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Selected vaccine authorities from CDC, FDA, and manufacturers discuss, in a closed meeting, the possibility of neurodevelopment disorders resulting from vaccine components.

Emphasis and comments in square brackets added by K.P. Stoller, M.D.

[The CDC published a study in late 2003, repudiating any possible link between thimerosal and developmental problems such as autism, but the CDC did have data supporting such a link which it secretively kept from the public.

Documents released through the Freedom of Information Act detail the transcript of a meeting held in June of 2000 between members of the CDC, the FDA, and representatives from the vaccine industry.

This top secret meeting was held to discuss a study done by Dr. Thomas Verstraeten and his co-workers using Vaccine Safety Datalink data as a project collaboration between the CDC's National Immunization Program (NIP) and four HMOs. The study examined the records of 110,000 children.

The transcript is titled "Scientific Review of Vaccine Safety Datalink Information," June 7-8, 2000, Simpsonwood Retreat Center, Norcross, Georgia, but it was also the first official meeting of the ACIP (Advisory Committee on Immunization Practices which sets CDC policy) work group on thimerosal and immunization. In attendance were Walter Orenstein, Director of the National Immunization Program (NIP) at the CDC; John Modlin, Chair of the ACIP and on the faculty at Dartmouth Medical School; and 50 other distinguished members of the government (11 consultants from the CDC), academia and the pharmaceutical industry. Vaccine industry representatives were: Harry Guess, M.D., Merck, Chief of Epidemiology; Jo White, M.D., North American Vaccine, Clinical Dev. & Research; Barbara Howe, M.D., Smith, Kline-Beecham, Clinical Research Group; Mike Blum, M.D., Wyeth, Safety and Surveillance for Vaccine Development.

Although this conference is apparently concerned with the effects of mercury in the form of thimerosal on infant brain development, participants seemed to have limited knowledge about mercury. None of the well known experts were invited, such as Dr. Ascher from Bowman Grey School of Medicine or Dr. Boyd Haley, who has done extensive work on the toxic effects of low concentrations on the CNS.

The conference followed a study that showed that mercury in vaccines may have caused neurodevelopment problems.

The following are in context excerpts of this 260 page transcript:]

Dr. Orenstein pg 1-2 "(For) those who don't know, initial concerns were raised last summer that mercury, as methylmercury (thimerosal) in vaccines, might exceed safe levels. As a result of these concerns, CDC undertook, in collaboration with investigators in the Vaccine safety Datalink, an effort to evaluate whether there were any health risks from mercury on any of these vaccines. Analysis to date raise some concerns of possible dose-response effect of increasing levels of mehylmercury in vaccines and certain neurologic diagnosis. Therefore, the purpose of this meeting is to have a careful scientific review of the data."

Dr. Bernier pg 8 : (Associate Director for Science in the NIP) "There was a Congressional Action in 1997 requiring the FDA to review Mercury in drugs and biologics…in October of 1999 the ACIP looked this situation over again and… said the vaccines could be continued to be used."

Dr. Johnston, pg. 14-15 & 19-20: (Chair of the meeting and a pediatrician-immunologist at the University of Colorado): "Thimerosal is cleaved (in the body) into ethylmercury and thiosalicylate which is inactive… The data on

its toxicity (shows) it can cause neurologic and renal toxicity, including death."

"It is particularly a concern in multi-dose vials because of the issue of re-entry multiple times in the vials, and it is also important in the manufacturing process for a number of vaccine including inactivated influenza and some of the earlier DPT vaccine, and is a constituent of all DPT vaccines, but not all DTAP vaccines."

"There are three licensed preservative in the United States, Thimerosal, ethyl and phenol. We won't talk about the other two today, but I thought I should mention them. Thimerosal is the most active and it has been utilized in vaccines since the 1930's."

