





8. On November 6, 2001, I have written notes instructing myself to run 4 group analyses and BLACK analyses. Again, I would have only been doing this if we had found concerning results for blacks. (See 2001-2002 notes dated November 6, 2001).
9. On November 8, 2001, I continued to write that the Black/White comparisons need to be continued. (See 2001-2002 notes dated November 8, 2001).
10. On February 20, 2002, all coauthors met and discussed statistical analyses for the Total Sample and the Birth Certificate Sample. (See page 14 of agendas attachment).
11. On May 22, 2002, all coauthors met and discussed analysis of the 24 month threshold for the Total Sample. We did this because there were many statistically significant effects at the 24 month threshold. (See page 16 of Agendas Attachment).
12. On June 28, 2002, all coauthors met and examined subgroup analyses by RACE for Whites and Blacks. (See page 17 in the Agendas Attachment and handout that includes Table 5).
13. In the Excel File named "describe\_results\_2002\_0702.xls", Table 7 shows the RACE analyses that I had run using ONLY the BIRTH CERTIFICATE Sample --- the unadjusted RACE effect was statistically significant. (OR=1.51, [95%CI 1.02 - 2.24]). At the bottom of Table 7, it also shows that for the NON-BIRTH Certificate Sample, the adjusted RACE effect statistically significance was HUGE. (OR=2.94 [95%CI 1.48 - 5.81]). That is the main reason why we decided to report the RACE effects for ONLY the BIRTH Certificate Sample.
14. In the Excel File named "describe\_results\_2002\_0801.xls", I split Table 7 into three different Tables (Table 7a, Table 7b, and Table 7c) to further investigate the RACE subgroup analyses.
15. All the coauthors met and decided sometime between August 2002 and September 2002 not to report any RACE effects for the paper.
16. Sometime soon after the meeting where we decided to exclude reporting any RACE effects, also between August 2002 and September 2002, the coauthors scheduled a meeting to destroy documents related to the study. Dr. Coleen Boyle was not present at the meeting even though she was involved in scheduling that meeting. The remaining 4 coauthors all met and brought a big garbage can into the meeting room and reviewed and went through all our hard copy documents that we thought we should discard and put them in the large garbage can. However, because I assumed this was illegal and would violate both FOIA laws and DOJ requests, I kept hard copies of all my documents in my office and I retained all the associated computer files. This included all the Word files (agendas and manuscript drafts), Excel files with analysis and results, and SAS files that I used to generate the statistical findings. I also kept all my written notes from meetings. All the associated MMR-Autism Study computer files have

been retained on the Immunization Safety Office computer servers since the inception of the study and they continue to reside there today.

17. On or about September 3, 2002, I informed Dr. Melinda Wharton, the Division Chief for the Branch I worked in, that we had concerning results from the MMR-Autism Study that we would like to discuss with her.
18. Dr. Melinda Wharton formally reprimanded Dr. Bob Chen, my Branch Chief, on September 18, 2002. As I stated in my e-mails to both Dr. Melinda Wharton and to Dr. Walt Orenstein, I believe this was an intimidating personnel action and threatened the credibility of the entire branch. It also put a big black cloud over our branch and demoralized many of the staff.
19. On October 9, 2002, Dr. Margarette Kolczak, an extremely reputable biostatistician, reviewed my SAS programs and made a suggestion for testing the RACE Interaction. This was a post-hoc decision and an attempt to absolve us from reporting the RACE effects.
20. On October 16, 2002, I asked Dr. Walt Orenstein to remove the formal reprimand of Dr. Chen because I said there was false information included in it. (See e-mail RE Dr. Robert Chen's Reprimand).
21. On October 20, 2002, I described to Dr. Orenstein the dilemma I was in regarding the concerning MMR-Autism Study results and the reprimand of Dr. Chen. I told him I felt intimidated by the move and I linked it to them knowing the results would be problematic if they were shared outside the CDC.
22. On October 22, 2002, Dr. Boyle was assigned to brief Dr. Orenstein and Dr. Jose Cordero (the new Center Director for the National Center of Birth Defects and Developmental Disabilities).
23. Between October 22, 2002 and January 2004, there were significantly fewer hand written notes for the MMR-Autism Study because we had finalized the results and were writing the manuscript up for publication. I have many draft manuscripts that were written and are dated.
24. On January 8, 2004, I began to present draft PowerPoint presentations of the MMR-Autism Study for the Institute of Medicine meeting that I was scheduled to present on February 9, 2004 in Washington DC. I have copies of each of those PowerPoint presentations. During the next 30 days, I presented the results to the Division Director of ESD in the National Immunization Program, and the Director of the National Immunization Program. I would also present the results in the offices of Dr. Julie Gerberding.
25. On January 27, 2004, I had lunch with Dr. Marshalyn Yeargin-Allsopp. She told me that Dr. Frank DeStefano still currently reported to her.

