

**IN THE UNITED STATES DISTRICT COURT FOR THE
DISTRICT OF COLUMBIA**

DR. MARK GEIER and DAVID GEIER)
14 Rodgate Court)
Silver Spring, Maryland 20905)

Plaintiffs,)

Vs.)

Case No. 1:05CV01749
Judge: Thomas F. Hogan

DEPARTMENT OF HEALTH AND HUMAN)
SERVICES)
200 Independence Avenue, SW)
Washington, DC 20201)

DR. SARAH K. PARKER and DR. JAMES TODD))
Children’s Hospital – Department of Pediatrics)
1056 East 19th Avenue)
Denver, CO 80218)

DR. BENJAMIN SCHWARTZ and)
DR. LARRY PICKERING)
National Vaccine Program Office)
Department of Health and Human Services)
200 Independence Avenue, SW – Room 725)
Washington, DC 20201)

THE AMERICAN ACADEMY OF PEDIATRICS)
601 13th Street, NW)
Suite 400- North)
Washington, DC 20005)

Defendants.)

DECLARATION OF DR. SARAH K. PARKER, M.D.

I, Dr. Sarah K. Parker, pursuant to 28 U.S.C. § 1746, declare as follows:

1. In my October 25, 2005 declaration, submitted in this case, I explained that I traveled to Washington, DC to attend the 39th National Immunization Conference from March 21-24, 2005. As I also explained, I presented a one-hour plenary session at that conference on "Hot Topics in Vaccine Safety."

2. I understand that plaintiffs in this action have raised questions about the contents of my remarks at the March 2005 National Immunization Conference. Subsequent to that conference, I was provided with a transcript of my presentation by conference organizers from the Centers for Disease Control. The transcript of my presentation at the March 2005 National Immunization Conference in Washington, DC is attached hereto as Attachment A.

EXECUTED this 6th day of January, 2006.

A handwritten signature in black ink, appearing to read "Sarah K. Parker MD", written over a horizontal line.

Sarah K. Parker, M.D.

DR. PARKER: Unlike our patients and our children, who are willing to go into vaccination with their eyes closed, we should not go into vaccination with our eyes closed because our parents are trying not to. If a parent were to Google vaccines and autism, they would get over 165,000 hits. Some of these have good information, but I would dare to say that much of it is misinformation. It is our job as health care providers to help parents sort through this information.

I have been following this controversy closely since it emerged in 1998, and I hope over the next 20 minutes to help give you the tools to speak with parents about this issue, all the way from mercury through the epidemiologic studies that have been done on the issue.

First of all, a brief amount about autism epidemiology. The rates do appear to be higher than they were 25 years ago. This, in large part, is due to change in diagnostic criteria over time and also due to improved identification and reporting for various reasons. In any case, the incidence of autism at this point is somewhere between four and seven in a thousand, and it appears that there may be epidemiologic pockets.

The average age of diagnosis with autism is about three to six years. However, the average age of first

concern is between 18 and 24 months. As the vaccine schedule is at 2, 4, 6, 12, and 15 months, you can see why the parent of a child with autism might make an association in their minds between the vaccine and that disease.

There are essentially two sources of the controversy: MMR, which I'm not going to talk about today, but I'm happy to field questions because I also follow that closely, and then thimerosal. Thimerosal is a vaccine preservative that's been used since the 1930s, and it's 50 percent ethylmercury. It is contained or it has been contained in the DTP vaccines, hepatitis B, Haemophilus flu influenza type B, and influenza.

Now, a little background about mercury. There are three kinds of mercury. The most common is the pollutant: inorganic or mercuric mercury. However, this can be converted by microbes in our oceans into organic mercury. This is the one that causes most of human disease and human outbreaks. There, therefore, is a global siphoning of mercury that results in allowing the contamination of many of our food sources. For example, in tuna there's about -- in one can about 28 micrograms of methylmercury. For reference, in a vaccine, there's about 12.5 to 25 micrograms.

Mercury is certainly known to be a neurotoxin.