"Acutely, it can cause neurologic and renal toxicity, including death, from overdose…"

"Dr. Halsey made a very impassioned plea that we do carefully controlled studies to in fact address the issues specifically, and that such studies be conducted by neurodevelopmentalists and environmental scientists employing specific endpoints of their study…"

"We just recently had another meeting that some of you were able to attend dealing with aluminum in vaccines. I would like to just say one or two words about that before I conclude."

"We learned at that meeting a number of important things about aluminum, and I think they also are important in our considerations today. "Aluminum salts are important in the formulating process of vaccines, both in antigen stabilization and absorption of endotoxin."

"Aluminum and mercury are often simultaneously administered to infants, both at the same site and at different sites."

"However, we also learned that there is absolutely no data, including animal data, about the potential for synergy, additively or antagonism, all of which can occur in binary metal mixtures that relate and allow us to draw any conclusions from the simultaneous exposure to these two salts in vaccines…"

Dr. Weil, pg. 24: "I think it's clear to me anyway that we are talking about a problem that is probably more related to bolus acute exposures, and we also need to know that the migration problems and some of the other developmental problems in the central nervous system go on for quite a period after birth. But from all of the other studies of toxic substances, the earlier you work with the central nervous system, the more likely you are to run into a sensitive period for one of these effects, so that moving from one month or one day of birth to six months of birth changes enormously the potential for toxicity. **There are just a host of neurodevelopmental data that would suggest that we've got a serious problem.** The earlier we go, the more serious the problem."

"The second point I could make is that in relationship to aluminum, being a nephrologist for a long time, **the potential for aluminum and central nervous system toxicity was established by dialysis data. To think there isn't some possible problem here is unreal."**

Dr. Verstraeten, pg. 31: "It is sort of interesting that when I first came to the CDC as a NIS officer a year ago only, I didn't really know what I wanted to do, but one of the things I knew I didn't want to do was studies that had to do with toxicology or environmental health. Now it turns out that other people also thought that this study was not the right thing to do, so **what I will present to you is the study that nobody thought we should do."**

Dr. Verstraeten, pg. 40: "…we have found statistically significant relationships between the exposure and outcomes for these different exposures and outcomes. First, for two months of age, an unspecified developmental delay, which has its own specific ICD9 code. Exposure at three months of age, Tics. Exposure at six months of age, an attention deficit disorder. Exposure at one, three and six months of age, language and speech delays which are two separate ICD9 codes. Exposures at one, three and six months of age, the entire category of neurodevelopmental delays, which includes all of these plus a number of other disorders."

Dr. Verstraeten, pg. 42: "But for one thing that is for sure, there is certainly an under-ascertainment of all of these because some of the children are just not old enough to be diagnosed. So the crude incidence rates are probably much lower that what you would expect because the cohort is still very young."

Dr. Verstraeten, pg. 44: "Now for speech delays, which is the largest single disorder in this category of neurologic delays. The results are a suggestion of a trend with a small dip. The overall test for trend is highly statistically significant above one."

Dr. Verstraeten, pg. 45: "What this represents is the overall category of developmental delays, of which I have excluded speech delays because of the impression we had was some of the calculations were driven by this speech group, which was making up about half of this category. After excluding this speech group, the trend is also apparent in this group and the test for trend is also significant for this category excluding speech."

Dr. Weil, pg. 75: "I think that what you are saying is in term of chronic exposure. I think that the alternative scenario is that this repeated acute exposures, and like many repeated acute exposures, if you consider a dose of 25 micrograms on one day, then you are above threshold. At least we think you are, and then you do that over and over to a series of neurons where the toxic effect may be the same set of neurons or the same set of neurologic processes; it is conceivable that the more mercury you get, the more effect you are going to get."

Dr. Verstraeten, pg. 76: "What I have done here, I am putting into the model instead of mercury, a number of antigens that the children received, and what do we get? Not surprisingly, we get very similar estimates as what we got for Thimerosal because every vaccine put in the equation has Thimerosal. So for speech and the other ones maybe it's not so significant, but for the overall group it is also significant….Here we have the same thing, but instead of number of antigens, number of shots. Just the number of vaccinations given to a child, which is also for nearly all of them significantly related."

