intersecting crescents we just don't know yet.

I had lunch with Rick Rollens, who assured me he believed we should marry the UK MMR effort. He was thrilled that we finally have all the US lawyers working in a united effort, and that we were working as fast as we can to unite with the UK effort. We have Canada with us too, by the way. And for some interesting legal reasons, Canada might even be the best first forum for the thimerosal can do it by itself science showdown. The most interesting thing I learned from Rick was that two weeks ago there was a major study planning meeting in Portland in conjunction with the Northwest Autism Society meeting, with the folks from MIND and with Buie and other east coast experts to design a gut biopsy study on the West Coast, too, on the measles issue. He said he thought it was going to happen. Buie has now done 500 kids, I heard today.

I also got to listen to Andy Wakefield for an hour this afternoon summarizing all his work and showing how the analogical disease of hepatic encephalopathy makes the likelihood that gut permeability confirmed by toxic type peptides in urine is a major contributing cause of autistic symptoms. What a hero he is and no jury would deny him his glory. No pharm would ever let us get him in front of a jury. We just need to get the green light somewhere and we can start getting many of these families some real money.

Based on what I learned this weekend (and it was an intensely scientific weekend), I think we can win the MMR causes autism case in the NVICP, now if we had to, more easily next year. We may be able to get Barr's legal aid corp paid back for all money spent on the MMR case to date, all the way back to 1996 or so, if we use in proving the NVICP case. Richard has a very important hearing on this in the morning in London, and was too preoccupied with the moment to discuss a merger tonight. The hearing is their attempt to revive the funding of the UK MMR litigation for three months while they try to decide what to do , and to remind them that even if the autism claim is out, there are still legitimate inflamatory bowel disease claims and some viral encephalopathy cases in the three where there was vaccine straine measles virus detected in their CSF. Or in autopsies.

Rollens is continuing to do wonders behind the scene at getting both state and federal money to do the right thing. He showed the Autism Dads California Connedted video today, and it overwhelmed me and the rest of the audience with the tragedy and the triumph of his own struggle and that of all the parents of an unnecessarily autistic child. Quite a weekend.

I am more committed than ever to this cause. Thanks for including me in your circle--- I am honored.

-----Original Message-----
From: Sallie Bernard [mailto:sbernard@arcresearch.com]
Sent: Saturday, October 04, 2003 3:20 PM
To: Mike Williams
Cc: Blaxill Mark; tlredwood@mindspring.com
Subject: RE: FW: Autism and thimerosal: questions re Danish Data

Mike:

You can reach me at 970 429-1460.

Yes, we are funding Deth. We are also helping to fund the monkey study. The brand study I'm not aware of. I can ask Robert Swayer for more details and what their thoughts are on getting the additional study subjects. We may be able to help.

My own hypothesis on how MMR works with thimerosal is that the immune dysfunction only partly explains the total disorder. The interesting part is that both xenobiotics act in the same direction in disruption of the cell cycle through a tendency to induce cell cycle arrest. Not all viruses work in this manner. In fact most viruses cause cell proliferation (eg AIDs) or work by membrane disruption. The ones besides measles that work through cell cycle arrest are those that tend to pop up in autism or cause "autistic-like" mouse models such as herpes, borna, and influenza. You only need a very small amount of measles virus to induce systemic cell cycle arrest - the effect is mediated by cytokines released by cells in response to the presence of the measles virus. We know that the most sensitive endpoint for mercury affects is disruption of the cell cycle, with a tendency toward cell cycle arrest. The harmful downstream effects are due to the dysregulation of protein synthesis in the cell - some proteins are over produced and some underproduced. This can this cause problems with protein degradation, accumulation of protein fragments, subsequent protein synthesis, and cell homeostatis. If things get too dysregulated, stress proteins are produced and apoptosis can occur. It is interesting that the other xenobiotic parents talk about is antibiotics, and the "pink stuff" in particular. Amoxycillan works its affects by inducing cell cycle arrest. Most other antibiotics to not act in this manner. So, if you have mercury, measles, and amoxycillan given to an infant and they are all causing the same pattern of disruption, it is easy to see why the child becomes impaired. It would also be easy to see how the impairment would persist if the mercury could not be excreted or the measles virus not cleared.

We'll see if my hypothesis is correct. Mark thinks it's biologically plausible but at this point mostly baloney! The point is, I do believe the measles and mercury are synergistic. Any theory must account for all the phenomena.

At 11:34 AM 10/4/2003 -0700, Mike Williams wrote:
I will call you first, Sallie, on Tuesday, maybe ten minutes before 10:30 our time. What number do I call to reach you?

In the meantime, I will try one more time to get him to look at what you did.

Yesterday, I met with Dr. Richard Deth for an hour, after I heard his presentation here at the DAN! conference. In my opinion, he is the best new scientist we have on our side in some time. He is unconnected with the litigation, and even not the parent of an autistic child, and yet he is one of the world's top researchers on the molecular biology and protonomics of dopamine receptors. I think you know all this, since he said he was getting some funding from Safeminds. One of his best friends, the dean of research at the Massachusetts College of Pharmacy, worked with me extensively in the fenphen litigation, so I had someone to vouch for my character to him, that always helps when you are a trial lawyer.

