

IN THE UNITED STATES COURT OF FEDERAL CLAIMS

**FILED**

OFFICE OF SPECIAL MASTERS

JUN 14 2005

U.S. COURT OF  
FEDERAL CLAIMS

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.

**PETITIONERS' FILING RE:  
SUBMISSION OF EXPERT REPORTS IN  
SUPPORT OF GENERAL CAUSATION**

AUTISM MASTER FILE

Special Master George Hastings

**INTRODUCTION**

Upon resolution of the Petitioners' Steering Committee (PSC) Motion to Compel Discovery,<sup>1</sup> Special Master Hastings requested that petitioners describe a schedule for the completion of expert reports in support of petitioners' case for general causation. The Special Master specifically directed the PSC to submit a schedule for expert discovery as a brief to be entered in the docket of the Autism Master File. This memorandum is submitted in response to the Special Master's request.

As will be detailed below, the PSC proposes that expert reports not become due until mid-2006 at the earliest, and the PSC therefore requests a continued open extension of time for setting a hearing (or hearings) on issues of general causation. The PSC is acutely aware of two

<sup>1</sup> The PSC originally filed a Motion to Compel in March 2004. The history of that issue is described in the docket of the Omnibus Autism Proceeding, and will not be recounted here. The filing of the PSC's Amended Motion and entry of the Special Master's Discovery Order resolved the immediate discovery disputes on April 15, 2005.

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**ORIGINAL**

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competing rationales relating to setting a general causation hearing. On the one hand, each of the approximately 4500 petitioners in the Omnibus Proceeding has a strong and compelling interest in resolving their claim sooner rather than later; if compensation is to be had, the petitioners more than anyone have an interest in the earliest possible award. Also creating pressure for a prompt resolution of the Omnibus claims is Congress' explicit mandate in the enabling statute that the compensation program provide speedy resolution of vaccine injury claims. Finally, the PSC recognizes that this process has already lasted significantly longer than the time period contemplated by the Chief Special Master in Autism General Order No. 1.

On the other hand, it is critical in this proceeding—involving very serious injuries to thousands of children—that legal decisions are based on the best possible science. It is the PSC's position that the scientific and medical evidence needed to resolve issues of general causation in the Omnibus Proceeding has not yet matured to the point that it can support a sound adjudication of the causation issues presented by these claimants. Petitioners are not requesting a perpetual extension of time for the filing of expert reports and hearings on general causation. Instead, petitioners request an extension sufficient to allow the specific scientific work described herein to be completed and published so that the Special Master can consider it.

There are three general categories of scientific research that petitioners and their experts are monitoring in requesting this extension of time for filing expert reports. First, the federal government itself is either directly conducting or funding a number of studies relating to the possible environmental causes of autism in general, and the possible association between mercury and thimerosal and autism in particular.

Second, private academic researchers are conducting research into the possible associations between thimerosal and mercury exposure and neurological injury. A number of

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those studies have been published in the peer-reviewed scientific literature during the nine months since the last evidentiary hearing the Special Master conducted in the Omnibus Proceeding, and more publications of relevant studies are anticipated in the next year.

In addition, petitioners and their experts continue to be denied access to the Vaccine Safety Datalink, a critical component in putting together an evidence-based series of expert reports in support of general causation, particularly regarding the possible association between thimerosal exposure and the injuries in this case. Petitioners cannot say with any certainty when they might produce expert reports when such a critical source of data for those reports remains beyond the reach of the PSC's experts, and when independent researchers not retained by the PSC cannot get access to the data, thereby preventing the publication of peer-reviewed journal articles that petitioners' experts expect to rely on.

Because the science investigating the possible links between the MMR vaccine and thimerosal in vaccines with the neurological injuries in this case is only now "coming to a head," the PSC is not prepared to offer expert reports before mid-1996. The PSC requests an ongoing extension of time so that the research and opinions presented to the Special Master are developed enough to support a sound, empirical, scientifically supported decision on the critical issues of general causation in the Omnibus Proceeding.