Dr. Guess, pg. 77: "So this essentially is a 7% risk per antigen, an antigen is like in DPT you've got three antigens."

Dr. Verstraeten, pg. 77: "Correct."

Dr. Egan, pg. 77: "Could you do this calculation for aluminum?"

Dr. Verstraeten, pg. 77: "I did it for aluminum…Actually the results were almost identical to ethylmercury because the amount of aluminum goes along almost exactly with the mercury one."

Dr. Verstraeten, pg. 78-79: "Then the last slide I wanted to show, there was a question of it there was any way from this data that we could estimate what would happen in the future if there is Thimerosal-free Hep B and Thimerosal-free haemophilus influenza vaccine and only DTP has Thimerosal"

"The second column would be the same scenario but now at six months. Assuming they have received two additional DPTs, so between three and six months of age they have increased their ethylmercury amounts by 50 micrograms. If I do in this current cohort with all its limitations, because there is also the Hep B that exists in the cohort*, I can't really take it out. It is significant for this one disorder which is language delay and is a combination of these two disorders, also becomes significant."

* Dr. Verstraeten could not determine which children got Hep B at birth in some cases so it was difficult to back the birth dose of Hep B out of the data.

Dr. Bernier, pg. 113: "We have asked you to keep this information confidential. We do have a plan for discussing these data at the upcoming meeting of the Advisory Committee of Immunization Practices on June 21 and June 22. **At that time CDC plans to make a public release of this information*,** so I think it would serve all of our interests best if we could continue to consider these data. The ACIP work group will be considering also. If we could consider these data in a certain protected environment. So we are asking people who have a great job protecting this information up until now, to continue to do that until the time of the ACIP meeting. So to basically **consider this embargoed information.** That would help all of us to use the machinery that we have in place for considering these data and for arriving at policy recommendations."

[*This never happened. SafeMind.org obtained this transcript via the Freedom of Information Act. Data published later were diluted into insignificance by including additional data from an HMO that had very uncharacteristic results.]

Dr. Keller, pgs. 116 & 118: "…we know the developing neurologic system is more sensitive than one that is fully developed…"

Dr. Verstraeten, pg. 142: "But if I can have the next slide, here instead of the proportional hazard model, we did a logistic regression model. I didn't use person time here and it's a bit tough to define exactly the control group. However, if I do it for all ages and not looking at different years, and this is for speech, the outcome is almost identical to the proportional hazard model, which suggests to me that it is not a question of bringing the diagnosis forward, but it is really the overall number that drives this estimate."

Dr. Rapin, pg. 143: "I would like to make a comment. We have been focusing on all these acquired causes including mercury and prematurity, and you had a list of confounding variables that should be considered in future studies. What we know today about all of the developmental disorders is that environmental factors are in fact rather unimportant in the case of these deficits and the major cause is genetic…I find it a little difficult knowing this and putting in autism. The major cause is not environmental, it is genetic and that we are focusing just on these environment events or adventitious events when we haven't considered, and you told us that you don't have data for example on siblings, your study does not lend itself to considering the major variable."

Dr. Johnson, pg 144: "Well, I think the assumption is that those genetic predispositions would be randomly distributed."

Dr. Rapin, pg. 144: "But you don't know that."

Dr. Johnson, pg. 144: "No, that's an interesting assumption."

Dr. Rapin, pg. 144: "I understand that, but you don't know that."

Dr. Johnson, pg. 144: "just on principle, Dr. Rapin, it seems to me that the more we learn about genetics or the more we learn about let's say autism, the more we shift towards focusing on genetic causes, but would you rule out the possibility, and let's move away from autism, that some of these are genetic predisposition and then the second hit?"

Dr. Rapin, pg. 144: "Not at all. I think that it is in fact an attractive hypothesis."

Dr. Johnson, pg. 145: "Right, thank you."