However, the toxic level is not very clear. If you were to look at the reference in your hospital, it would say that the normal value is between 5 and 20 micrograms per liter. However, this is a level above which or around which you should investigate that person's exposure to mercury. It is not a level at which known toxicity occurs. So I want to be clear that that level doesn't necessarily indicate that there's disease occurring.

Studies that have been done in outbreaks of methylmercury show that, to a growing fetus, somewhere between 58 and 216 micrograms per liter could cause disease. 216 was seen in Minimata disease, which was severe disease to a fetus. And then subtle neurologic changes have been seen around 58 micrograms.

We do not know what subtle CNS disease dose would cause postnatal problems. So after a baby's born, we don't know the bottom end of what might cause health toxicity. It certainly should be above what causes toxicity to a fetus.

In 1997, the APA revised their mercury guidelines. They revised these guidelines in light of the studies that I showed you in Minimata, Japan, and then some other outbreaks. This was set to avoid toxicity to a fetus. It was based on oral ingestion of methylmercury, not ethylmercury. Vaccines are ethylmercury. It assumes daily ingestion over months,

and that's because mercury can accumulate because it has a very long half-life. It does not exit the body fast. So it does accumulate.

They also built in at least a ten-fold safety factor. They set their level at .1 micrograms per kilogram per day, and the FDA's was -- and it still is -- still four times that amount. However, the FDA felt that they needed to look at the medical use of mercury at that time when the APA revised their guideline.

So medical use of mercury was essentially in the form of thimerosal, again, a preservative used in vaccine since the 1930s. Vaccines, again, can contain up to 25 micrograms per dose of mercury. And a child who receives all possible immunizations and all of those that contain mercury that they possibly can, by six months, would have received 200 micrograms of mercury and by two years 275 micrograms. At six months, this did exceed the APA's recommendation, but not the FDA's recommendation. Now, again, that EPA recommendation was for methylmercury and based on other assumptions about daily consumption.

Now, in 1999 then, the AAP and the FDA did send a letter to manufacturers, asking that mercury be removed, where possible, from vaccinations. This was accomplished in 2001, and now in the regular vaccine schedule for children the only vaccine that contains

significant amounts of mercury is the multidose influenza and then later tetanus boosters.

However, thimerosal is still used extensively in developing countries as a preservative in multidose vials. Without a preservative, we would need single-dose vials and a cold chain, both of which are prohibitively expensive and would decrease the amount of vaccine available in those countries.

So what do we know about ethylmercury? Again, vaccines contain ethylmercury, not methyl. And the studies that I told you about before were based on methylmercury. There have been really two pharmacokinetic studies. Now, both of these are pilot studies, and so they were not done in an ideal manner. However, we did derive a certain amount of information from them.

The Stajich et al. study looked at 15 premature and five term infants and measured their levels of thimerosal three days after receiving vaccine. They did not have any in the toxic range, but they did have one child who had a level of 24 micrograms. Again, I'll remind you that the levels for toxicity in cord blood to a fetus is about 58 micrograms at its lowest.

The Pichichero et al. study looked at 40 two- to six-month-olds and checked levels at various times from 3 to 28 days. Significantly, they had no abnormal levels. But maybe, more importantly, they

showed that the half-life of ethylmercury is likely to be much shorter than methylmercury; so seven days instead of 50. And this has implications for the ability of this product to build up in the body.

So what do we know about epidemiology as a support of causation of autism between a prorubricyte and thimerosal? Ideally, all of us would want to test this hypothesis by doing a large, double-blind, randomized placebo-controlled trial. However, this has not been done, and it probably will not be done for various reasons.

One of the reasons is the sample size needed. In order have a key of .05 and a power of .8, to detect a difference of one in a thousand, you would need at least 100,000 children. To detect a difference of one in a million, you would need at least a billion children. And this really prohibits our ability to study this very well.

There have been retrospective cohort studies and ecological studies. The retrospective cohort studies -- three look at the VAERS database, and others look at a gradation of thimerosal exposure. And let me go through those briefly.