26. On February 2, 2004, I met with Dr. Steve Cochi (the new Director of the National Immunization Program) and Dr. Melinda Wharton. During that meeting I provided Dr. Cochi with a draft of my letter to Dr. Julie Gerberding and sought his input. He requests that I remove any criticism of NIP in the letter.
27. During the February 2 meeting with Dr. Cochi and Dr. Wharton, I also requested that Dr. Walter Orenstein be brought into the meeting because he had arrived in the building that morning. Dr. Cochi suggested that Dr. Orenstein was “heading off into the sunset” and that we shouldn’t bother him with these issues. Although Dr. Orenstien had announced his retirement in January 2004, he was still coming for meetings on a regular basis.
28. On this same day, Brooke Barry, a CDC public health analysis and someone I trusted very much, informed me that the “autism caucus” was meeting on February 3<sup>rd</sup> and that they were initiating or requesting a formal investigation of the National Immunization Program.
29. On February 2, 2004, after meeting with Dr. Cochi and Dr. Wharton, I delivered my letter for Dr. Julie Gerberding regarding my concerns regarding results from the MMR-Autism Study just before I had to present them to the Institute of Medicine on February 9, 2004. (See scanned letter to Dr. Gerberding dated February 2, 2004).
30. On March 9<sup>th</sup>, I was put on administrative leave. In the Annex to the memorandum, they provided a list of my “inappropriate and unacceptable behavior in the work place” which included “you criticized the NIP/OD for doing very poor job of representing vaccine safety issues, claimed that NIP/OD had failed to be proactive in their handling of vaccine safety issues, and you requested that Dr. Gerberding reply to your letter from a congressional representative before you made your presentation to the IOM.” (See scanned Memorandum dated January 9, 2004.). I stand by that statement and I do not think it was unacceptable to convey that to Dr. Gerberding.

## **Conclusion**

I believe we intentionally withheld controversial findings from the final draft of the DeStefano et al (2004) Pediatrics paper. We failed to follow the final approved study protocol and we ran detailed in depth RACE analyses from October 2001 through August 2002 attempting to understand why we were finding large vaccine effects for blacks. The fact that we found a strong statistically significant finding among black males does not mean that there was a true association between the MMR vaccine and autism-like features in this subpopulation. This result would have probably have led to designing additional better studies if we had been willing to report the findings in the study and manuscript at the time that we found them. The significant effect of early vaccination with the MMR vaccine might have also been a proxy for the receipt of thimerosal vaccines early in life but we didn’t have the appropriate data to be able to code the level of thimerosal exposure from the MADDSP school records.

In addition to significant effects for black males, we also found significant effects for “isolated autism cases” and for the threshold of 24 months of age. If we had reported the 24 month effects, our justification for ignoring the 36 month significant effects would not have been supported. In the discussion section of the final published manuscript, we took the position that service seeking was the reason we found a statistically significant effect at 36 months. This was a post-hoc hypothesis regarding the findings after we confirmed one of our primary hypotheses. Because we knew that the threshold for 24 months was also statistically significant, reporting it would have undermined the hypothesis that service seeking was the reason we found an effect at 36 months. (See published paper).

