ORIGINAL

IN THE UNITED STATES COURT OF FEDERAL CLAIMS

OFFICE OF SPECIAL MASTERS

IN RE: CLAIMS FOR VACCINE INJURIES RESULTING IN AUTISM SPECTRUM DISORDER, OR A SIMILAR NEURODEVELOPMENTAL DISORDER,

Various Petitioners,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

PSC EXPERT REANALYSIS OF THE THIMEROSAL SCREENING ANALYSIS

AUTISM MASTER FILE

Special Master George Hastings

The Special Master in his Discovery Order of April 14, 2005, directed that respondent make available to petitioners' experts certain information regarding the data and computer programs relied upon in a published science journal article entitled "Safety of Thimerosal-Containing Vaccines: A Two-Phased Study of Computerized Health Maintenance Organization Databases;" Verstraeten, T.; *Pediatrics,* November 3, 2003.

The Order allowed what was essentially a limited reanalysis of the final datasets and programs used to generate the results of the published paper *only*, and did not provide access to raw data, datasets, data files, programs, protocols, or any other materials used or relied upon by the study investigators in any earlier iterations of the study. The Special Master directed petitioners to file the completed reanalysis as an Exhibit in petitioners' list of exhibits in support of general causation. The reanalysis subject to the Order is attached to this filing as Exhibit 91.

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DATED this 12th day of December, 2006

WILLIAMS LOVE O'LEARY CRAINE & POWERS P.C.

By: _____

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A Re-analysis of the Vaccine Safety Datalink (VSD) Project Conducted by the Centers for Disease Control and Prevention Pertaining to Safety Issues Related to Thimerosal-Containing Vaccines

In Re: Claims for vaccine injuries resulting in autism spectrum disorder or a similar neurodevelopmental disorder.

Office of Special Masters: Autism Master File

Prepared by:

Harland Austin, DSc
Cathy Lally, MSPH

December 7, 2006

EXECUTIVE SUMMARY

Dr. Austin and Ms. Lally visited the Research Data Center (RDC) maintained by the Centers for Disease Control and Prevention (CDC) in Hyattsville, Maryland on August 9 and 10 to conduct a re-analysis of data from the Vaccine Safety Datalink (VSD) study that had been published in *Pediatrics* on November 3, 2003 (Verstraeten T, *et al*: "Safety of Thimerosal-Containing Vaccines: A Two-Phased Study of Computerized Health Maintenance Organization Databases" *Pediatrics* 112: 1039-1048, 2003). The purpose of the Austin/Lally re-analysis was an attempt to resolve some apparent discrepancies between the findings appearing in the published manuscript in *Pediatrics* and the findings reported from the same study that had appeared in an earlier unpublished report. Specifically, Dr. Austin and Ms. Lally were to evaluate the impact of six differences in methodology used in the preparation of the published and unpublished reports. These changes are:

1. Do not require at least one clinic visit for comparison children;
2. Stop following children at time of first disenrollment;
3. Do not adjust for clinic at HMO B;
4. Report findings for combined categories of neurologic degenerative and neurodevelopmental disorders;
5. Combine the data for HMO A and HMO B;
6. Do the following analysis combining all 3 HMO's: Evaluate any outcome reported in the interim analysis of February 29, 2000, or in the Pediatrics publication for which there are at least 50 cases overall at the 3 HMOs. The data will be stratified by HMO and an overall rate ratio will be obtained.

Objectives 1 through 3 are methodologic criteria that were applied in the analysis of the published report, but were not applied, or applied differently, in the analysis that produced the unpublished report. The purpose of objectives 1 through 3 was to evaluate if these changes in study methodology had a meaningful impact on the findings. Criterion 1 and 2 did not have a meaningful impact. That is, the published study findings did not change meaningfully with the use of the comparison group of the unpublished report. The published findings did not change meaningfully if children were dropped from the study at the time of their first disenrollment from the HMO as they were in the unpublished report. Criterion 3 did impact the findings for language delay. That is, an analysis that does not adjust for clinic at HMO B (the unpublished report) produces stronger positive associations between language delay and TCV's than does an analysis that does adjust for clinic. We do not know, and the CDC investigators did not explain why, clinic confounds the language delay findings. A careful evaluation of clinic within HMO B and language delay would facilitate an interpretation of these findings. However, we note that even after adjustment for clinic at HMO B, statistically significant associations remain between language delay and TCV's.

