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.	AUTISM MASTER FILE Special Master Hastings

RESPONDENT'S RESPONSE TO PETITIONERS' SECOND MOTION TO COMPEL AND MOTION FOR ISSUANCE OF THIRD-PARTY SUBPOENAS

Respondent herein responds to Petitioners' Motion to Compel and for Issuing Third-Party Subpoenas ("Motion"). For the reasons set forth below, petitioners' Motion must be denied.

SUMMARY OF RESPONDENT'S POSITION

Over four years into the Omnibus Autism Proceeding, the Petitioners' Steering Committee ("PSC") now seeks to conduct original, epidemiologic research in an attempt to support its claim that autism is caused by thimerosal-preserved vaccines and/or by the MMR vaccine. Litigation-driven research, such as that proposed by the PSC, has been repeatedly condemned by courts confronted with the issue as inherently unreliable. In order to grant the Motion, the Special Master would have to make the unprecedented decision that he needs original research to resolve the factual issues, and that he has the power under the Vaccine Act to order discovery permitting the PSC's retained experts to conduct new research.

The PSC provides no factual basis for the discovery it now seeks. This Motion is not a renewal of a previous discovery motion, as the PSC implies. Rather, it is a broad, new request that seeks access to post-2000 Vaccine Safety Datalink ("VSD") data on two million children enrolled in Managed Care Organizations ("MCOs"), and inquires about a host of conditions ranging from immune disorders to cardiac problems. The PSC provides no evidence whatsoever that the Centers for Disease Control and Prevention ("CDC") has control of the post-2000 data such that the CDC could be compelled to turn over that data. Nothing in the PSC's Motion contradicts the fact that post-2000 data remain under the possession and control of the MCOs. In an attempt to confer control of this post-2000 data on the CDC, the PSC incorrectly represents the VSD Project, the CDC Data Sharing Program, and the post-2000 data as being one in the same. They are not.

If the study that the PSC proposes to undertake, and the post-2000 data necessary to perform the study, were as critical to the PSC's case as it now maintains, the PSC certainly would have revealed such a study proposal, and sought the data for that study, before now, a scant two months before the PSC's deadline to file its causation evidence. The timing of the PSC's request, and the eleventh hour formulation of its proposed study, cannot be reconciled with the PSC's assertion that the study is critical to its case. More significant still, as results of the study the PSC proposes to undertake cannot be known before that study is completed, the PSC cannot credibly maintain that the study will aid its causation case.

In the Motion, the PSC acknowledges that the MCOs possess the post-2000 data, but the PSC provides no rationale at all to support the claim that patient data held by third parties is properly within the ambit of the Act's limited discovery.

The PSC has provided no reason for the Special Master to engage in original research. This Motion seeks discovery that is unprecedented, unwarranted, and unauthorized under the Vaccine Act. Therefore, the Motion must be denied.

DISCUSSION

I. The PSC's Discovery Request Is Beyond The Limited Discovery Provided Under The Vaccine Act, And Is Also Beyond The Bounds Of Discovery Allowed In Traditional Civil Litigation.

As respondent has repeatedly emphasized since the inception of the Omnibus Autism Proceeding, a unique and prominent aspect of the Vaccine Act, as compared with traditional civil litigation, is that the right of discovery is not conferred to any party in a case brought under the Act. Rather, the right to discovery is expressly withheld from the parties and reserved exclusively for the special master. "There may be **no discovery** in a proceeding on a petition . . . ." the Act states plainly, "other than the discovery required by the special master." 42 U.S.C. § 300aa-12(d)(3)(B) (emphasis added). Specifically, the special master is given the power to require "such evidence as may be reasonable and necessary," "the submission of such information as may be reasonable and necessary," and "the testimony of any person and the production of any documents as may be reasonable and necessary." 42 U.S.C. § 300aa-12(d)(3)(B)(i-iii).

In *In re: Claims for Vaccine Injuries Resulting in Autism Spectrum Disorder or a Similar Neurodevelopmental Disorder*, Autism Master File, Ruling Concerning Motion for Discovery From Merck Re: MMR Vaccine, 2004 WL 1660351 (Fed. Cl. Spec. Mstr. July 16, 2004), this Court has already stated what it considers to be "reasonable and necessary" in the context of discovery:

> [I]t seems to me that the 'reasonable and necessary' standard means that the special master should require production if the master concludes that, given the overall context of the factual issues to be decided by the master, he or she could not make a *fair and well-informed* ruling on those factual issues without the requested material.

Id. at *9.

The PSC moves to compel production of post-2000 VSD data for the sole purpose of enabling its paid experts to conduct an original epidemiologic study, as outlined in Petitioners' Exhibit ("Pet. Ex.") 86, in an attempt to prove a causal association between receipt of thimerosal and/or the MMR vaccine and the development of neurodevelopmental disorders. The PSC is not seeking access to post-2000 VSD data to challenge the methodology of an existing study. Rather, the PSC's experts intend to use the post-2000 VSD data to conduct new research entirely. The PSC couches its discovery request as information "critical to the Special Master's general causation inquiry" (Motion at 13), yet the PSC fails to explain why the Special Master is unable to make a fair and well-informed ruling without "evidence" that currently does not exist. See Schneider v. HHS, 64 Fed. Cl. 742, 746 (2005) ("At its most basic level, discovery is concerned with the search for relevant information among existing evidence.").

Additionally, the PSC's contention that the post-2000 VSD data is necessary to the Special Master's evaluation of the factual issues, rather than potentially useful to the PSC in an attempt to prove its claim, is belied by the PSC's own assertion that access to post-2000 VSD data "will provide nearly 5,000 neurologically and neurodevelopmentally injured children with their best chance of success in the Program." Motion at 3-4; see also Schneider v. HHS, No. 99-0160V, 2005 WL 318697, at *5 n.6 (Fed. Cl. Spec. Mstr. Feb. 1, 2005), aff'd, 64 Fed. Cl. 742 (2005) ("Congress restricted sharply discovery [under the Vaccine Act] . . . placing the emphasis

on the production of information that will assist the special master in evaluating a claim rather than on the production of just any potentially sensitive information that a petitioner desires in an attempt to establish a basis for a claim."). Scientific standards require that the outcomes of research must **not** be known or predetermined before a study begins. Hence, it is simply not reasonable or consistent with scientific standards for the PSC to know in advance that these data will be the evidence necessary to prove its case, as the PSC claims in its Motion.

In addition to the Vaccine Act's restriction that all discovery must be reasonable and necessary to the special master, a special master is further charged to consider only "relevant and reliable evidence" when determining whether an immunization in fact caused a petitioner's injury. See Rules of the United States Court of Federal Claims ("RCFC"), Appendix B, Vaccine Rule 8(c); McCarren v. HHS, No. 92-764V, 1997 WL 341694, at *16 n.18 (Fed. Cl. Spec. Mstr. June 6, 1997) ("special master is obliged to consider 'all relevant, reliable evidence . . . .'") (citation omitted). The special master must weigh the potential relevance and/or reliability of the information sought through discovery with the burdens and expense it places on a party and the proceedings. See RCFC 26(b)(1).

This Motion is squarely aimed at the creation of what will purportedly be scientific evidence. In the context of scientific or technical evidence, the requirement for reliability is, if anything, more keen. That special masters are not bound by common law or statutory rules of evidence does not signify that the Vaccine Act, or the Rules of the United States Court of Federal Claims, place no limits on the admissibility of purportedly scientific, technical or other specialized testimony or evidence. On the contrary, special masters are required to screen such evidence. Indeed, the Vaccine Rules mandate that special masters must ensure that all scientific

evidence sought to be admitted is not only relevant to the issues in the case, but reliable.