Finally, the expert reports should not come due until mid- to late-2006 because the legal standard for proving a "causation in fact" case is unresolved. As the Special Master is aware, Chief Special Master Golkewicz attempted to establish a generally applicable standard in Stevens, but the Stevens opinion was reversed on appeal and the standard was rejected. The PSC is aware of two pending cases on appeal to the Federal Circuit regarding the applicable standard of proof in causation-in-fact cases. One case is fully briefed and argued, and the other case is

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being briefed. It is likely that the Federal Circuit will issue an opinion (in the first case at least) in late 2006. Given the unsettled state of what petitioners would need to prove—and thus what their experts would need to testify to—regarding causation, it would be premature to require the PSC to file the expert reports before the issue is resolved by the Federal Circuit.

**“STATE OF THE SCIENCE”: ONGOING GOVERNMENT STUDIES**

Petitioners have deposed six representatives of respondent’s client agencies<sup>2</sup> to inquire specifically about ongoing research that the federal government is either conducting or funding relating to the alleged association between the MMR vaccine and neurological injuries, or thimerosal exposure and neurological injuries. Two additional depositions are scheduled for June 27, 2005. It is clear from the testimony of those government representatives that significant scientific research is underway, and that most of the ongoing work will not be complete and published until mid- to late-2006.

Petitioners believe that the peer-reviewed, published reports of the following specific research studies are reasonably necessary to the Special Master’s evaluation of the causation issues in the Omnibus Proceeding, and to the preparation of the reports of the PSC’s expert

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<sup>2</sup> Coleen Boyle, Ph.D., CDC, Associate Director of Science and Public Health, National Center on Birth Defects and Developmental Disabilities; 12/9/2003.

Dr. Dennis E. Jones, D.V.M., Agency for Toxic Substances Disease Registry; 12/9/2003.

Dr. Melinda Wharton, M.D., CDC Infectious Disease Specialist; 12/9/2003.

Susan Ellenberg, Ph.D., FDA, Director of the Office of Biostatistics and Epidemiology in the Center for Biologics Evaluation and Research; 5/27/04.

Cindy Lawler, Ph.D., NIH, Program Administrator, National Institute of Environmental Health Sciences, 5/24/2005.

Annette Kirschner, Ph.D., NIH, Program Administrator, National Institute of Environmental Health Sciences, 5/24/2005.

witnesses:

1. Infant Environmental Exposures and Neurodevelopmental Outcomes at Ages 7-10 Years; CDC grant funded; anticipated publication date of December 2005. Deposition of Dr. Melinda Wharton, Exhibit 14, attached as Exhibit A.
2. Italian Thimerosal NDD Proposed Study; CDC and NIP study; anticipated publication date of September 2006. Wharton Depo., Ex. 14, attached as Exhibit B.
3. Vaccine Safety Datalink Thimerosal/Autism Case-Control Study; CDC study with external, contract co-participants; anticipated publication date of September 2006. Wharton Depo., Ex. 14, attached as Exhibit C.
4. NIH MMR/Regressive Autism Study; CDC; no testimony as to anticipated publication date. Wharton Depo., Ex. 14, attached as Exhibit D.
5. Investigation of Measles Virus Sequences in Bowel Biopsies of Autism Spectrum Disorder Children; CDC grant funded; anticipated publication in 2005. Wharton Depo., Ex. 14, attached as Exhibit E.
6. Autism and Developmental Disabilities Monitoring Networking; CDC study with grant-funded co-participants; publication of first-year data anticipated in 2005 or 2005, and ongoing after that. Deposition of Coleen Boyle, Ph.D., Exhibit 5, attached as Exhibit F.
7. Atlanta-Based Autism Studies; CDC; prevalence data published annually beginning in 2004. Boyle Depo., Ex. 9, attached as Exhibit G.
8. Danish Medical Research Council (ongoing autism epidemiological project); CDC grant funded; projection completion anticipated in 2009, with some components completed earlier. Boyle Depo., Ex. 9, attached as Exhibit H.
9. Environmental Factors in the Etiology of Autism; EPA and NIH grant-funded through the

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National Institute of Environmental Health Sciences; anticipated completion date of September 2006, with interim reports and publications during the course of the project. Deposition of Cindy Lawler, Ph.D., exhibit to follow upon receipt of deposition transcript. Exhibit I is intentionally left blank to accommodate receipt of this deposition exhibit.