We could not accomplished objective #4 because the data made available to us at the RDC did not contain the variables necessary for defining categories of overall neurologic degenerative and neurodevelopmental disorders.

Combining data from the HMO's (objectives #5 and #6) produced statistically significant positive associations for language delay at 3 and 7 months, tics at 7 months, and sleep disorders at 7 months. The positive findings for language delay and tics are apparent in the published report, but are understated because the CDC investigators did not aggregate the data across HMO's. We note in our analysis below that the positive findings for tics and sleep disorders for the aggregated data can be obtained from tabulated data in the published document.

With the exception of their failure to combine data across HMO's, we generally believe that the methodology employed by the CDC investigators was sound and that their findings are valid. Neither we, nor they, found any positive and consistent evidence of an association between autism or attention deficit disorder and TCV's. However, as is discussed below, the study design cannot rule out moderate, or small, increases in autism and attention deficit disorder potentially attributable to TCV's.

We emphasize that our analysis and our access to the VSD data had limitations. For this reason, we do not attempt in this report to interpret the findings pertaining to language delay, tics, and sleep disorders with respect to causation. This is so because we had only very limited access to the VSD data through the CDC constructed analytic data set and the Discovery Order did not mandate a detailed and independent analysis on our part.

BACKGROUND

In response to a Discover Order issued by the United States Court of Federal Claims (Re: Claims for Vaccine Injuries Resulting in Autism Spectrum Disorder or a Similar Neurodevelopmental Disorder) filed on April 14th, 2005, Dr. Harland Austin and Ms. Cathy Lally were granted access to the analytic dataset that was used by researchers at the Centers for Disease Control and Prevention (CDC) for the preparation of a manuscript that was published in *Pediatrics* on November 3, 2003 (Verstraeten T, *et al*: "Safety of Thimerosal-Containing Vaccines: A Two-Phased Study of Computerized Health Maintenance Organization Databases" *Pediatrics* 112: 1039-1048, 2003). This study utilized data collected from the on-going Vaccine Safety Datalink (VSD) Project. The purpose of the Austin/Lally re-analysis was an attempt to resolve some apparent discrepancies between the findings appearing in the published manuscript in *Pediatrics* and the findings reported from the same study that had appeared in an earlier unpublished report (Verstraeten T, *et al*: "Risk of neurologic and renal impairment associated with thimerosal-containing vaccines", dated June 1, 2000). Dr. Austin and Ms. Lally were to re-analyze the data and evaluate the impact of six specific changes in the methodology used by the CDC researchers in preparing the published report. These changes reflected differences in methodology used in the unpublished and published reports. The six specific changes are:

1. Do not require at least one clinic visit for comparison children;
2. Stop following children at time of first disenrollment;
3. Do not adjust for clinic at HMO B;
4. Report findings for combined categories of neurologic degenerative and neurodevelopmental disorders;
5. Combine the data for HMO A and HMO B;
6. Do the following analysis combining all 3 HMO's: Evaluate any outcome reported in the interim analysis of February 29, 2000, or in the Pediatrics publication for which there are at least 50 cases overall at the 3 HMOs. The data will be stratified by HMO and an overall rate ratio will be obtained,

The specific changes are referred to as objectives 1 through 6 below. Dr. Austin and Ms. Lally re-analyzed the data at CDC's Research Data Center (RDC) in Hyattsville, Maryland on August 9 and 10.

The Results section below is divided into two parts. The first part examines the impact of modifying certain aspects of the study methodology (objective #1-3 above) on the published study findings. As is shown below, these modifications either had little impact on the study results or, in the case of objective #3 did impact the language delay findings.