The rule that scientific evidence must be reliable before it can be relied upon necessarily contemplates a certain degree of evidentiary regulation. In Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 591-92 (1993), the United States Supreme Court provided all federal courts with a flexible analytical framework for evaluating the admissibility, credibility and reliability of scientific evidence. The application of this framework in Vaccine Program cases was approved by the U.S. Court of Federal Claims and adopted by the United States Court of Appeals for the Federal Circuit. See Terran v. HHS, 41 Fed. Cl. 330, 336 (1998) ("While the Supreme Court designed the test to determine whether evidence is relevant and reliable in the context of the Federal Rules of Evidence, it is equally capable of being used to determine whether information is relevant and reliable in the context of the Vaccine Act."), aff'd, 195 F.3d 1302 (Fed. Cir. 1999).[1]

In the Motion, the PSC argues that they "seek access to the VSD that will allow a team of highly qualified investigators to conduct a specific study explicitly designed to directly address the central causation questions presented in the Omnibus Proceeding." Motion at 8. Additionally, the PSC asserts that the discovery of post-2000 VSD Project data is "critical to addressing broader vaccine policy issues: the integrity of the immunization program, public trust in the government's immunization safety oversight, and transparency in science and policy-making." Id. at 13-14. The underlying premise of the PSC's Motion betrays a fundamental

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[1] Likewise, special masters have accepted and applied the Daubert standards to expert testimony in other vaccine cases. See, e.g., Corder v. HHS, No. 97-0125V, 1999 WL 476256, at *6 n.15 (Fed. Cl. Spec. Mstr. May 28, 1999); Trojanowicz v. HHS, No. 95-0215V, 1998 WL 774338, at *3 (Fed. Cl Spec. Mstr. July 1, 1998) ("Daubert is helpful in providing an analytical framework for evaluating the reliability of scientific evidence.").

misunderstanding of the Vaccine Act.

The Vaccine Act was not intended to subsidize private scientific research. The drafters of the Vaccine Act clearly recognized and understood that research concerning vaccine-related injuries was not complete. See McClendon v. HHS, 24 Cl. Ct. 329, 335 (1991); see also H.R. Rep. No. 99-908, at 18 (1986), as reprinted in 1986 U.S.C.C.A.N. 6344, 6359. Congress, therefore, required as part of the Vaccine Act that further research would be funded by the National Vaccine Program to "[e]valuat[e] the need for and the effectiveness and adverse effects of vaccines and immunization activities." Id. at 10-11, 6351-52. Congress hoped that "research on vaccine injury and vaccine safety mandated by [the Vaccine Act] will soon provide more definitive information about the incidence of vaccine injury." Widdoss v. HHS, 25 Cl. Ct. 251, 262 (1992), aff'd in part, rev'd in part on other grounds, 989 F.2d 1170 (Fed. Cir. 1993).[2] The research provided for by the Vaccine Act, however, is to be conducted by "the National Institutes of Health, the Centers for Disease Control, the Office of Biologics Research and Review of the Food and Drug Administration, the National Center for Health Statistics, the National Center for Health Services Research and Health Care Technology Assessment and the Health Care Financing Administration" – not by private litigants with claims pending before the U.S. Court of

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[2] Congress further authorized the Secretary to "revise and update" the Vaccine Injury Table based upon "more accurate information that would become available as a result of the research on vaccine injuries mandated by the Vaccine Act." Terran v. HHS, 195 F.3d 1302, 1308 (Fed. Cir. 1999) (citing the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, § 312, 100 Stat. 3743 (1986)); see also Pub. L. No. 99-660, § 311, 100 Stat. 3743 (1986)("The Secretary shall establish in the Department of Health and Human Services a National Vaccine Program to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines") and H.R. Rep. No. 99-908, at 18 (1986), reprinted in 1986 U.S.C.C.A.N. 6344, 6359.

Federal Claims, or their experts. See National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, § 311, 100 Stat. 3743 (1986).

Indeed, the Vaccine Act specifically provides that the Director of the National Vaccine Program is responsible for "coordinat[ing] and provid[ing] direction for research . . . to prevent adverse reactions to vaccines. 42 U.S.C. § 300aa-2(a)(1). The National Vaccine Advisory Committee supports the Director of the National Vaccine Program by "recommend[ing] research priorities and other measures the Director of the Program should take to enhance the safety and efficacy of vaccines." 42 U.S.C. § 300aa-5(b)(2). Moreover, Congress directed that research into possible adverse reactions to vaccines, which may require a change in the Vaccine Injury Table, be conducted by the Secretary and aided by the Advisory Commission on Childhood Vaccines. National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, § 312, 100 Stat. 3743 (1986).

As one special master has concluded:

> [I]n the intricate statutory structure [of the Vaccine Act], Congress has provided both a mechanism distinct from the [Vaccine Injury Compensation] Program to foster fitting scientific or medical research regarding vaccine safety and a mechanism distinct from the [Vaccine Injury Compensation] Program to foster fitting review of scientific or medical research regarding vaccine safety.

Schneider, 2005 WL 318697, at *5. In affirming the special master in Schneider, the Court of Federal Claims similarly acknowledged that the courtroom is not the proper venue for studies into vaccine safety:

> [T]he task of ensuring the safety of the nation's vaccine program rests not with the courts but rather with the Secretary of the Department of Health and Human Services and the advisory bodies that the Secretary is authorized to appoint, specifically, the National Vaccine Advisory

Committee and the Advisory Commission on Childhood Vaccines.

Schneider, 64 Fed. Cl. at 746.

As the statutory language and legislative history make clear, the courtroom is not the place for scientific research.[3] Special masters are not called upon to diagnose vaccine injuries, nor is the Court of Federal Claims "to be seen as a vehicle for ascertaining precisely how and why" certain vaccines may cause injury to some individuals "while safely immunizing most others." Knudsen v. HHS, 35 F.3d 543, 549 (Fed. Cir. 1994). Rather, that "research is for scientists, engineers, and doctors working" outside the judicial arena, "in hospitals, laboratories, medical institutes, pharmaceutical companies, and government agencies." Id. Special masters have specifically noted that the Vaccine Injury Compensation Program is not the appropriate forum for conducting scientific and medical studies because "scientific or medical 'research' conceived and conducted in the context of litigation poses an inherent danger," as it is not subjected to peer review and publication. See Werderitsh v. HHS, No. 99-319V, 2005 WL 3320041, at *14 (Fed. Cl. Spec. Mstr. Nov. 10, 2005); Schneider, 2005 WL 318697, at*5 ("the [Vaccine Injury Compensation] Program is not the appropriate forum for – and a special master should not preside over wide-ranging discovery, or should not devise unique procedures, aimed at – developing original scientific or medical theses."). See also Daubert, 509 U.S. at 593 ("[S]ubmission to the scrutiny of the scientific community is a component of 'good science,' in part because it increases the likelihood that substantive flaws in methodology will be detected.").

"Law lags science; it does not lead it." Rosen v. Ciba-Geigy Corp., 78 F.3d 316, 319 (7th

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[3] See Perry v. United States, 755 F.2d 888, 892 (11th Cir. 1985) ("[T]he examination of a scientific study by a cadre of lawyers is not the same as its examination by others trained in the field of science or medicine.").