The importance of this ongoing government and government-funded research cannot be overemphasized in the context of the Special Master's evaluation of the causation issues in this proceeding. The "Infant Environmental Exposures and Neurodevelopmental Outcomes at Ages 7-10 Years (Ex. A)," for example, is a follow-up study to the CDC's earlier work in the Thimerosal Screening Analysis, and specifically will examine whether "increasing exposure to thimerosal is associated with neurodevelopmental disorders." Ex. A., p. 4. The CDC itself claims that the study "will assist in the interpretation of the results obtained in the Thimerosal Screening Study." Ex. A, p. 5. In addition, both the Italian Thimerosal/NDD Study (Ex. B) and the VSD Thimerosal/Autism Case-Control Study (Ex. C) were specifically recommended by the Institutes of Medicine in 2001.

The federal government, including respondent's own agencies, has decided that the science on the etiology of autism in general, and any alleged links between vaccines and autism and other neurodevelopmental injuries in particular, needs further development. The government has further decided to spend millions of dollars to answer the currently unknown causation questions, through a combination of intramural and external, grant-funded research. Petitioners should not be required to put forth their case for causation when the government's own institutional opinion is apparently that significant additional research is needed to provide a clearer picture of the science. Petitioners' experts should not be required to anticipate the IOM, CDC, FDA, NIH, EPA and those agencies' contract partners in academia by submitting expert

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reports on causation based on the peer-reviewed, published research to date. Any reports submitted at this point would likely need to be substantially revised and rewritten in light of the anticipated research publications described above. It is not in the interest of either petitioners or the Program to produce reports that might be rendered obsolete (or at least in need of substantial revision) upon analyses of the anticipated publications in 2006.

In examining the anticipated dates of completion of several of the research projects (either the entire project or interim publications), it is clear that a substantial body of new science will be available to petitioners and their experts, and to the Special Master, between September and December 2006. Petitioners therefore propose to submit their expert reports and set a schedule for adjudication of the general causation hearings in that late 2006 time period.

**“STATE OF THE SCIENCE”: EMERGING AND ONGOING EXTERNAL, PRIVATE RESEARCH**

The past 14 months has seen a proliferation of significant articles published in the peer-reviewed scientific literature directly relating to potential causation theories in the Omnibus Proceeding.<sup>3</sup> The number of publications is not surprising, given the increased scientific and academic interest in the etiology of pediatric neurological injuries engendered by the July 1999 AAP/FDA joint announcement concerning thimerosal, the 2001 IOM report calling for research into the hypothesized link between thimerosal and adverse neurological outcomes, publication of the Thimerosal Screening Analysis in November 2003, and ongoing media coverage of the issue. Researchers contacted by PSC attorneys, whether retained as experts or merely consulted,

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<sup>3</sup> Petitioners have collected a representative sample of recent publications relevant to the causation issues in this matter, and attach the published articles as Exhibit J. Each article is numerically tabbed within Exhibit J, and the exhibit contains an index to the twenty articles that have appeared since mid-2004.

indicate that additional relevant, timely and significant additional published research is expected during the next year.

Petitioners emphasize that this is *not* research prepared by retained experts for the sake of litigation in civil cases or use in the Omnibus Proceeding, but is instead independent academic research destined for publication in the peer-reviewed literature. This is exactly the type of research that petitioners' experts will rely on to prepare their reports, and is precisely the type of valid scientific work the Special Master will necessarily rely on in evaluating the issues of general causation. It would be premature for petitioners' experts to generate reports without benefit of the rapidly evolving literature on the causation issues.