The second part of the Results section evaluates the impact of combining the data from the HMO's (objectives #5-6). The CDC investigators did not aggregate data from the HMO's in the published manuscript. They analyzed outcomes within individual HMO's and only reported findings based on 50 or more cases within an HMO. With respect to HMO's A and B, we see no justification, whatsoever, for not combining the findings, particularly if the results are comparable at the two HMO's. With respect to HMO C, the CDC authors wished to confirm selected positive associations seen in HMO's A and B using the data from HMO C. Although, in principle, this approach is desirable and methodologically sound, in practice, it is not. This is so because HMO A included 13,337 children, HMO B included 110,883 children, and HMO C included 16,717. HMO C is too small relative to the combination of HMO's A and B to provide the necessary precision to validate their phase I findings (HMO's A and B) with data from HMO C (their phase II data). Thus, we believe the best approach for analyzing this data is to combine the information from all 3 HMO's and therefore we emphasize these findings below.

RESULTS

The findings using the methodology of the CDC authors applied to HMO A and HMO B combined (objective #5 above) are displayed in our Table 1 below. The results in this table are nearly identical to those displayed in Table 4 of the Verstraeten published report, although that report considered only HMO B, whereas our table includes HMO A and HMO B. We found, as did the CDC investigators, statistically significant findings

for language delay at 3 and 7 months. However, in contrast to the CDC, we also note statistically significant findings for tics and sleep disorders at 7 months.

We add HMO C in our Table 2 and display the findings for all 3 HMO's combined (objective #6). The effect estimates are nearly identical to those displayed in our Table 1. The P values for tics and sleep disorders at 7 months are appreciably smaller than are those in our Table 1, providing stronger statistical evidence that these positive findings are not due simply to chance.

In Table 3 the findings for all 3 HMO's are displayed after eliminating the requirement that comparison children had at least one clinic visit at the time of a case diagnosis (objective #1 above). The findings essentially are identical to those in our Table 2, although the P values for tics, sleep disorders, and language delay are smaller; probably reflecting the inclusion of appreciably more comparison children.

In Table 4 the findings of an analysis that stopped following children at the time of first disenrollment are displayed (objective #2 above). The results for tics and sleep disorders at 7 months are still statistically significant, but the P values are higher than are those in our Table 2. Language delay is no longer statistically significant at 3 or 7 months. There are statistically significant findings for emotional disturbances at 1 month and autism at 7 months, but in both cases the data indicates that TCV's are *protective* against these disorders. It is our opinion that re-enrollment of children following disenrollment from an HMO should be permitted since the increased sample size results in better precision and increased statistical power.

In Table 5 the findings for all 3 HMO's are displayed without adjustment for clinic at HMO B (objective #3). In this analysis, the findings for language delay are very strong and highly statistically significant, especially at 1 and 3 months. In the unpublished report of the VSD data, adjustment for clinic at HMO B was not done and hence those results would have left a strong impression regarding a positive association between language delay and TCV's. Adjustment for clinic attenuates the language delay effect, although the findings do remain statistically significant at 3 and 7 months.

We discuss below 3 outcomes which we believe show evidence of a positive association if the data from the HMO's are aggregated, but whose significance was missed within individual HMO analyses.

Language Delay:

The CDC investigators report a statistically significant association between language delay at 3 and 7 months at HMO B (Verstraeten published report, Table 4). They did not report the findings for HMO A because the number of cases was below 50. We did, however, combine the data for HMO's A and B (HMO C does not have codes for language delay) and the results for a continuous measure of exposure was statistically significant at 3 and 7 months (our Table 1).

A categorical analysis of language delay is displayed in our Table 6. There is a statistically significant positive trend (increasing rates of language delay with increasing thimerosal exposure) both at 3 and 7 months.

In the first paragraph of the Discussion section of the published report, the CDC investigators argue that the results of the VSD study with respect to speech and language disorder were not consistent at the HMO's. However, with respect to language delay only, the findings for HMO A and B are statistically consistent. That is, in both HMO A and HMO B there is a direct association between increased prevalence of language delay and increasing thimerosal exposure.