Cir. 1996).[4] The law does not concern itself with "the exhaustive search for cosmic understanding but for the particularized resolution of legal disputes." Carnegie Mellon Univ. v. Hoffmann-LaRoche, Inc., 55 F.Supp.2d 1024, 1033 (N.D. Cal. 1999) (quoting Daubert, 509 U.S. at 597). In the traditional civil arena, even where a plaintiff's experts have "stumbled onto something truly remarkable, such breakthroughs should not be resolved by a court of law in the first instance." Brief for American Association for the Advancement of Science, et al., as Amici Curiae, submitted in Daubert, 509 U.S. 579, 1993 WL 13006281, at *22. The Supreme Court has pointed out that important differences exist between truth seeking in the courtroom and in the laboratory:

> Scientific conclusions are subject to perpetual revision. Law, on the other hand, must resolve disputes finally and quickly. The scientific project is advanced by broad and wide-ranging consideration of a multitude of hypotheses, for those that are incorrect will eventually be shown to be so, and that in itself is an advance. Conjectures that are probably wrong are of little use, however, in the project of reaching a quick, final, and binding legal judgment – often of great consequence – about a particular set of events in the past. We recognize that, in practice, a gatekeeping role for the judge, no matter how flexible, inevitably on occasion will prevent the jury from learning of authentic insights and innovations.

Daubert, 509 U.S. at 597.

The Supreme Court instructed lower federal courts to play the critical role of "gatekeeper" to evaluate expert witnesses and determine whether their proffered testimony will

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[4] See also Sierra Club v. Hodel, 848 F.2d 1068, 1096 (10th Cir. 1988) ("Environmental study is for the agency to conduct in the field, not for the judiciary to construct in the courtroom."), overruled on other grounds by Vill. of Los Ranchos De Albuquerque v. Marsh, 956 F.2d 970 (10th Cir. 1992); United States v. Brown, 557 F.2d 541, 556 (6th Cir. 1977) ("A courtroom is not a research laboratory.").

"'assist the trier of fact to . . . determine a fact in issue.'" Daubert v. Merrell Dow Pharm., Inc., 43 F.3d 1311, 1320 (9th Cir. 1995) ("Daubert II") (quoting Fed. R. Evid. 702). Thus, lower federal courts, including special masters, must make a preliminary determination that the proffered expert scientific testimony is both relevant and reliable; i.e., that proffered expert testimony reflects "scientific knowledge," amounts to "good science," and is "derived from the scientific method." As the Ninth Circuit, in Daubert II, explained:

> One very significant fact to be considered is whether the experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying. . . . [I]n determining whether proposed expert testimony amounts to good science, we may not ignore the fact that **a scientist's normal workplace is the lab or the field, not the courtroom or the lawyer's office**. . . . That an expert testifies based on research he has conducted independent of the litigation provides important, objective proof that the research comports with the dictates of good science. . . . That the testimony proffered by an expert is based directly on legitimate, preexisting research unrelated to the litigation provides the most persuasive basis for concluding that the opinions he expresses were 'derived by the scientific method.'"

Daubert II, 43 F.3d at 1317 (emphasis added) (footnote and citation omitted); see also Washburn v. Merck & Co., Inc., 213 F.3d 627, No. 99-9121, 2000 WL 528649, at *2 (2nd Cir. 2000) (Table) (holding expert's testimony inadmissible under Daubert because expert's opinion "did not emanate from his own research in the field, but rather was developed for purposes of litigation."); Grant v. Pharmavite, LLC, 452 F.Supp.2d 903, 908 (D. Neb. 2006) (stating that "[e]xpert opinions generated as a result of litigation have less credibility than opinions generated outside of litigation" and holding that expert's opinion was inadmissible because "it was developed only after [the expert was] contacted by plaintiffs' attorneys in connection with [the] litigation"); Armitage v. United States, 1989 WL 7913, at * 9-10 n.2 (D. Kan. 1989) ("As a

general matter, the Court is convinced that the panel [of the . . . study] did not perform as an independent body conducting a scientific examination. Whether inadvertently or intentionally, the panel's report is injected with the bias characteristic of experts retained by a party for purposes of litigation.").[5] An expert who proposes to do nothing more with seemingly remarkable discoveries than submit them to judges and juries is not acting in a manner characteristic of scientists. Such an expert should be discredited, not because he is "necessarily incorrect, but because [his findings are] not sufficiently reliable and therefore too likely to lead the factfinder to an erroneous conclusion." See In re TMI Litigation, 193 F.3d 613, 666 (3d Cir.1999).

The PSC's Motion brings into crisp relief the evidentiary reliability issue. The research it proposes is born of this litigation and entirely driven by it. The evidentiary reliability of such research is inherently suspect, which is why research of that ilk has been repeatedly and consistently criticized by the courts confronted with it.

Finally, a special master is obligated to "minimize the cost and complexity of" Vaccine Act proceedings. Skinner v. HHS, 30 Fed. Cl. 402, 410 (1994). Congress specifically directed

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[5] A prime example of the inherent unreliability of litigation-driven research is the experience of Dr. Andrew Wakefield, who alleged a link between MMR vaccine and autism in children. After it was discovered that Dr. Wakefield did not disclose that his research was being funded by lawyers seeking evidence to use against vaccine manufacturers, the editor of *The Lancet*, Dr. Richard Horton, made the following statement:

> 'There were fatal conflicts of interest in this paper. In my view, if we had known the conflict of interest Dr. Wakefield had in this work I think that would have strongly affected the peer reviewers about the credibility of this work and in my judgement it would have been rejected.'

See BBC News, Journal regrets running MMR study, Feb. 20, 2004. Available at: *http://news.bbc.co.uk/1/hi/health/3508167.stm*

that the special masters should place limitations on the use of discovery in Program proceedings in order that the compensation system would be less adversarial, less expensive, and move more quickly than ordinary tort litigation. Vant Erve v. HHS, No. 92-341V, 1997 WL 763462, at *8 (Fed. Cl. Nov. 21, 1997). For this reason, formal discovery is not granted as a matter of right in Program cases. The broadness of the PSC's discovery request magnifies the potential cost burden to the Program, as the PSC seeks data from over two million participants enrolled in eight MCOs. Their Motion, if granted, guarantees substantial delay and, at best, will result in the creation of evidence of questionable reliability.

II. The PSC's New Discovery Request Is Markedly Distinct From Its 2004 Motion to Compel.

The PSC inaccurately portrays this Motion as simply a continuation of its earlier effort to obtain post-2000 VSD data. The PSC has obvious reasons for trying to convince the Special Master that its latest discovery request is not new. First, the PSC must persuade the Special Master that he should grant the request to continue discovery at this late stage in the proceeding, disrupting and delaying the trial process that the PSC itself proposed.

Second, the PSC's portrayal of this Motion as a renewal of its earlier Motion to Compel creates the impression that the evidence submitted by the PSC in 2004 supports the new Motion. None of that evidence establishes that the Special Master needs the discovery now sought, nor does it support the contention that the CDC has control over the targeted patient data such that the CDC could be compelled to provide that data. Indeed, the PSC's own experts, Dr. Austin and Ms. Lally, never addressed the need for the extensive data sought here.

Finally, portraying the new Motion as a renewal of the 2004 Motion to Compel masks a

critical distinction between the two. While the PSC first sought access to VSD data to enable the Special Master to understand what weight to give the Thimerosal Screening Analysis, this Motion seeks VSD data to create an entirely new study. The PSC even describes its foray as a "research proposal." Motion at 3. While not made explicit in the new Motion, for the Special Master to compel the discovery the PSC now seeks, he would have to determine that it is reasonable and necessary for him to conduct original scientific research.