Dr. Chen, pg. 151: "One of the reasons that led me personally to not be so quick to dismiss the findings was that on his own Tom independently picked three different outcomes that he did not think could be associated with mercury and three out of three had a different pattern across different exposure levels as compared to the ones that again on a priority basis we picked as biologically plausible to be due to mercury exposure."

Dr. Brent, pg. 161: "Wasn't it true that if you looked at the population that had 25 micrograms you had a certain risk and when you got to 75 micrograms you had a higher risk."

Dr. Verstraeten, pg. 161: "Yes, absolutely, but these are all at the same time. Measured at the same age at least."

Dr. Brent, pg. 161: I understand that, but they are different exposures."

Dr. Verstraeten, pg. 161: "Yes."

Dr. Brent, pg. 161: "What is your explanation? What explanations would you give for that?"

Dr. Verstraeten, pg. 161: "Personally, I have three hypotheses. My first hypothesis is it is parental bias. The children that are more likely to be vaccinated are more likely to be picked and diagnosed. Second hypothesis, I don't know. There is a bias that I have not recognized, and nobody has yet told me about it. Third hypothesis. It's true, **it's Thimerosal**. Those are my hypotheses."

Dr. Brent, pg. 161: "If it's true, which or what mechanisms would you explain the finding with?"

Dr. Verstraeten, pg. 162: "You are asking for biological plausibility?"

Dr. Brent, pg. 162: "Well, yes."

Dr. Verstraeten, pg. 162: "When I saw this, and I went back through the literature, I was actually stunned by what I saw because I thought it is plausible. First of all there is the Faeroe study, which I think people have dismissed too easily, and there is a new article in the same Journal that was presented here, the Journal of Pediatrics, where they have looked at PCB.

They have looked at other contaminants in seafood and they have adjusted for that, and still mercury comes out. That is one point. Another point is that in many of the studies with animals, it turned out that there is quite a different result depending on the dose of mercury. Depending on the route of exposure and depending on the age at which the animals, it turned out that there is quite a different result depending on the dose of mercury. Depending on the route of exposure and depending on the age at which the animals were exposed. Now, I don't know how much you can extrapolate that from animals to humans, but that tells me mercury at one month of age is not the same as mercury at three months, at 12 months, prenatal mercury, later mercury. There is a whole range of plausible outcomes from mercury. On top of that, I think that we cannot so easily compare the U.S. population to Faeroe or Seychelles populations. We have different mean levels of exposure. We are comparing high to high in the Seychelles, high to high in the Faeroe and low to low in the U.S., so I am not sure how easily you can transpose one finding to another one. So basically to me that leaves all the options open, and that means I can not exclude such a possible effect."

Dr. Orenstein, pg. 184: "Well, the second issue is we don't know causality. We don't know about causality, but is this something that really warrants some urgent attention?"

Dr. Clover, pg. 187: "…no one around here is going to say that mercury per say is not a concern."

Dr. Weil, pg. 187 & 188: **"Although the data presents a number of uncertainties, there is adequate consistency, biological plausibility, a lack of relationship with phenomenon not expected to be related, and a potential causal role that is as good as any other hypothesized etiology of explanation of the noted associations. In addition, the possibility that the associations could be causal has major significance for public and professional acceptance of Thimerosal containing vaccines. I think that is a critical issue. Finally, lack of further study would be horrendous grist for the anti-vaccination bill. That's why we need to go on, and urgently I would add.***

Dr. Brent, pg. 188-191: "I am impressed with the fact that some people here have information and believe that like the incidence of learning difficulties, behavior disorders and attention deficit is increasing in our population. I don't know whether it is or it isn't, but that kind of information you just can't throw around and say it's true or isn't true without data. And it is such an important area in our society. I mean it is the thing that makes a human being different from the other species, so it is such an important area of research…"

"…(thimerosal) Causing learning disabilities and behavioral disorders. ADD is a tremendous problem in our society and I think it is one that we should be very concerned about."