This morning I met with Richard Barr (lead attorney for the UK MMR claimants), Kirsten (last name?) (the head of their

science tema) and Andy Wakefield. We are trying to form a single alliance, as they have so much detailed information about not only measles virus problems, but also on thimerosal. Now that they have had their legal aid funding stopped, ilt is possible they may decide to send the cases over here, since every one of the three vaccines they are after were either developed or manufactured in the USA.

They say they have detected a "brand effect" that their epidemiologists are excited about--a pattern of things like sleep disturbance and odd physical behaviors that are documented in the medical records of one brand's victims, not the others. They are replicating this in a series of interviews with the parents.

Other very persuasive evidence they have includes at least three autopsies on autustic kids with measles virus in the brain, and some challenge rechallenge examples. They also claim that the epidemiology even in this country shows a decline in one long term horrible outcome of measles infection, Subacute Sclerosing Panencephalopathy (SSP) until shortly after MMR started being used, and now it is again on the rise. Wakefield says there is a united theory, that thimerosal disrupts and weakens the immune system and that the MMR mixed lot of live virus permits the measles virus to persist, in the gut of many and in the brains of a few. I remain highly skeptical, but we can't ignore the work they have done. I think we have to scrutinize it and take it into account somehow.

They say they need two million dollars to finish the key studies underway, namely a monkey study in Pittsburgh where the infant monkeys to be vaccinated are starting to be born (four groups, as I understand it: one non thimerosal vaccines but no MMR, one with thimerosal and no MMR, one with thimerosal and mmr and one with mmr only. You may know more about this then I learned in our brief chat this morning. The other key study they want to complete is to extend their brand effect data to a larger group of kids (their present count is just over 100, and their statisticians tell them to really nail it they need 450 cases).

Talking to Kirsten, I think she knows as much about ASD and the immune system and vaccines as anyone I have ever talked to, present company included. On the other hand, I think you folks in Safeminds are far ahead of the brits on thimerosal science. We have to find a way, I think, to raise this money and finish these studies. Even if some of it is fronted by the law firms, it will have to go through a genuinely independent foundation board and funding committee--we cannot have plaintiff lawyers directly involved in scientific research because the credibility of it can too easily be questioned.

We need to talk about all of this soon. I would very much like your input into this decision--if you decide it is a good idea to join forces with them and to help them complete their studies, then it will be much easier for me to get the rich Texans to back this with real money.

Finally, there is a new paper the Geiers told me about this week which I haven't yet seen, but am trying to get: Godfrey, ME, et al., Apolipoprotein E genotyping as a potential biomarker for mercury neurotoxicity; J. Alzheimer's Disease, 2003; 5:189-96. The Geiers told me this (I have not verified this yet): In this paper, these New Zealand scientists have 400 workers with mercury poisoning and 400 controls. On chelation the workers showed 9 times as much mercury as the controls, and there was clearly a pattern of the alleles for ApoE: if you had two ApoE 4 genes, let us say, you had total protection from the effects of mercury, but if you had two ApoE 2 genes, you were highly susceptible,and if you had a mix of 2 and 4 or 3, you were in between. The genes code either for a thiol containing protein or not, apparently. Obviously we need to get the paper.

Talk to you Tuesday.

-----Original Message-----
From: Sallie Bernard [mailto:sbernard@arcresearch.com]
Sent: Friday, October 03, 2003 1:51 PM
To: Mike Williams
Cc: Blaxill Mark; tlredwood@mindspring.com
Subject: Re: FW: Autism and thimerosal: questions re Danish Data

> Yes, there is definitely a communication breakdown. The age bands for the youngest cohort is clearly stated as 0-4 year olds. Besides, not having one year data is irrelevant to the argument. I didn't assume the new cases were totals. I added the new cases TO the totals for the previous year. Why is that so difficult to understand?
>
> I agree that my assumption on outpatient cases is an estimate based on what the 1999 registry year proportion was. If we can get a better estimate for 1992 from the Danish health agency I'd be glad to factor it in instead.
>
> I am available for the phone call on Tuesday.
>
> At 01:24 PM 10/3/2003 -0700, Mike Williams wrote:
> Sallie, there may still be miscommication with Grandjean on this. See his most recent comment below. We are scheduled to talk to him on the phone this coming Tuesday, Oct. 7, at 10:30 am pdt, 11:30 Aspen time, and if you would

like us to conference you in, tell me what number to call. If you have anything else to send him to clarify this, I will be glad to pass it on.