Comparison of the 2004 Motion to Compel with the current Motion readily reveals that what the PSC now seeks is vastly more extensive in scope, and for a markedly different purpose, than what it sought in 2004. At that time, the PSC sought limited post-2000 data: 1) access to post-2000 data for the population of the Thimerosal Screening Analysis out to 2004; and 2) access to post-2000 data "as needed to validate and expand upon the epidemiological VSD analysis conducted by the Drs. Geier." See Petitioners' Motion to Compel Discovery in the Autism Omnibus Proceeding, Mar. 9, 2004, at 4. In April, 2005, the PSC withdrew its 2004 request "based on discovery to date." See Petitioners' Amended Motion to Compel Discovery in the Omnibus Autism Proceeding, Apr. 8, 2005, at 2. While the PSC reserved the right to renew the 2004 request, the PSC also stated that it was "applying for access to the data" from the MCOs. Id. Nowhere in the Motion, however, does the PSC assert that it ever applied to the MCOs for access to the post-2000 data.

The PSC no longer seeks access to post-2000 patient data on the Thimerosal Screening Analysis population or data for use in Mark and David Geier's research projects through the Data

Sharing Program.[6] Data sought now by the PSC is for original research. The PSC proposes to take a significantly larger study population than that studied in the Thimerosal Screening Analysis, follow that population over a longer period, and explore additional health conditions arising within the expanded population. The total study population involved in the Thimerosal Screening Analysis was 140,887 children. The PSC's proposed study would involve approximately two million patients – over fourteen times as many children. The PSC now seeks data for a seven-year period rather than for the five-year period initially sought. While the Thimerosal Screening Analysis investigated potential associations between one exposure – thimerosal – and twelve conditions (represented by twelve ICD-9 diagnostic codes), the PSC proposes to study two exposures – thimerosal and MMR – and seventy possible associations (represented by thirty-five different ICD-9 diagnostic codes investigated for each exposure.

The PSC further appears to be expanding the scope of the factual inquiry before the Special Master. For example, the PSC includes cardiac and renal conditions among the possible associations to be examined by their experts. Their Motion reveals a more subtle attempt to shift the focus of the overall inquiry before the Special Master away from autism and autistic spectrum disorders to general adverse neurological consequences. Autism General Order #1 described the situation leading to the Omnibus Autism Proceeding as a "concern in recent years that certain childhood vaccinations might be causing or contributing to an apparent increase in the diagnosis

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[6] The 2004 Motion to Compel mentioned Mark and David Geier's ongoing VSD projects, but the PSC never articulated what discovery it was seeking with regard to the Geiers' projects, nor did the PSC provide any evidence to support such a request. Rather, the sole focus of the 2004 Motion was on obtaining data concerning the Thimerosal Screening Analysis to permit the PSC's experts to conduct a reanalysis of that study. In short, in 2004, the PSC obliquely raised the notion of needed discovery in aid of the Geiers, but the PSC did not pursue such discovery then and does not pursue it now.

of a type of serious neurodevelopmental disorder known as 'autism spectrum disorder,' or 'autism' for short," and proceeded to describe the latter condition in accordance with the National Institute of Mental Health definition. Autism General Order #1, 2002 WL 31696785 (Fed. Cl. Spec. Mstr. July 3, 2002), at *1. In keeping, the Order described the focus of the Omnibus Autism Proceeding as being on "autism and/or similar disorders." Id. at 2. From the outset, then, these proceedings were centered on autism or disorders similar to autism. Yet in reading the PSC's Motion, autism or autism spectrum disorder is used only once to describe the inquiry before the Special Master. Motion at 2 ("neurological disorders on the autism spectrum"). Rather, the PSC now substantially broadens the inquiry, describing the pertinent issues of the Omnibus Autism Proceeding as "adverse neurological or developmental outcomes," "neurological or neurological injuries," or, more broadly still, "adverse health outcomes," using these or similar phrases no less than twelve times total in the course of the Motion. If the PSC is attempting to broaden the scope of the inquiry before the Special Master four and a half years into the Omnibus Autism Proceeding, and a mere two months before its causation evidence is due, the PSC should be required to explicitly so state. Both the Special Master and respondent have been preparing for a proceeding that would address whether there is sufficient evidence to conclude that thimerosal-preserved vaccines or the MMR vaccine cause autism or autistic spectrum disorders. If with two months remaining before revealing its causation case the PSC lacks evidence to prove its claim, and instead is now seeking evidence to prove something else, the PSC must be forthcoming with that fact.

III. The CDC Does Not Possess Or Control The Post-2000 VSD Data.

Even were the Special Master to conclude that under the Vaccine Act's truncated

discovery he needed to conduct new research, or that he possessed the raw power to compel the unprecedented discovery the PSC now seeks, the Special Master's specific authority to force the CDC to hand over MCO patient data necessarily requires that the CDC controls that data. The lynchpin in the PSC's argument that the CDC controls post-2000 data is its contention that because the CDC regulates access to the VSD, the CDC necessarily controls the VSD data:

> The CDC's very active role in regulating any and all access to the VSD, in short, clearly demonstrates that while the agency may no longer have 'possession' of the VSD itself, the agency continues to assert meaningful 'control' over the database in a manner that makes the CDC appropriately subject to an Order of the Special Master compelling the agency to make the VSD available to the petitioners' experts.

Motion at 3. The PSC's argument is wrong on several levels.

The PSC's contention that the CDC controls post-2000 data is incorrect regardless of whether the pivotal issue is viewed as one of possession or control of access. The CDC neither possesses nor controls the post-2000 data, and, accordingly, cannot be compelled to provide access to that data. The post-2000 data are exclusively possessed by and under the control of the individual MCOs, which collect the data from their members.

A. The VSD, The Data Sharing Program, And The Post-2000 VSD Data Are Separate And Distinct Entities.

The PSC presents a fundamentally inaccurate portrayal of the operation of the VSD and obscures the distinction among three separate entities: (1) the Vaccine Safety Datalink Project – a government conceived and managed research program; (2) the post-2000 MCO patient data used in VSD Project studies; and (3) the Data Sharing Program – a public access research program that makes available pre-December 31, 2000 VSD-derived data owned by the CDC. At various points in its Motion, the PSC misleadingly uses the term "VSD" to describe all three. The three

entities are separate and distinct.

The Vaccine Safety Datalink Project, established in 1990, is a government conceived and managed research program. More specifically, the VSD Project is "a collaboration with a consortium of several managed care organizations (MCOs) to allow timely investigations of vaccine safety concerns." Institute of Medicine of the National Academies, Vaccine Safety Research, Data Access, and Public Trust 28 (Nat'l Academies Press 2005) ("IOM Report") (filed as Pet. Ex. 87). The VSD Project originally consisted of four participating MCOs and eventually expanded to eight. Id.

The CDC contributes scientific and technical expertise to the VSD Project, proposes VSD Project studies, and provides some of the funding necessary to make the program work. The MCOs provide data collected from their patient records. Along with the CDC, the MCOs propose collaborative research studies to be conducted under the VSD Project, provide scientists and technicians to conduct the studies, and contribute resources to support the VSD Project. See generally Declaration of James M. Baggs, Ph.D., Acting Project Officer of the VSD, dated Jan. 19, 2007, at ¶¶ 7-8, 10 ("Baggs Dec.") (attached as Tab A).