"Finally, the thing that concerns me the most, those who know me, I have been a pin stick in the litigation community because of the nonsense of our litigious society. This will be a resource to our very busy plaintiff attorneys in this country when this information becomes available. They want business and this could potentially be a lot of business."

Dr. Koller, pg. 192: "…As you increase the vaccination, you increase effects, but you don't know. You have modified live viruses. You have different antigens. There is a lot of things in those vaccinations other than mercury, and we don't know whether this is a vaccination effect or a mercury effect. But I am almost sure it is not a mercury effect. Positive as a matter of fact, and there are several experts particularly that have reviewed this, the methylmercury aspect who would agree with that due to dose response."

Dr. Johnson, pg. 193: "Are you really comfortable with the way the neurologic function was tested in the Seychelles?"

Dr. Koller, pg. 193: "I have to admit that there were many other tests that could have been conducted…We are talking about very subjective, very sensitive assays and yes, there could have been others done and there should be more done…"

Dr. Johnson, pg. 198: "This association leads me to favor a recommendation that infants up to two years old not be immunized with Thimerosal containing vaccines if suitable alternative preparations are available."

"My gut feeling? It worries me enough. Forgive this personal comment, but I got called out at eight o'clock for an emergency call and my daughter-in-law delivered a son by C-section. Our first male in the line of the next

generation, and **I do not want that grandson to get a Thimerosal containing vaccine until we know better what is going on.** It will probably take a long time. In the meantime, and I know there are probably implications for this internationally, but in the meantime I think I want that grandson to only be given Thimerosal-free vaccines."

Dr. Bernier, pg 198: "the negative findings need to be pinned down and published."

Dr. Weil, pg. 207: "The number of dose related relationships are linear and statistically significant. You can play with this all you want. They are linear. They are statistically significant. The positive relationships are those that one might expect from the Faroe Islands studies. They are also related to those data we do have on experimental animal data and similar to the neurodevelopmental tox data on other substances, so that I think you can't accept that this is out of the ordinary. It isn't out of the ordinary."

Dr. Weil, pg. 208: "The rise in the frequency of neurobehavioral disorders whether it is ascertainment or real, is not too bad. It is much too graphic. We don't see that kind of genetic change in 30 years."

Dr. Brent, pg. 229: "The medical/legal findings in this study, causal or not, are horrendous and therefore, it is important that the suggested epidemiological, pharmacokinetic, and animal studies be performed. If an allegation was made that a child's neurobehavioral findings were caused by Thimerosal containing vaccines, you could readily find junk scientist who would support the claim with "a reasonable degree of certainty". But you will not find a scientist with any integrity who would say the reverse with the data that is available. And that is true. So **we are in a bad position from the standpoint of defending any lawsuits** if they were initiated and I am concerned."

Dr. Meyers, pg. 231: "Can I go back to the core issue about the research? My own concern, and a couple of you said it, there is an association between vaccines and outcome that worries both parents and pediatricians. We don't really know what that outcome is, but it is one that worries us and there is an association with vaccines. We keep jumping back to Thimerosal, but a number of us are concerned that Thimerosal may be less likely than some of the potential associations that have been made. Some of the potential associations are number of injections, number of antigens, other additives. We mentioned aluminum and I mentioned yesterday aluminum and mercury. Antipyretics and analgesics are better utilized when vaccines are given. And then every body mentioned all of the ones that we can't think about in this quick time period that are a part of this association, and yet all of the questions I hear we are asking have to do with Thimerosal. My concern is we need to ask the questions about the other potential associations, because we are going to the Thimerosal-free vaccine. I f many of us don't think that this is a plausible association because of the levels and so on, then we are missing looking for the association that may be the important one."

Dr. Caserta, pg. 234: "One of the things I learned at the Aluminum Conference in Puerto Rico that was tied into the metal lines in biology and medicine that I never really understood before, is the interactive effect of different metals when they are together in the same organism. It is not the same as when they are alone, and I think it would be foolish for us not to include aluminum as part of our thinking with this."