Tics:

The CDC investigators report a statistically significant effect for tics in relation to a continuous measure of Hg exposure at 3 months at HMO A (RR = 1.89, 95% CI: 1.05, 3.38, their Table 3). They report an inverse association for a continuous measure of Hg exposure (RR = 0.95, their Table 4) for tics at 3 months at HMO B and a positive association for HMO C (RR = 1.26, their Table 6).

Combining HMO's A and B (objective #5) yields a non-significant effect for tics at 3 months and a statistically significant effect for tics at 7 months (see our Table 1). The addition of HMO C (objective #6) still results in a non-significant effect at 3 months, but the effect at 7 months is increased and now is highly statistically significant ($P < 0.0001$).

The CDC investigators report in their published paper the rate ratios for an increase of 12.5 μg of Hg for tics at 7 months for each HMO (HMO A, RR = 1.12; HMO B, RR = 1.09; and HMO C, RR = 1.18). The weighted average of these 3 RR's is 1.11 with 95% CI (1.03, 1.21) and a P value of about 0.01. Our analysis of the VSD data (see Table 2) produced nearly identical findings.

The categorical analysis of the tic data is displayed in Table 7. There is no association between tics and thimerosal at 3 months at either HMO's A and B combined (objective #5) or at all 3 HMO's (objective #6). On the other hand, there is a consistent and statistically significant positive trend between tics and thimerosal exposure at 7

months at HMO's A and B combined (our Table 7). For all 3 HMO's, the positive trend at 7 months is appreciably stronger.

Sleep Disorders:

The CDC investigators did not report any statistically significant findings for sleep disorders in their published report. However, when we combined HMO's A and B, the P value associated with a continuous measure of Hg exposure was statistically significant at 7 months (P = 0.03, our Table 1). Inclusion of HMO C reduces this P value to about 0.01 (our Table 2).

The categorical analysis of the sleep disorder data is displayed in Table 8. The findings at 3 months are not statistically significant and the trend is erratic across the 3 ordinal categories at all 3 HMO's combined. At 7 months, there is a statistically significant ordinal trend across the 3 categories. However, although this association is statistically significant, it is weak.

The CDC investigators report in their published paper the following RR's for sleep disorders at 7 months associated with an increase of 12.5 μg of Hg: HMO A, RR = 1.08; HMO B, RR = 1.09; and HMO C, RR = 1.05. The weighted average of these 3 RR's is 1.06 (1.02, 1.11) with a P value of about 0.01. Our analysis yielded the same point estimate (RR = 1.06) and P value (our Table 2).

DISCUSSION

Using the analytic data set provided to us by CDC investigators, we were able to duplicate the major findings reported in the *Pediatrics* paper. With the exception of their failure to combine data from the HMO's, we believe that the methodology used by the CDC investigators was proper and that their study results are valid.

It is important to note that we, as did the CDC investigators, found no evidence of a positive association between autism and attention deficit disorder and TCV's. However, the imprecision of the study findings must be considered in interpreting this statement. For example, consider the effect of an increase of 25 μg of Hg (the amount of exposure resulting from two doses of the HBV vaccine) on the risk of autism. The RR for autism associated with a 25 μg increase of Hg at 3 months is 1.2 with 95% CI: 0.82, 1.6, while at 7 months the RR is 0.93 (0.79, 1.10). Thus, because of the imprecision of the study, increases in autism risk as large as 60% at 3 months and 10% at 7 months cannot be ruled out. For attention deficit disorder, the corresponding values at 3 and 7 months are 12% and 7%, respectively.

The analytic changes in the methodology of the published report that we employed in our analysis had little impact on the study findings. In an attempt to control confounding by health care-seeking behavior, the CDC investigators compared cases to comparison children who had a visit in the same month as had the case. This restriction was not applied in the analysis that produced the findings in the unpublished report. This

restriction would diminish considerably the size of the comparison group and we thought that it might explain some of the perceived discrepancies in the findings of the published and unpublished report. In our opinion, the restriction in the selection of comparison children had little impact on the study findings.