The patient data used in VSD Project studies are provided by the MCOs pursuant to contract with the CDC. Since the inception of the VSD Project, the MCOs have provided data in two distinct manners. Under the initial contracts between the CDC and the participating MCOs, "the automated data files that contained VSD data before 2001 were contract deliverables from the MCOs . . . Those data files were maintained at CDC and considered a database owned by CDC." IOM Report at 29. In 2002, the contract provisions changed and substantially altered the terms concerning control of VSD data. Under the terms of the current contract, which pertains to

the post-2000 data sought here, the MCOs no longer provide the CDC with datasets. Rather, as the Institute of Medicine ("IOM") acknowledged, "ownership of VSD data generated after December 31, 2000, remains with the MCOs." Id.

While MCO-derived patient information provides the data for the epidemiological studies conducted under the VSD Project, the VSD Project itself is more than a database. The VSD Project is a research program, originally conceived by the CDC and operated, in part, with CDC funds. It is hardly surprising, therefore, that the CDC has extensive involvement in and oversight of research conducted through the VSD Project. As will be discussed in greater detail, the fact that the CDC has oversight responsibility for the VSD does not mean that the CDC has control over the MCOs' patient data.

The MCOs have extensive involvement in all aspects of the VSD Project, hence prompting the IOM to use the terms "consortium" and "collaboration" to describe the joint CDC-MCO effort that comprises the VSD Project. While the PSC portrays the CDC as "controlling the VSD," that is not accurate. The MCOs are full participants in the research effort. Research priorities are developed in consultation with the MCOs, scientists from the MCOs are investigators on VSD Project studies, and MCO resources are used to maintain their data for use in VSD Project studies. Moreover, all studies using VSD Project data must be approved by an Institutional Review Board ("IRB") at the MCOs whose data will be used in the study – a fact that applies with equal force to CDC-owned data as it does to MCO-owned data. See generally Baggs Dec. at ¶¶ 7-8, 10-11, 15.

The CDC's Data Sharing Program is different than the VSD Project. The Data Sharing Program was formally established on August 30, 2002, "because of heightened interest in public

access to" the data generated by the VSD Project. IOM Report at 33. The CDC Data Sharing Program requirements, make clear the distinction between data that are available under the Data Sharing Program and post-2000 VSD Project data. The Data Sharing Program requirements state that there are two types of VSD Project data that can be accessed under the Data Sharing Program: "[1] a relational database containing data through December 31, 2000 . . . and [2] final datasets that were used for published studies from August 2002 and beyond." CDC/National Center for Health Statistics, Research and Development, Procedures and Costs for Use of the Research Data Center, Appendix IV ("Project-Specific Requirements[:] Vaccine Safety Datalink (VSD) Data Sharing Program) at 17-18. In contrast, post-2000 VSD Project data are not available through the CDC Data Sharing Program:

> Data from the VSD project collected after December 31, 2000 are not available through the RDC VSD Data Sharing Program. VSD data beyond 2001 can be accessed through a formal collaboration with an MCO and the external researcher must work through MCO procedures. It should be noted that collaboration is at the discretion of the MCO. Such collaboration would be outside the scope of the VSD Data Sharing Program and, therefore, data would not be accessed at the RDC. CDC cannot guarantee external investigators' ability to gain access to the VSD data at the MCOs.

Id. at 18.

In the Motion, the PSC implies that external researchers have the same right of access to post-2000 VSD Project data as they have to pre-December 31, 2000, data available under the CDC Data Sharing Program. The PSC is wrong. Under the Data Sharing Program, access to CDC-owned VSD Project data is limited, the key limitation being that all proposed studies using CDC-owned data must still be approved by each MCO whose patient data will be used in the study. Researchers from outside the VSD Project may obtain access to VSD Project data from

December 31, 2000, and earlier through the Data Sharing Program, but such access does not extend to VSD Project data from 2001 and beyond. The CDC Data Sharing Program does not encompass post-2000 data other than final datasets that were used for published studies from August 2002 and beyond. The provisions regarding data access under the Data Sharing Program are not relevant to the discovery now sought by the PSC.

The existence of the Data Sharing Program neither demonstrates the CDC's control of post-2000 data nor creates any rights to access beyond those explicitly provided under the Data Sharing Program. In its brief, the PSC ignores the fact that the VSD Project is distinct from the CDC's Data Sharing Program. For example, the PSC erroneously states that "[t]he CDC describes the VSD project as a 'data sharing program.'" Motion at 12. The PSC's statement incorrectly implies that there is data sharing across the breadth of the VSD Project, rather than just for the discrete data possessed by the CDC and made available under the Data Sharing Program. More misleading still is the PSC's statement that "the ability of external researchers . . . to conduct studies involving the VSD is governed in large part by the CDC and its related entities, including the Research Data Center of the National Center for Health Statistics, and is conducted pursuant to procedures established and administered by the CDC." Motion at 2-3. In support of this statement, the PSC recounts an experience its researchers had accessing data at the Research Data Center ("RDC") (Motion at 3, n.2), but the PSC fails to disclose that the incident concerned access to CDC-owned data made available through the Data Sharing Program, not access to post-2000 data that the PSC now seeks. See generally Declaration of Robert S. Krasowski, M.A., M.S., Statistician at the RDC, dated Jan. 19, 2007, at ¶¶ 5, 8 ("Krasowski Dec.") (attached as Tab B).

B. The PSC's List of Ten "Ways" In Which The CDC "Controls Access to the VSD" Does Not Establish That The CDC Controls Or Possesses The MCOs' Data.

As discussed above, the VSD Project is a research program through which investigators from the CDC and the MCOs work together on studies designed to monitor the safety of vaccines administered to infants, children, adolescents, and adults. Baggs Dec. at ¶ 6. As a government program, the CDC has oversight responsibility for the VSD Project. Baggs Dec. at ¶ 9. The fact that the CDC oversees the VSD Project does not mean, as the PSC argues, that the CDC possesses or controls the post-2000 VSD data. The PSC's list of ten "ways" in which the CDC "controls access to the VSD" shows nothing more than agency oversight of a research program. Motion at 11-12. A careful review of the "evidence" cited by the PSC reveals that such evidence pertains nothing to the CDC's alleged "control" over post-2000 data.

For example, the PSC notes that the CDC receives monthly activity reports on VSD Project activity, as well as reports and updates on ongoing VSD Project studies, from America's Health Insurance Plans ("AHIP"). Motion at 11. By contractual agreement, the CDC's contractor for the administration of the VSD Project is AHIP. 2002 Contract between AHIP and CDC ("Contract") at 1 (referenced pages attached as Tab E). AHIP provides the CDC with a monthly activity report, as required by contract. Id. at 10. This "activity report includes updates from each of AHIP's subcontractors to the VSD [Project], i.e., the MCOs." Baggs Dec. at ¶ 9. These "updates include information such as any changes to staff made during the month, and financial information regarding how much money and time is being billed by an MCO to AHIP," and, in turn, by AHIP to the CDC. Id. Such "billing information is an important way in which CDC monitors the progress of a study." Id. In addition, "[t]he activity reports are not scientific

in nature, nor do they require or include information regarding any data. Id.

Similarly, the reports and updates regarding ongoing VSD Project studies include information on the status of those studies. Baggs Dec. at ¶ 9. AHIP "coordinates a monthly VSD Project conference call among AHIP, CDC, and the MCOs. Id.; see also Deposition of AHIP by and through its Designee, Barbara Lardy, in Sykes v. Glaxo-SmithKline, No. 06-CV-1111, dated Oct. 10, 2006, at 62-64 ("Lardy Dep.") (referenced pages attached as Tab D). Pursuant to contract, AHIP prepares minutes of the conference call and sends the minutes to CDC. Contract at 10; Lardy Dep. at 63-64. Both "[p]roposed and ongoing studies are discussed among the participants," and "VSD data are not discussed." Baggs Dec. at ¶ 9. Indeed, when questioned about the content of conference call minutes prepared by AHIP, Barbara Lardy, the AHIP deponent, testified that "there's no data revealed in the minutes . . . there's no data that's discussed in the calls." Lardy Dep. at 63. Reflecting the collaborative nature of the VSD Project, the CDC can decline any study proposal made by the MCOs, and the MCOs can decline to participate in any study proposal offered by the CDC. Baggs Dec. at ¶ 10.