The MIND Institute housed at the University of California Davis campus, for example, is in the middle of a multi-phase, multi-discipline research program specifically directed at examining the role of environmental risk factors that might contribute to the incidence and severity of childhood autism and other neurodevelopmental disorders. Included in the project are discrete studies focusing on mercury exposure and thimerosal exposure. The research project includes projects focusing on environmental epidemiology, non-human animal models (primates and mice), and molecular and cellular mechanisms (neuro-immunotoxicology). The first phase of the project will not be completed until well into 2006. A copy of the MIND Institute Research Proposal as submitted to NIH (the grant proposal was approved, and NIH is providing funding for the research) describes the research project in detail, and is attached as Exhibit K.

In addition, virtually every one of the recently published studies explicitly points out the need for additional research, describing the significant gaps in the current state of the medical community's understanding of the possible environmental causes of neurological injuries such as



autism spectrum disorders.<sup>4</sup> More remarkably, a very recent article published in a journal of the federal government's own National Institute of Environmental Health Sciences (a subdivision of the respondent DHHS in this proceeding) took direct issue with the IOM's contention in 2004 that no additional research into thimerosal's possible association with neurological injuries was needed:

*“Results from an initial IOM review of the safety of vaccines found that there was not sufficient evidence to render an opinion on the relationship between ethylmercury exposure and developmental disorders in children (IOM 2001). The IOM review did, however, note the possibility of such a relationship and recommended further studies be conducted. A recently published second IOM review (IOM 2004) appears to have abandoned the earlier recommendation as well as back away from the American Academy of Pediatrics goal. ***This approach is difficult to understand, given our current limited knowledge of the toxicokinetics and developmental neurotoxicity of thimerosal, a compound that has been (and will continue to be) injected in millions of newborns and infants.***”*

Burbacher, T., Comparison of Blood and Brain Mercury Levels in Infant Monkeys Exposed to Methylmercury or Vaccine Containing Thimerosal, Env. Health Perspectives; ehponline.org,

<sup>4</sup> See, e.g., Fallon, J., Could One of the Most Widely Prescribed Antibiotics Amoxicillin/Clavulanate “Augmentin” be a Risk Factor for Autism?, Med. Hypotheses, 2005; 64(2) at 314 (“In light of these findings, it is important that further studies be undertaken.”); Ex. J, Tab 5.

Geier and Geier, Neurodevelopmental Disorders Following Thimerosal-Containing Childhood Immunizations: A Follow-Up Analysis, Int.J. Toxicol., 2004 Nov-Dec; 23(6) at 375 (“It is clear that the results of the present study mandate that additional research should be undertaken, not only for autism, but other childhood neurodevelopmental disorders . . .”); Ex. J, Tab 6.

Jyonouchi, H., Dysregulated Innate Immune Responses in Young Children with Autism Spectrum Disorders: Their Relationship to Gastrointestinal Symptoms and Dietary Intervention, Neuropsychobiology 2005; 51(2) at 85 (“Better understanding of these abnormalities in relation to CNS functions will be helpful to develop preventive and therapeutic measures . . .”); Ex. J, Tab 12.

Larsson, HJ, Risk Factors for Autism: Perinatal Factors, Parental Psychiatric History, and Socioeconomic Status, Am.J. Edipem. 2005; 161; at 924 (“Because none of the single significant risk factors found in this study were present in the majority of cases, we still have much to learn about the many different factors that contribute to autism and how they may potentially interact.”); Ex. J, Tab 13.

Waly, M., Activation of Methionine Synthase by Insulin-Like Growth Factor-1 and Dopamine: A Target for Neurodevelopmental Toxins and Thimerosal, Mol. Psychiatry; 2004 April; 9(4) at 368 (“Further studies are needed to establish the functional significance of regulated MS activity and to evaluate the possibility that vaccine components (i.e. thimerosal and aluminum) may have contributed to the risk of autism, ADHD and other developmental disorders.”), Ex. J, Tab 20.

April 2005, at 19 (emphasis added), Ex. J, Tab 2.