In the unpublished report, children were dropped from the analysis at the time of first disenrollment. In the published report, such children came under observation again if they were re-enrolled into their HMO. Re-enrollment would increase the study size and we believe that re-enrollment should have been permitted. However, it is our perception that the study findings are about the same whether or not re-enrollment was allowed.

Adjustment for clinic at HMO B was not done in the analysis that produced the unpublished findings, but was done for the published report. Clinic is a confounder of the language delay findings. That is, failure to adjust for clinic yields effect estimates considerably larger than those obtained from an analysis that does not adjust for clinic. Thus, adjustment for clinic does explain some of the differences in the results of the published and unpublished reports, although the VSD study is positive for language delay with and without adjustment for clinic at HMO B. We do not know, and the CDC investigators did not explain why, clinic confounds the language delay findings and we could not explore the issue with the analytic data set made available to us. The lack of an explanation as to why clinic at HMO B is a confounder is a limitation of the published report. Failure to adjust for clinic does explain some of the apparent discrepancy in the published and unpublished reports of the VSD data.

Combining the data from the HMO's yields positive findings for language delay, tics, and sleep disorders. The CDC acknowledged the positive findings for language delay at HMO B, but state in the published manuscript that the findings are not consistent across the 3 HMO's for speech and language delay. However, the results for language delay only are consistent at HMO's A and B and are statistically significant. There is no evidence of an association between the codes for speech delay and thimerosal at any of the HMO's.

The findings for tics and sleep disorders are statistically significant in the aggregated data from the 3 HMO's. It is important to note, as we did above, that the CDC investigators reported the results for tics and sleep disorders (their tables 3, 4, and 6 in the published report) for the individual HMO's. One can take a weighted average of the rate ratios (RR) in their tables and conclude that the combined findings for tics and sleep disorders at 7 months are statistically significant. The fact that these weighted averages of the RR's agree almost exactly with those in our Table 2 (which we obtained from a statistical model applied to the analytic data set) supports the opinion that our separate analyses are valid.

LIMITATIONS

The re-analysis of the VSD data presented in this report has several limitations. Firstly, we took on good faith that the analytic data set provided by the CDC was constructed properly. The data set that we were provided took the raw VSD data and applied restrictions on which children were included, determined the beginning and ending dates of follow-up for each child, determined who did and did not develop disorders, determined which children should be used as comparison children, and reviewed each child's vaccination history and calculated their cumulative thimerosal exposure at 1, 3, and 7 months. The construction of such an analytic data set is a complicated process which would require detailed knowledge of the structure of the VSD data base. It would also require a close collaboration with data managers at each of the participating HMO's. The construction of our own analytic data set was beyond the scope of the Discovery Order. We have no reason to believe that the CDC investigators did not produce a valid data set, but we emphasize that we were not able to check the steps they used in constructing the analytic data set.

We did not attempt to interpret the findings with respect to causation. This is so because we limited the scope of our work to the six specific objectives listed in the Discovery Order. We did not have the mandate, nor did we have sufficient access to the raw data to do an independent analysis.

In summary, we believe that the methodology employed by the CDC was generally sound and that their findings are valid. The findings of the published report generally appear less "positive" than do those of the unpublished report. We believe that this perception results, in no small part, from the fact that the data from the HMO's were not combined in the published report, but were in the unpublished report. We also believe that the data from the 3 HMO's should be combined.