Although the CDC provides overall management for the VSD Project, the CDC does not have unfettered access to the data, nor do the MCOs send completed data files to the CDC on a regular basis. Baggs Dec. at ¶ 16. The CDC only receives completed, analytical data files for ongoing VSD Project studies that have the necessary IRB approval and the required Data Use Agreement. Id. at ¶¶ 15-16. The data files CDC receives from the MCOs contain only the minimum necessary information needed to run a particular study. Id. at ¶ 16. Each MCO participating in a study transfers its data files to the lead VSD Project investigator for that study; "[e]ighty-two percent of the time, the lead VSD project investigator [on a study] is from one of

the MCOs and not CDC." Id. at ¶ 10.

Contrary to what the PSC would have this court believe, there is no such thing as a post-2000 VSD database. For post-2000 data, "[t]here is no one database or dataset" that contains all data from all participating MCOs, and "[e]ach MCO owns and manages its data, and only has access to its own data." Baggs Dec. at ¶ 14. Similarly, "[e]ach MCO is responsible for safeguarding its [own] data, which are securely kept at each MCO site." Id. For data "to be used effectively in a VSD Project study, the MCOs and the CDC have developed a standard format" in which the data are stored at each MCO. Id. The data can be used in a study only after IRB approval and a Data Use Agreement are in place. Id. at ¶¶ 14-15.

Two qualified CDC investigators "are permitted to conduct quality control reviews of the MCOs' data to ensure that appropriate data elements are expressed in the standard format" used for VSD research, and to "conduct inquiries into data suitability for study planning purposes." Bags Dec. at ¶ 16. Moreover, "[a]ny quality control review or data suitability inquiries undertaken by the CDC are monitored by the MCOs." Id. The CDC cannot access this data for use in a particular study without going through the IRB process and entering into a Data Use Agreement. Id. at ¶¶ 7, 15.

In support of its contention that the CDC controls the post-2000 data, the PSC argues that "CDC decides what VSD studies ought to be conducted, and sets priorities among the VSD studies to be conducted." Motion at 11. Once again, this "evidence" provides no support whatsoever for the contention that the CDC controls the data.

The VSD Project "considers input from numerous sources to determine potential research topics, as well as methods to conduct the studies." Baggs Dec. at ¶ 10. Because the VSD Project

is a collaborative process between the CDC and the participating MCOs, investigators at the MCOs and the CDC propose potential VSD Project studies. Id. The "VSD Project has finite resources," and therefore, the CDC and MCOs must designate "priority studies" to be done using the VSD Project. Id. The "participating MCOs are expected to allocate their resources to complete the priority studies in an efficient and timely manner." Id. Priority studies are established through a collaborative process between the CDC and the MCOs. Id. Each year, the list of priority studies is reviewed by AHIP, the MCOs, and the CDC, and modified as necessary. Id.

The PSC argues that the 2005 IOM report "make[s] it clear" that "the CDC itself has access to the VSD not available to external researchers." Motion at 10-11. The PSC further argues that the fact that external researchers must collaborate with an investigator from the CDC or an MCO to conduct a VSD Project study proves that the CDC controls the data. Id. at 11. The PSC is wrong. The CDC has not prevented the MCOs from sharing their data with others. As the PSC knows, the CDC has in no way prevented the PSC's experts from entering into a contractual or collaborative relationship with the MCOs to obtain the data they seek.

Indeed, the IOM report cited so extensively in the PSC's Motion refers only to the CDC's management of the VSD Project, not to its alleged control over post-2000 data. In fact, the IOM specifically states that "[a]ccording to the VSD contract provisions, data for events on January 1, 2001, and later **remain the property of the MCOs, and the [CDC is] bound by the contract restrictions**." IOM Report at 61 (emphasis added). It was certainly not the IOM's intent that a court be permitted to dictate to the CDC or the MCOs how the VSD Project should be run or what studies should be conducted using the VSD Project's finite resources. In fact, the IOM

acknowledges that proposals by external researchers for VSD Project studies "should be reviewed by an independent committee that has expertise in vaccines, immunology, epidemiology, statistics, and research with administrative databases," not decided by a court. Id. at 82.

Furthermore, the IOM recognizes the need for external researchers to continue collaborating with a CDC or MCO investigator when conducting a VSD Project study:

> Because the quality of automated data cannot be guaranteed, the inclusion of chart-review-verified data in new vaccine safety studies improves the quality of such studies. Chart-review-verified data can be obtained only by collaborating with [CDC]-affiliated or MCO-affiliated researchers. Thus, it is important for independent external researchers to try to collaborate with a [CDC]-affiliated or MCO-affiliated researcher to produce a new, high-quality vaccine safety study with recent VSD data. . . . The committee sees no alternative to that situation for an independent external researcher who cannot or will not collaborate with [CDC]-affiliated or MCO-affiliated VSD researchers, and this underscores the need for a system that supports and, to the extent feasible, ensures collaboration when requested.

IOM Report at 61.

The IOM never contemplated that a court could assert itself in the operation of the VSD Project and force, by court order, the CDC and the MCOs to collaborate with an external researcher. In fact, the IOM states that "collaboration by its very nature cannot be forced." IOM Report at 62. The IOM further recognizes that the operation of the VSD Project is contractual in nature and that "ensuring a workable system for collaboration may have implications for renegotiation of the VSD contract." Id.

The PSC's discussion of the "ways" in which the CDC purportedly controls access to post-2000 data is more in the nature of a complaint about the way the VSD Project is structured

than proof that the CDC can be compelled to permit access to that data. The PSC desires a research program that permits its experts greater access to VSD Project data. In fact, the PSC wants more access to data than the CDC is even permitted, as the CDC is obliged to have its research studies approved by an IRB at the MCOs. By its Motion, the PSC would not have that restriction apply to its experts' research.

While the PSC may not be satisfied with the scope of research opportunities available to its experts, the PSC provides no legal basis for the Special Master to step in and craft a different VSD Project. For the Special Master to dictate new terms for VSD Project access, as the PSC suggests, it would necessarily thrust him into the role of determining research policy for the CDC.

C. The PSC's Acknowledgment That The MCOs Own And Control The Post-2000 Data Contradicts Its Argument That The Same Data Are Controlled By The CDC.

The PSC recognizes the irrefutable fact that the post-2000 data it now seeks is owned and controlled by the MCOs. The PSC acknowledges that "[a]ll post-2000 data generated by the VSD . . . is no longer delivered to the CDC, and instead remains with the MCOs and is considered to be owned by the MCOs." Motion at 13. The PSC further recites a list of factors that demonstrate MCO control of the data:

> The MCOs generate the data upon which the VSD is based, they organize and consolidate the data to create the VSD, they review the data for accuracy and completeness, they develop protocols to make data entries consistent over time, they update the VSD annually, and they retain both the 'source' data and any datafiles generated by the VSD.

Id. The PSC reaches a final conclusion that simply cannot be reconciled with its argument that the CDC controls the data they seek in declaring that "[t]here is no doubt, therefore, that the

MCOs have both possession and control of the VSD, and specifically of the post-2000 data that is the subject of petitioners' Motion." Id.