This statement by NIH-funded researchers, combined with similar statements calling for more research from virtually every researcher investigating the possible links between environmental exposures and childhood neurological injuries and neurodevelopmental delays, sends a clear signal to petitioners that their own expert reports should also wait for additional science to develop. The direct criticism of the IOM's 2004 report echoes the concerns expressed in a published letter to the editor of the journal *Pediatrics* by Dr. Thomas Verstraeten, the author of the published Thimerosal Screening Analysis, making it clear that his 2003 study is *not* a "negative" study and urging further research:

"The article [published in the November 2003 issue of *Pediatrics*] does not state that we found evidence against an association, as a negative study would. It does state, on the other hand, that additional study is recommended, which is the conclusion to which a neutral study must come. Does a neutral outcome reduce the value of a study? It may make it less attractive to publishers and certainly to the press, but it in no way diminishes its scientific and public health value. A neutral study carries a very distinct message: the investigators could neither confirm nor exclude an association, and therefore more study is required . . . The bottom line is and always has been the same: an association between thimerosal and neurological outcomes could neither be confirmed nor refuted, and therefore, more study is required."<sup>5</sup>

Again, petitioners do not propose waiting *ad infinitum* to prepare and present expert opinion testimony, but instead ask for reasonable leave for anticipated academic research to be published. As is the case with ongoing government studies, it appears that a significant body of additional medical literature will be developed by mid- to late-2006, and that is why the PSC proposes a schedule of expert production for late 2006.

#### **OBSTACLE TO PSC EXPERT PREPARATIONS: VSD ACCESS**

As the Special Master and respondent are aware, the PSC requested that respondent

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<sup>5</sup> *Pediatrics*, Aug. 2004, at 932.

produce data from the Vaccine Safety Datalink describing the diagnostic outcomes after December 31, 2000 for children included in the “thimerosal exposed” cohorts in the Thimerosal Screening Analysis.<sup>6</sup> That discovery request then became a subject of the PSC’s Motion to Compel, and access to the “post-2000 VSD” data was a topic of expert testimony at hearings on the Motion to Compel.<sup>7</sup> Expert testimony was presented to the Special Master in support of petitioners’ claim that production of the requested post-2000 data was reasonably necessary to the general causation inquiry.<sup>8</sup> Respondent’s own expert agreed in cross-examination that consideration of the requested data would be very helpful in resolving the causation questions raised by the Thimerosal Screening Analysis.<sup>9</sup> The Special Master himself described why the additional data might be useful to his inquiry.<sup>10</sup> During those hearings it was respondent’s position that none of the respondent’s agencies were in possession or control of the requested data, and petitioners were in effect told to search for the data by other means, and from other sources.<sup>11</sup>

Petitioners then attempted to obtain the VSD data from the organization hired by the CDC to administer the VSD. This third-party contractor, America’s Health Insurance Plans, the national trade association for the health maintenance organizations and managed care organizations, replied that it did not have the data, and that in fact it never receives or sees any

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<sup>6</sup> Verstraeten, T., Safety of Thimerosal-Containing Vaccines: A Two-Phased Study of Computerized HMO Databases, Pediatrics Nov. 2003; 112(5):1039-1048.

<sup>7</sup> September 23, 2004; November 1, 2004.

<sup>8</sup> Omnibus Proceeding Hearing, September 23, 2004, Harland Austin. Ph.D., pp. 82-85, Ex. L.

<sup>9</sup> Omnibus Proceeding Hearing, November 1, 2004, Dr. Walker, p.92, Ex. M.

<sup>10</sup> Omnibus Proceeding Hearing, November 1, 2004, Special Master Hastings, pp.164-168, Ex. N.

<sup>11</sup> Omnibus Proceeding Hearing, November 1, 2004, Respondent’s Counsel, pp. 169-171, Ex. O.

data, in any form, generated by the VSD.<sup>12</sup>

Petitioners then learned that Dr. Mark Geier and David Geier, external researchers *not* retained as testifying experts by the PSC, have submitted several research proposals to the institutional review boards of some of the HMOs participating in the VSD, and that those researchers received IRB approval for studies that would include the post-2000 data that petitioners have been seeking since March 2004.<sup>13</sup> The PSC assumed that upon publication of the research generated by the Geiers' approved studies, petitioners' experts would be able to rely on that peer-reviewed work in developing their opinions, and the evidence would be admissible before the Special Master. The prospect of published scientific literature that would probably include an analysis of the post-2000 VSD diagnostic data, in short, appeared to address the need raised in petitioners' original discovery request.