Table 1. Rate Ratios According to an Increase of 12.5 μg of Hg Exposure from Thimerosal Containing Vaccines - HMO A and B combined

		1-month Cumulative Hg		3-month Cumulative Hg		7-month Cumulative Hg	
Outcome	**N**	**RR**	**P value**	**RR**	**P value**	**RR**	**P value**
Autism	223	1.20	> 0.20	1.09	> 0.20	0.98	> 0.20
Other child psychosis	128	1.11	> 0.20	0.99	> 0.20	1.02	> 0.20
Stammering	173	0.71	0.16	1.12	> 0.20	1.10	0.078
Tics	263	0.90	> 0.20	1.03	> 0.20	1.10	0.042
Sleep disorders	229	1.10	> 0.20	1.08	> 0.20	1.09	0.033
Eating disorders	102	0.86	> 0.20	0.97	> 0.20	1.01	> 0.20
Emotional disturbances	404	0.79	0.14	1.01	> 0.20	0.98	> 0.20
ADD	1110	0.90	> 0.20	0.99	> 0.20	1.00	> 0.20
Language Delay	621	1.07	> 0.20	1.14	0.018	1.07	0.006
Speech Delay	2635	1.03	> 0.20	1.04	0.14	1.00	> 0.20
Language/speech delay	3018	1.05	> 0.20	1.04	0.066	1.01	> 0.20
Coordination disorders	109	1.60	0.13	1.21	> 0.20	1.03	> 0.20

1. Stratified on HMO, sex, month/year birth at HMO A and by sex, month/year birth, and clinic at HMO B.

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Table 2. Rate Ratios According to an Increase of 12.5 μg of Hg Exposure from Thimerosal Containing Vaccines - HMO A, B and C combined

		1-month Cumulative Hg		3-month Cumulative Hg		7-month Cumulative Hg	
Outcome	**N**	**RR**	**P value**	**RR**	**P value**	**RR**	**P value**
Autism	230	1.09	> 0.20	1.08	> 0.20	0.96	> 0.20
Other child psychosis	169	1.03	> 0.20	1.00	> 0.20	1.00	> 0.20
Stammering	264	0.73	0.069	1.05	> 0.20	1.04	> 0.20
Tics	309	0.90	> 0.20	1.07	> 0.20	1.11	0.0095
Sleep disorders	728	0.98	> 0.20	1.03	> 0.20	1.06	0.008
Eating disorders	119	0.89	> 0.20	0.95	> 0.20	1.02	> 0.20
Emotional disturbances	421	0.75	0.065	1.00	0.14	0.96	> 0.20
ADD	1207	0.90	> 0.20	0.99	> 0.20	1.00	> 0.20
Language Delay	621	1.07	> 0.20	1.14	0.018	1.07	0.0055
Speech Delay	3769	0.98	> 0.20	1.01	> 0.20	0.99	> 0.20
Language/speech delay	4152	1.00	> 0.20	1.01	> 0.20	1.00	> 0.20
Coordination disorders	109	1.60	0.13	1.21	> 0.20	1.03	0.13

1. Stratified on HMO, sex, month/year birth at HMO A and C and by sex, month/year birth, and clinic at HMO B.

Table 3 - Rate Ratios According to an Increase of 12.5 μg of Hg Exposure from Thimerosal Containing Vaccines - HMO A, B and C combined. No requirement of at least one clinic visit for comparison children (objective #1).

		1-month Cumulative Hg		3-month Cumulative Hg		7-month Cumulative Hg	
Outcome	**N**	**RR**	**P value**	**RR**	**P value**	**RR**	**P value**
Autism	230	1.03	> 0.20	1.07	> 0.20	0.98	> 0.20
Other child psychosis	169	1.03	> 0.20	1.02	> 0.20	1.00	> 0.20
Stammering	264	0.74	0.067	1.06	> 0.20	1.06	0.092
Tics	309	0.96	> 0.20	1.13	= 0.094	1.16	< 0.0001
Sleep disorders	728	0.98	> 0.20	1.03	> 0.20	1.06	0.0046
Eating disorders	119	0.98	> 0.20	1.05	> 0.20	1.03	> 0.20
Emotional disturbances	421	0.89	> 0.20	1.07	> 0.20	1.01	> 0.20
ADD	1207	1.01	> 0.20	1.03	> 0.20	1.02	> 0.20
Language Delay	621	1.07	> 0.20	1.18	0.0014	1.09	0.0004
Speech Delay	3769	0.99	> 0.20	1.02	> 0.20	1.01	> 0.20
Language/speech delay	4152	1.00	> 0.20	1.03	0.077	1.01	0.10
Coordination disorders	109	1.61	0.096	1.28	0.067	1.08	0.19