Respondent will not presume to speak for the MCOs on the specific considerations raised by the PSC's attempt to obtain the MCOs' patient data, on the confidentiality laws that are binding on those organizations, or any agreements the MCOs may have with their members pertaining to use of medical information.[7] Respondent, however, can offer the general observation that the Special Master's analysis of any discovery issue must always start with the premise that discovery is limited under the Vaccine Act. In the context of the Omnibus Autism Proceeding, regardless of whether the CDC or the MCOs are targeted by a discovery request, the Special Master must conclude that he needs the results of the PSC's proposed study in order to resolve the factual issues before him. Furthermore, whether the PSC has presented sufficient justification for its discovery request, whether its proposed study is sufficiently detailed to assess its value, or whether the proposed study is even feasible, must be considered regardless of whether the discovery is sought from the CDC or from the MCOs.

IV. The PSC Offers No Justification For The Necessity Of The Study It Proposes Or For The Timing Of Its Motion.

Notwithstanding the lack of a legal and factual basis for the PSC's Motion, the PSC has offered no justification whatsoever to explain why the court should grant its eleventh hour discovery request. In an attempt to justify its actions, the PSC contends that an order granting

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[7] Another consideration of significance to the MCOs is the release of proprietary information. The IOM recognized that "[o]ne consequence of the use of MCO administrative data is the need for protection of proprietary information," and that the provisions of the contract between the CDC and the MCOs regarding VSD data were designed, in part, to safeguard such proprietary information. IOM Report at 31.

access to post-2000 data will "obviate the need for civil lawsuits to secure access to the data," and will provide petitioners "with their best chance of success." Motion at 3-4. Indeed, the PSC goes so far as to describe the study it has proposed as "critical" to the Special Master's resolution of the causation issue, if any epidemiological evidence is to be considered at all. Motion at 13. Yet, the PSC goes on to refute each of these assertions, either in word or in action.

Civil lawsuits are filed regardless of what this court does. The PSC mentions that "private litigants have used the civil discovery process in at least one US District Court to address VSD access and control issues with AHIP itself," in a case brought against a vaccine manufacturer. Motion at 10. The PSC does not mention that certain of its members represent the plaintiffs in that civil case. Furthermore, discovery has limited application in Vaccine Act cases. The PSC cannot persuasively argue that Congress intended proceedings under the Act to obviate the need for discovery in civil litigation. If Congress had so intended, it would have provided discovery under the Act to be at least as extensive as that available in civil proceedings.

More importantly, the actions of the PSC belie the assertion that its newly proposed study is "critical" to its case. Court Exhibit E to Autism General Order #1 required that the PSC file its discovery request no later than August 2, 2002, and further required that any follow-up discovery request be filed no later than February 3, 2003. In addition, discovery was to be completed by August 22, 2003. Id. If the newly proposed study were as critical to the PSC's case as the PSC contends, the PSC would have requested access to the data necessary to conduct the proposed study at the outset of this litigation, and continuously pursued the request throughout. The PSC would not have waited four years into the proceeding, and two months before its causation evidence is due, to propose a new epidemiological study of two million children.

While the PSC claims to have pursued VSD Project data "vigorously" over the past three years, it has filed only one motion seeking VSD Project data during that time period, and that motion was not for the purpose of conducting new research. Rather, the PSC only sought data pertaining to the Thimerosal Screening Analysis. The PSC ultimately amended its original motion, removing the request for access to post-2000 data on the Thimerosal Screening Analysis, understanding that such data could only be obtained directly from the MCOs. Presumably, the PSC would have pursued a collaborative effort with the MCOs if the data were so important to its case. The PSC has filed no evidence demonstrating that it attempted to work with the MCOs to obtain the post-2000 data.

Even with respect to the data that the PSC's experts did obtain to conduct their reanalysis of the Thimerosal Screening Analysis, the experts waited over a year before availing themselves of the data.[8] Significantly, it was only after the PSC's experts, Dr. Austin and Ms. Lally, reviewed the data from the Thimerosal Screening Analysis and concluded that "the methodology employed by the CDC was generally sound and that their findings are valid " did the PSC change course, hiring new experts and proposing original research. Pet. Ex. 91 at 9.

The timing of the PSC's new discovery request cannot be explained, as the PSC implies, by a belated revelation that the CDC "controls" the post-2000 data. First, the IOM Report cited so heavily by the PSC in its Motion not only affirms the fact that the MCOs possess and control the post-2000 data, but it was published in 2005, over one year ago. In status conferences, the PSC suggested that it learned of the CDC's control of post-2000 data after taking the deposition

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[8] The data sought was made available at the RDC in April, 2005. The PSC's experts did not review the data until August, 2006.

testimony of AHIP's representative, Barbara Lardy. In the Motion, the PSC argues that Ms. Lardy's testimony "makes clear" that the CDC "'outsourc[ed]' the management of VSD data, particularly post-December 2000 data," to AHIP. Motion at 10. In fact, Ms. Lardy's deposition testimony directly contradicts the PSC's contention that AHIP essentially controls the data the PSC now seeks. Ms. Lardy explained AHIP's role in the VSD Project as follows:

> AHIP has purely an administrative role under the contract. We work with – we monitor the work of the sites. We receive monthly reports and annual reports from the sites. We receive monthly invoices. We generally oversee the work of our subcontracts. And as I said, AHIP's deliverables under the contract all fall into the administrative arena. We arrange conference calls. We schedule meetings, that sort of thing. . . . We [do] not have a scientific role in the contract . . . We don't receive any data. We only receive monthly reports . . . and invoices that do not contain any data.

Lardy Dep. at 37-38.

Ms. Lardy testified consistent with the terms of the CDC/AHIP contract, a document that respondent had already given to the PSC long before they even sought the deposition. Nothing in Ms. Lardy's testimony supports the PSC's purported justification for its eleventh hour discovery Motion, nor does it support the PSC's alleged factual basis for the Motion.

Similarly, the PSC cites no provision from the CDC/AHIP contract that demonstrates CDC control. The contract demonstrates that CDC cannot grant "access" to post-2000 data to external researchers. The IOM was explicit on this point: "[t]he contract provisions allow independent external researchers access only to automated data for events before January 1, 2001, for new studies." IOM Report at 61. "[D]ata for events on January 1, 2001, and later remain the property of the MCOs . . . ." Id. With respect to that data, the IOM warned that the CDC is "bound by the contract restrictions." Id.

When the PSC first alerted the Special Master that the Motion seeking post-2000 data would be forthcoming, the PSC stated that the Motion was prompted, in part, by the experience of certain of its experts, who had been barred from working on VSD data at the Research Data Center. The PSC's verbal assertions created the impression that these researchers had sought and obtained access to post-2000 VSD Project data and were summarily banned from continuing their study at the whim of the CDC. In the Motion, the PSC has considerably diminished its reliance on the experience of these researchers in its attempt to demonstrate CDC control over post-2000 data. The incident is reduced to a mere footnote. Motion at 3, n.2.

The PSC now reveals that the studies these researchers had undertaken "were not explicitly designed to investigate an association between thimerosal exposure and pediatric neurological or developmental injuries, as is the case with the proposed study in this Motion" (Motion at 3, n.2), raising the legitimate question of how this interrupted investigation is relevant to the issue before the Special Master or how it justifies the PSC's proposal to undertake completely new research.