The PSC has since been informed that the Research Data center of the National Center for Health Statistics (that is, the physical site where the approved researchers would gain access to, and use of, the dataset assembled for their IRB-approved project) has not delivered the requested dataset to the external researchers and has taken the position—contrary to the health maintenance organization IRB approval documents—that the research is *not* approved.<sup>14</sup>

The PSC here is not asking the Special Mater to directly intervene on behalf of the Geiers, but the Geiers' ongoing, frustrated efforts to get access to the data they need in order to complete their IRB-approved research has a direct impact on the ability of petitioners' retained

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<sup>12</sup> Letter from PSC counsel to AHIP, and AHIP's email response, Ex. P.

<sup>13</sup> IRB approval letters for VSD research project proposals submitted by Geier and Geier, from Kaiser-Permanente Northern California and Kaiser-Permanente Northwest, Ex. Q.

<sup>14</sup> Correspondence between Geiers and CDC/RDC staff, May 31, 2005 and June 3, 2005, Ex. R.

experts to prepare reports relying on the anticipated VSD research described in the Geiers' approved project applications. Petitioners' experts cannot even say when they might complete such reports, as government-imposed delays on the study investigators have pushed the research and publication far behind schedule. The continued obfuscation of VSD access issues presents serious obstacles to the ability of the petitioners to develop their case for causation, and it deprives the Special Master of essential information needed to evaluate the petitioners' case.<sup>15</sup>

### CONCLUSION

For all of the reasons described above, the PSC respectfully requests an ongoing extension of time in which to file expert reports in the Autism Omnibus Proceeding, at least until September 2006. Petitioners fully understand the many compelling reasons for proceeding with expert testimony earlier rather than later, they do not make this request lightly, and they do not make this request in order to create delay. Instead, petitioners strongly believe that the critical decisions about general causation in these thousands of serious injury claims deserve the best possible science that can be expected in the near future. Petitioners urge the Special Master not to let these legal proceedings get ahead of the science. Rather, petitioners urge the Special Master to recognize that a significant body of relevant, peer-reviewed, independent, published science, unavailable today, will likely will be available to petitioners, respondent, and the court within the next twelve months. For that reason, petitioners' expert reports should not become due until late 2006.

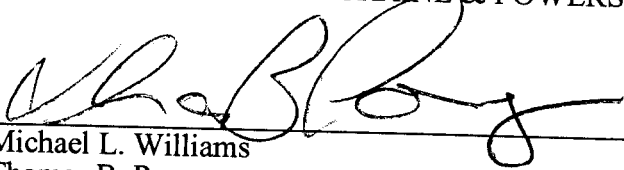
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<sup>15</sup> Petitioners anticipate the need for seeking the Special Master's intervention in untangling the labyrinth in which the CDC, AHIP, HMOs, and the RDC simultaneously manage to produce a system that ultimately functions to virtually foreclose access to the VSD. The issue of a remedy for the ongoing denial of VSD access is beyond the scope of this submission, and will be addressed as appropriate by conferring with respondent and with the Special Master during regularly scheduled status conferences, and if needed by a motion for appropriate relief by the PSC.

DATED this 13<sup>th</sup> day of June, 2005.

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

By:



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**CERTIFICATE OF SERVICE**

I hereby certify that on June 13, 2005, I served the foregoing **PSC FILING RE: EXPERT REPORT AND SCHEDULE** on the following

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CERTIFICATE OF SERVICE

(An extensive set of exhibits, attached to this filing of the Petitioners' Steering Committee, has been filed into the Autism Master File, but is not being placed on the website for the Omnibus Proceeding due to the provisions of 42 U.S.C. § 300aa-12(d)(4)(A).)