1. Stratified on HMO, sex, month/year birth at HMO A and C and by sex, month/year birth, and clinic at HMO B.

Table 4 - Rate Ratios According to an Increase of 12.5 μg of Hg Exposure from Thimerosal Containing Vaccines - HMO A, B and C combined. Subjects were dropped at time of first disenrollment (objective #2).

		1-month Cumulative Hg		3-month Cumulative Hg		7-month Cumulative Hg	
Outcome	**N**	**RR**	**P value**	**RR**	**P value**	**RR**	**P value**
Autism	208	1.35	> 0.20	0.90	> 0.20	0.86	0.03
Other child psychosis	158	1.20	> 0.20	1.02	> 0.20	0.96	> 0.20
Stammering	245	0.72	0.12	0.98	> 0.20	0.99	> 0.20
Tics	280	1.05	> 0.20	1.19	0.13	1.13	0.02
Sleep disorders	706	0.92	> 0.20	0.99	> 0.20	1.05	0.04
Eating disorders	113	0.63	0.18	1.07	> 0.20	1.09	> 0.20
Emotional disturbances	355	0.58	0.04	1.04	> 0.20	0.90	0.06
ADD	986	0.83	0.17	0.98	> 0.20	0.97	> 0.20
Language Delay	582	0.92	> 0.20	1.11	> 0.20	1.05	> 0.20
Speech Delay	3587	0.97	> 0.20	0.99	> 0.20	0.99	> 0.20
Language/speech delay	3946	0.98	> 0.20	1.00	> 0.20	0.99	> 0.20
Coordination disorders	103	1.95	0.19	1.19	> 0.20	0.99	> 0.20

1. Stratified on HMO, sex, month/year birth at HMO A and C and by sex, month/year birth, and clinic at HMO B.

Table 5 - Rate Ratios According to an Increase of 12.5 μg of Hg Exposure from Thimerosal Containing Vaccines - HMO A, B and C combined. The findings are not adjusted for clinic at HMO B (objective #3).

	1-month Cumulative Hg		3-month Cumulative Hg		7-month Cumulative Hg	
Outcome	**RR**	**P value**	**RR**	**P value**	**RR**	**P value**
Autism	1.02	> 0.20	0.98	> 0.20	0.93	0.034
Other child psychosis	1.08	> 0.20	1.01	> 0.20	0.99	> 0.20
Stammering	0.81	0.13	1.05	> 0.20	1.07	0.057
Tics	0.96	> 0.20	1.05	> 0.20	1.11	0.0019
Sleep disorders	0.97	> 0.20	1.01	> 0.20	1.05	0.027
Eating disorders	0.83	> 0.20	0.98	> 0.20	0.99	> 0.20
Emotional disturbances	0.78	0.02	0.98	> 0.20	0.99	> 0.20
ADD	0.87	0.019	0.99	> 0.20	1.01	> 0.20
Language Delay	1.44	<0.0001	1.25	<0.0001	1.06	0.011
Speech Delay	1.04	> 0.20	1.01	> 0.20	0.99	> 0.20
Language/speech delay	1.07	0.04	1.03	0.13	1.00	0.13
Coordination disorders	1.52	0.10	1.24	0.14	1.03	0.14

1. Stratified on HMO, sex, month/year birth.

Table 6 - Relative Rates of Language Delay by Category of Cumulative Hg Exposure at 3 and 7 months.