Dr. Clements, pg 247- 249: "I am really concerned that we have taken off like a boat going down one arm of the mangrove swamp at high speed, when in fact there was not enough discussion really early on about which was the boat should go at all. And I really want to risk offending everyone in the room by saying that **perhaps this study should not have been done at all, because the outcome of it could have, to some extent, been predicted, and we have all reached this point now where we are left hanging, even though I hear the majority of consultants say to the Board that they are not convinced there is a causality direct link between Thimerosal and various neurological outcomes."**

"I know how we handle it from here is extremely problematic. The ACIP is going to depend on comments from this group in order to move forward into policy, and I have been advised that whatever I say should not move into the policy area because that is not the point of this meeting. But nonetheless, we know from many experiences in history that the pure scientist has done research because of pure science. But that pure science has resulted in splitting the atom or some other process which is completely beyond the power of the scientists who did the research to control it. And what we have here is people who have, for every best reason in the world, pursued a direction of research. But there is not the point at which the research results

have to be handled, and **even if this committee decides that there is no association and that information gets out, the work that has been done and through the freedom of information that will be taken by others and will be used in ways beyond the control of this group. And I am very concerned about that as I suspect it already too late to do anything regardless of any professional body and what they say."**

"My mandate as I sit here in this group is to make sure at the end of the day the 100,000,000 are immunized with DTP, Hepatitis B and if possible Hib, this year, next year and for many years to come, and that will have to be with Thimerosal containing vaccines unless a miracle occurs and an alternative is found quickly and is tried and found to be safe."

"So I leave you with the challenge **that I am very concerned that this has gotten this far, and that having got this far, how you present in a concerted voice the information to the ACIP in a way they will be able to handle it and not get exposed** to the traps which are out there in public relations. My message would be that any other study, and I like the study that has just been described here very much. I think it makes a lot of sense, but it has to be thought through. What are the potential outcomes and how will you handle it? **How will it be presented to a public and media** that is hungry for selecting the information they want to use for whatever means they in store for them?"

"…but I wonder **how on earth you are going to handle it from here."**

Dr. Bernier, pg. 256: "…As difficult as science is, there are two other equally tricky, complex challenges. The policy crafting has to take into consideration some very diverse and complex issues. There is another group that will deal with that, and then we have the communication and how we handle this, which I think I am no expert at, but seems equally daunting to me as the scientific and the policy issue."

"I don't think we can set a rule here because some people have gotten these documents. For example, some of the manufacturers were privileged to receive this information. It has been important for them to share it within the company with the experts there, so they can review it. Some of you may have questions. You may have given a copy, but I think if we will all **just consider this embargoed information, if I can use that term, and very highly protected information,** I think that was the best I can offer.

Excerpts from:

Bob Chen, M.D., CDC's chief of Vaccine Safety and Development, National Immunization Program

Tom Clarkson, M.D., University of Rochester, New York, Mercury program

John Clements, World Health Organization (WHO) representing expanded program on immunization

Bob Davis, M.D., University of Washington, associate professor of pediatrics and epidemiology

Bill Egan, Ph.D., FDA's Center for Biologics, Evaluation & Research

David Johnson, M.D., Michigan state public health officer, Advisory Committee on Immunization Practices (ACIP)

Dick Johnston, M.D., University of Colorado School of Medicine and National Jewish Center for Immunology and Respiratory Medicine, immunologist and pediatrician

Loren Koller, D.V.M., Oregon State University College of Veterinary Medicine, pathologist, immunotoxicologist

Martin Meyers, M.D., CDC's acting director, National Immunization Program

Walter Orenstein, M.D. CDC's director, National Immunization Program

Isabelle Rapin, M.D., Albert Einstein College of Medicine, neurologist for children

Tom Verstraeten, M.D., CDC's National Immunization Program presently employed by Glaxo-Welcome, vaccine company

Bill Weil, M.D., retired pediatrician, representing American Academy of Pediatrics' (AAP)