-----Original Message-----
From: Philippe Grandjean [mailto:PGrandjean@health.sdu.dk]
Sent: Thursday, October 02, 2003 1:04 AM
To: Mike Williams
Subject: SV: Autism and thimerosal: questions re Danish Data

Hi I used the new casesspreadsheet. The problem with the other spreadsheets is also that we dont have 1-year age data. My impression is that the data are OK given the caveats that the authors emphasize. Sallie assumed that the newcases were totals. She then used her own calculation for outpatient cases, which may or may not be correct. So her conclusions are based on two assumptions, of which at least one appears to be wrong. - Philippe

-----Oprindelig meddelelse-----
Fra: Mike Williams [mailto:michael_williams@wdolaw.com]
Sendt: 2. oktober 2003 00:34
Til: Philippe Grandjean
Emne: RE: Autism and thimerosal: questions re Danish Data

Phillipe, there is a tab for new cases and a tab for total cases. Can you recheck? Also, do you know or can you find out if we can get a breakdown of the count of current autism cases by birth year, and how far back?

I will send you some more specific questions soon, but the main one is: What is wrong with the Safeminds' analysis of the data, if anything.

-----Original Message-----
From: Philippe Grandjean [mailto:PGrandjean@health.sdu.dk]
Sent: Wednesday, October 01, 2003 2:43 AM
To: Mike Williams
Subject: SV: Autism and thimerosal: questions re Danish Data

Hi Mike I started looking at the papers (some of which I had not read in detail before). I also looked at the data sheet, which has been used by Sallie Bernard in her critical comments. It seems to me that the data sheet includes only new cases, so that cases previously diagnosed are not included later on. The data therefore do not indicate anything about loss of cases, and I believe from my knowledge about the registry that losses would be highly unlikely. However, the time trends are affected by changing diagnostic criteria, incomplete retrieval and lack of outpatient records from the early years. Because the data are recorded in 5-yr age groups, they are difficult to use for our purposes. Subjects recorded as cases will be included in, say, the total for 5-9-yr-olds. Thus, for example, the cases included in that group for 2002 were born between 1993 and 1997. This information is therefore difficult to relate in detail to the changes in vaccinations.
For illustration of the general tendencies, I did some preliminary calculations. Children were in the 0-4 age group in 1988-1992 are assumed to have entered the 5-9 age group in 1993-1997 and the 10-14 group in 1998-2002. If you add these numbers, you get a total of 334 cases among children who were born and vaccinated before the final phase-out of the mercury-containing tussis vacc. I then looked at the children aged 0-4 in 1993-1997, who would be in the 5-9 group in 1998-2002. There is a total of 598. The most recently born group who was 0-4 during 1998-2002 is 432, only counting cases diagnosed up to the age of 4 years. These numbers while highly approximate due to the nature of the data sheet appear to be in full accordance with the publications that you sent me.
I wanted to pass on these numbers and comments to you now so that you can perhaps respond if I have misunderstood something about the data. Also, Id like to know what you want to ask me about these papers so that I can prepare.
Best regards - Philippe

-----Oprindelig meddelelse-----
Fra: Mike Williams [mailto:michael_williams@wdolaw.com]
Sendt: 29. september 2003 20:33
Til: Philippe Grandjean
Emne: RE: Autism and thimerosal: questions re Danish Data

Phillipe, my schedule on Thursday is uncertain, but it is likely I will have some time in the morning (in Philadelphia is where I will be then, so only six hours difference). Please tell me again what number to call. It is likely to be around 9 am edt, which is 3 pm for you? or would another time be better.

also, the Safeminds critique has been polished slightly and you should use this new more final version attached.

-----Original Message-----
From: Philippe Grandjean [mailto:PGrandjean@health.sdu.dk]
Sent: Monday, September 29, 2003 11:02 AM
To: Mike Williams
Subject: SV: Autism and thimerosal: questions re Danish Data
Hi Mike will start looking at these materials tomorrow, should not be too hard since I have followed the studies at a distance. I hope to be ready by Thursday this week, although this is very soon, otherwise early next week. Im 9 hours ahead, so best morning your time. How does that fit with your schedule? Best - Philippe

-----Oprindelig meddelelse-----
Fra: Mike Williams [mailto:michael_williams@wdolaw.com]
Sendt: 29. september 2003 19:39
Til: Philippe Grandjean; Philippe Grandjean
Cc: Kathleen Dailey; tho@williamsbailey.com
Emne: Autism and thimerosal: questions re Danish Data

Phillipe, I hope this finds you well. We could use some consulting time with you on a peculiarly Danish problem. I attach to this email three items: (1) a new study due to appear tomorrow in JAMA, concluding that there is no association between thimerosal conntaining vaccines and autism, and (2) a critique of that study (and (3) the database on which the critique is based).

In my next email, I will also send you the other three articles now published from this same registry data, and a submitted by not yet accepted letter to the editor about one of these studies.

We thought you might have some interesting comments after you get a chance to read all of this.

Let me know when you would have the time to chat on the phone about this in the next few days, we hope.

Yours truly, Mike Williams <<JAMA denmark - first analysis9-29-03.doc>> <<autisme_us(DanishRegData).xls>> <<Thimerosal-Containing Vaccine and AutismJAMAOct03.pdf>>