			HMO A and B		
Outcome	Hg	N[1]	Persons[1]	RR[2]	95% CI
3 months					
Language Delay	0-25	25	9,344	1.0	----
	37.5-50	425	72,957	1.46	0.92, 2.3
	>=62.5	171	41,818	1.90	1.1, 3.3
					$P^2_{trend} = 0.02$
Outcome	Hg	N[1]	Persons[1]	RR[2]	95% CI
7 months					
Language Delay	0-75	76	17,727	1.0	----
	76-174	432	79,251	1.20	0.91, 1.6
	>=175	113	27,141	1.47	0.96, 2.2
					$P^2_{trend} = 0.01$

1. N is the number of cases and persons is total number of non-cases.
2. Stratified on HMO, sex, month/year birth at HMO A and by sex, month/year birth, and clinic at HMO.

Table 7 - Relative Rates of Tics by Category of Cumulative Hg Exposure at 3 and 7 months.

HMO A and B

Outcome	Hg	N[1]	Persons[1]	RR[2]	95% CI
3 months					
Tics	0-25	15	9,327	1.0	
	37.5-50	154	72,804	0.95	0.48,1.8
	>=62.5	94	41,712	0.79	0.36,1.7
					$P^2_{trend} > 0.20$
Outcome	Hg	N[1]	Persons[1]	RR[2]	95% CI
7 months					
Tics	0-75	20	17,705	1.0	
	76-174	171	79,076	1.6	0.9,2.7
	>=175	72	27,062	2.4	1.2,5.0
					$P^2_{trend} = 0.04$

HMO A, B and C

Outcome	Hg	N[1]	Persons[1]	RR	95% CI
3 months					
Tics	0-25	16	9,862	1.0	----
	37.5-50	174	76,525	1.0	0.53,1.9
	>=62.5	119	54,229	1.0	0.49,2.1
					$P^2_{trend} > 0.20$
Outcome	Hg	N[1]	Persons[1]	RR	95% CI
7 months					
Tics	0-75	20	17,951	1.0	----
	76-174	198	85,830	1.7	1.0,2.8
	>=175	91	36,835	2.5	1.3,5.0
					$P^{2,3}_{trend} << 0.04$

1. N is the number of cases and persons is the total number of non-cases.
2. Stratified on HMO, sex, month/year birth at HMO A and C and by sex, month/year birth, and clinic at HMO B.
3. We do not have this P value because of a programming error. We discovered this error after our return from the RCD in Hyattsville, MD.

Table 8 - Relative Rates of Sleep Disorders by Category of Cumulative Hg Exposure at 3 and 7 months.

HMO A and B

Outcome	Hg	N[1]	Persons[1]	RR	95% CI
3 months					
Sleep Disorders	0-25	24	9,313	1.0	----
	37.5-50	120	72,835	1.33	0.68, 2.6
	>=62.5	85	41,720	1.57	0.76, 3.2
					$P^2_{trend} > 0.20$

Outcome	Hg	N[1]	Persons[1]	RR	95% CI
7 months					
Sleep Disorders	0-75	35	17,688	1.0	----
	76-174	129	79,110	1.04	0.64, 1.7
	>=175	65	27,070	1.52	0.81,2.8
					$P^2_{trend} = 0.03$

HMO A, B and C

Outcome	Hg	N[1]	Persons[1]	RR	95% CI
3 months					
Sleep Disorders	0-25	36	9,822	1.0	----
	37.5-50	275	76,297	1.66	1.1, 2.6
	>=62.5	417	53,505	1.30	0.83, 2.0
					$P^2_{trend} > 0.20$

Outcome	Hg	N[1]	Persons[1]	RR	95% CI
7 months					
Sleep Disorders	0-75	41	17,923	1.0	----
	76-174	360	85,445	1.15	0.76, 1.7
	>=175	327	36,256	1.26	0.81, 1.9
					$P^2_{trend} = 0.01$

1. N is the number of cases and persons is total number of non-cases.
2. Stratified on HMO, sex, month/year birth at HMO A and C and by sex, month/year birth, and clinic at HMO B.

CERTIFICATE OF SERVICE

I hereby certify that on December 12, 2006, I served the foregoing **PSC EXPERT REANALYSIS OF THE THIMEROSAL SCREENING ANALYSIS** on the following individual(s):

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