The three that look at the VAERS database are by the same authors: Mark and David Geier. And because they're very similar, I'm going to discuss them together. This is cohort data. They looks at the

VAERS database. That's the Vaccine Adverse Event Reporting System. They -- this is -- what they do is they look at children who are exposed to thimerosal in the diphtheria/tetanus/pertussis vaccine between 1992 and 2000 and those who were not exposed to thimerosal, who received that same vaccine between 1997 and 2000.

They extracted the diagnoses of autism, speech disorder, mental retardation, and heart arrest. They also extracted some control diagnoses, such as fever. This is what they used for the numerator. In the denominator, they used the vaccines administered in the United States by manufacturer per the Centers for Disease Control.

So their results: They found a risk ratio for autism of 6.0; for speech disorders of 2.2; mental retardation of 6.0; and heart arrest 4.0. So they said that there's an association for all of these disorders and thimerosal. They stated that all these were statistically significant, though they did not give their confidence intervals. They also stated that children receiving an additional 75 micrograms were at added risk.

And their second and third papers actually break down the thimerosal dose into 37.5 micrograms and 87.5 micrograms of mercury. They then stated that the data points follow an exponential distribution and that the odds ratio of autism is increased by .012 per

microgram of mercury. And this is one of their graphs here. You can see what they think is an increase in autism with the increasing dose.

So I'd like to go over the numerator and the denominator in some detail. For your reference, I have here what you need to calculate an odds ratio. Essentially, you need cases, exposed and not exposed; and in the denominator, you need not cases, so people who did not get autism, in the exposed and not-exposed groups.

So I'm going to go over the denominator first. Again, they thought -- they referenced the Centers for Disease Control biologic surveillance summaries for the denominator. If you were to look this up -- and you can get that on the Internet -- what it will give you is the doses distributed in the United States of each vaccine. It does not, however, give you the vaccine by manufacturer. That information is proprietary between the CDC and the manufacturers.

And we did have to print a correction to a paper that I published this summer, stating that the Geiers did actually obtain that information. But you and I could not do that. But they did obtain that information, so they had the information by manufacturer to use as the denominator.

There are still problems with that denominator. First of all, it's doses distributed, not doses

administered. And with the multidose schedule, this becomes complicated. So if you have a child, for example, that gets three DTaP vaccines and two of them contain thimerosal and one does not, basically, one-third of that child will be put in the denominator of no thimerosal and two-thirds of that child will be put in the thimerosal group. So that creates a problem.

And then I do not understand how they calculated, in their second and third papers, the denominator broken down into 37.5 and 87.5 micrograms. They also -- it's clear because they had eight cases in the autism group that were exposed to thimerosal and only one case that was not exposed to thimerosal, so nine children total in the autism group, that they did not capture all cases. This would not be of particular importance if you could rely on the numerator.

However, I don't think that the numerator is reliable either. Again, this is based on the Vaccine Adverse Event Reporting System. This is a passive reporting system, and it's not required by law, as stated by the authors. It's notorious for underreporting and incomplete reporting. It's also subject to media bias, and the authors do not report how many of the cases that they have occurred after 1998 when this topic broke in the news.

Thimerosal exposure is also not really known in the cases, and this is, maybe, the most objectionable

part of the numerator for me. In the VAERS database, only the vaccine associated with the adverse event is reported. Previous vaccination history is not reported. So a child who was stated as not receiving thimerosal actually may have at another point in time. And the dose of thimerosal total that a child received also is not reported.

In addition, the diagnoses in the study were not validated, and there may be some diagnostic overlap. For example, many children with autism also have mental retardation. They don't state how they dealt with that issue. And also there are children diagnosed with autism who were very young to be diagnosed with autism, which I think brings the validity into question. And they did not do any chart review to validate that diagnosis.

And even though they report statistical significance, that does not reflect the statistical fragility of their analysis. If only one child was misclassified or not reported, their odds ratio would become insignificant.

The other cohort studies -- there are two in the -- one in the United States, one in Denmark, and two in England. The Verstraeten study, which I just heard there's going to be a follow-up to this later this year-- was done in the United States, looking at the vaccine safety datalink data. This is a database that

was meant to follow up any signals that comes in VAERS.

They looked at 140,000 children in three HMOs and, essentially, didn't find a significant association. They found some mild associations with tics and speech disorders. However, those were thought to be due to multiple measures, and they weren't consistent across the HMOs. And so it didn't look like it was real. It -- autism was only studied in the biggest HMO, and no association was found.

The two done in the U.K. -- the first involves 101,000 children, and they also look at a hazards ratio to mercury exposure over time. They found a mild association with tics. However, when they tried to validate that diagnosis, they had a very poor validation.

Then there was a Heron study done on 13,000 children, which is very small. However, this was done prospectively. That information was gathered, and they, again, found one association with prosocial behavior, but this was felt to be due to multiple measures. Notably, in all three of these studies, there were negative associations found, implying that thimerosal is actually protective. But again, that's likely due to multiple measures and not a true phenomena.

Maybe the best cohort example is the Hviid study

from Denmark. This looks at national registries and has half a million children and almost 2 million person years. This country discontinued thimerosal use in 1992. So they had a real advantage to study this. So they looked at children and were able to link them to their vaccine databases and their site databases, which is actually much easier for them than it is for us here.

The risk ratio for autism was .885, but it did cross 1.0, so it wasn't protective. There certainly was no association. They, however, did not look at any other neurodevelopmental orders. Some problems with these cohort studies are, again, diagnostic accuracy. In the Enders' study, 90 percent of tics were transient. That's the one association they found.

Thimerosal doses and schedules differ from the United States, where we use more thimerosal, even though in other countries it's used a little earlier. And of course, the limitations of cohort studies always include that it's used by us to quantify risk, not to really prove its absence. And that's always a problem.

Ecological studies supporting an association are again done by the Geiers. And this is an example of their data. They looked at the U.S. Department of Education and four children in that system who have

autism. And then they divide that by mercury distributed in the United States. So again, they look at that biologic surveillance study and actually add up the amount of mercury distributed in a certain year and divide that by the birth year cohort.

Now, that's where my main problem with this study comes because at their height they have 291 micrograms per child. And no child, based on a vaccine schedule, would have ever received this amount. So it's too high, and it just illustrates the problems with using the biologic surveillance studies for your denominator.

So ecological studies, again, with an association, that are two. And I'm just summarizing them here. These are very simple and straightforward. In 1992, both in Denmark and in Sweden, again, thimerosal use was stopped. So they just look at the incidence of autism in comparison to that. There's a line on the graph on the left, and then you can see the bars for thimerosal on the graph on the right, and then the incidence of autism, which continues to go up, despite stopping thimerosal.

So the conclusions: The half-life of ethylmercury is likely shorter than the half-life for methylmercury. Mercury blood levels postvaccination are not known to be in the toxic range. The well-designed epidemiologic studies don't support an

association between thimerosal and autism. And I hope that I have proven that to you here.

Consistency between the well-designed studies, even if you didn't believe each one on its own, lends strength to the individual conclusions. So I don't believe that thimerosal needs to be removed in countries where it's currently being used or in California. Autism is increasing, and research dollars certainly should be directed towards areas of more promising research.

And then, just a quick word about cohort studies. I think, especially with the first Iowa report, a lot of it -- it's true that good epidemiologists will say epidemiology cannot exclude a rare event. Somehow, this gets twisted into it might cause a rare event, that there's actually a one in a million risk. And for parents, a one in a million risk is really too much for an active commission, and I think that's why we have so much refusal, especially when the diseases are perceived as gone.

So as practical advice, I would like you-all to clarify with your parents that the risk is not one in a million. We have no good reason to believe that thimerosal causes autism. You need to dispel the myth that vaccine-preventable diseases are gone; that they're harmless; that herd immunity is enough; and that the alternate schedule, as proposed by some

authors, is as protective or is as safe.

Thank you.

(APPLAUSE)