What the PSC does not reveal is that the data its researchers were accessing were CDC-owned data made available through its Data Sharing Program, not the post-2000 VSD Project data that are the target of this Motion. Krasowski Dec. at ¶ 8. The PSC further fails to reveal the true nature of the course of events: that its researchers had sought approval from the MCOs to alter their study design by combining datasets; that the MCOs did not approve the request; that the researchers combined the datasets anyway; and that when the RDC staff learned that the researchers were acting outside the scope of their IRB approved protocol, the RDC staff followed the instructions of MCOs and barred the unapproved work. Id. at ¶¶ 10-13.

These PSC researchers were not working on the study proposed here, they were not working with post-2000 VSD Project data, and they were barred from continuing their research because they refused to comply with the MCOs' IRB-approved protocol. This event cannot explain or in any way justify the PSC's latest discovery endeavor.

V. The Study Proposed By The PSC Is Scientifically Flawed And Not Feasible.

Missing from the PSC's study proposal are any details on the feasibility of the study. The PSC's experts who will conduct the study have no experience with the VSD Project, and have provided no evidence that they understand how to design a study using the VSD Project data. The PSC's proposal has not been reviewed by experts familiar with the VSD or by the MCOs whose patient data would be utilized. In fact, though the PSC portrays the study as "specific," and "explicitly designed to directly address the central causation questions presented in the Omnibus Proceeding" (Motion at 8), many questions about what is being proposed are left unanswered. There are gaps in the description of the study design and a lack of clarity or explanation concerning the use of comparison groups, exposure assessment, outcome assessment, required additional data collection, and how confounding variables will be addressed – all areas the PSC's experts would have to resolve before the PSC could accurately assert that its study would yield the information it claims, or that the study could even be completed. Baggs Dec. at ¶¶ 17-19.

Many of the specific problems with the proposed study stem from a lack of understanding of the VSD Project data. For example, in the "Statistical Methodology" section of the proposal, the PSC's experts propose to use the "clinic most often visited," a data field that is not always reliable under the VSD Project, and which would be problematic to use in the manner proposed.

Pet. Ex. 86 at 3; see also Baggs Dec. at ¶ 19. Even the areas of the proposal that are not specific to the VSD Project lack clarity. For example, with two main exposures (thimerosal and MMR) examined for 35 different ICD-9 diagnoses, the study will examine 70 possible associations, increasing the likelihood that positive associations will occur by chance alone. Yet, the proposal does not address chance occurrences or make clear how many positive associations the PSC's experts expect due to chance. Id. at ¶ 20. Further, the study does not acknowledge that most of the diagnoses to be examined may be congenital diagnoses, and it provides no method for distinguishing between congenital conditions and those that arose later. These are just a handful of problems with the PSC's proposed study or areas where sufficient explanation about the proposal is lacking.

One area that is certainly of interest to the Special Master is an estimate of the length of time the PSC's proposed study will take to complete. A realistic estimation is that the proposed study will necessarily take three to five years to complete. Baggs Dec. at ¶ 24. Some of the information needed for the PSC's proposal can only be obtained through chart review of the MCOs' patient records, which considerably increases the time required for completion of the study and drives up the study's cost. Id. at ¶ 24. Chart review could be necessary to determine whether for certain vaccines administered, thimerosal-preserved or preservative-free vaccinations were received by patients in the study population. See generally Declaration of Joanne C. Binkley, Director of the Division of Disclosure and Oversight Management, Food and Drug Administration, dated Jan. 19, 2007 (attached as Tab C). In addition, the PSC does not provide the Special Master with an estimate of how much money the proposed study will cost, or how the study will be financed. Experience with VSD Project studies that involved smaller populations

and investigated more limited outcomes indicates that the PSC's proposed study will cost well in excess of five million dollars. Baggs Dec. at ¶ 23. Even assuming that the Special Master had the authority to order original research be done for his benefit, if the Special Master were to order the PSC's proposed study to be performed, he would have to conclude that a several year delay in the resolution of the issue before him is warranted while a multimillion dollar study is undertaken.

VI. The Continued Viability of the VSD May Be Severely Impacted If The Special Master Were To Grant The PSC's Motion.

Should the Special Master conclude that the CDC can be compelled to produce the data sought, or can be compelled to force the MCOs to produce that data, his order would be one with which respondent could not possibly comply. That data is both physically and legally beyond the CDC's reach. Respondent would be left with no alternative but to seek extraordinary relief. Should the Special Master step beyond the bounds of the Act's limited discovery and order the MCOs to produce their patient data, respondent anticipates that the MCOs would fully endeavor to protect it.

The MCOs' participation in the VSD Project is voluntary. An order granting the PSC's Motion, and thereby forcing the MCOs to turn over their patient data, would seriously jeopardize the continued existence of the VSD Project research. Should the MCOs continued participation in the VSD Project carry with it the danger of compromise of patient data, significant additional resource costs, and legal entanglements, the MCOs may well leave the VSD Project, effectively terminating it. As the CDC warned in its responses to the IOM's recommendations regarding the VSD Project:

> Imposing additional requirements on the MCOs that participate in the VSD Research Project is a disincentive to participate in the VSD Research Project and threatens the continued viability of this project which has proven to be an important resource for vaccine safety data for the nation. . . . If the MCOs were not provided assurances regarding the protection and confidentiality of their patient level data, many, if not all of the participating MCOs would reconsider their involvement in the VSD Project. The impact of losing the VSD Project as a national and international source for monitoring vaccine safety in a scientifically rigorous manner cannot be overstated. It is considered to be the largest database available in the world for objectively assessing vaccine safety issues.

CDC Responses to Recommendations Made in the IOM Report, Vaccine Safety Research, Data Access, and Public Trust (February 2005), dated June 21, 2006.

The Special Master must have a far greater showing that he needs to conduct the proposed study before he risks the termination of a vitally important research program.

CONCLUSION

For the reasons set forth above, the PSC's Motion must be denied.

Respectfully submitted,

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Date: January 19, 2007

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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.	AUTISM MASTER FILE Special Master Hastings
SECRETARY OF HEALTH AND HUMAN SERVICES,	
Respondent.	

DECLARATION OF JAMES BAGGS, PH.D.
CENTERS FOR DISEASE CONTROL AND PREVENTION

I, James M. Baggs, declare that:

1. I am an epidemiologist at the Centers for Disease Control and Prevention ("CDC"), Office of the Chief Science Officer, Immunization Safety Office, Vaccine Safety Datalink Project Team. I have served in this capacity for the last five years. I earned my Ph.D. in epidemiology at the Rollins School of Public Health at Emory University in Atlanta, Georgia, in 1999.

2. In my current position as **Acting Project Officer of the Vaccine Safety Datalink ("VSD") Project**, my responsibilities include leading and providing oversight for the development, execution, and presentation of collaborative studies to investigate research questions regarding vaccine safety and other relevant immunization-related topics. I assist the Managed Care Organizations ("MCOs") that participate in the VSD Project in evaluating study proposals and/or manuscripts, conducting exploratory data analyses for study planning, attending VSD Project meetings, participating/leading VSD Project conference calls, and being available as a general resource in epidemiology.

3. In addition, I serve as a CDC resource in vaccine safety in that I participate in the writing of manuscripts for peer-reviewed journals and

abstracts for national conferences. I attend these conferences and present relevant findings.. I routinely provide subject matter expertise on scientific matters related to the VSD Project, and I represent the VSD Project to other CDC units engaged in research.

4. I am submitting this Declaration in response to a request from the United States Department of Justice to provide information on the VSD Project with respect to "Petitioners' Motion to Compel and for Issuing Third-Party Subpoenas" ("Motion"). The Department of Justice also asked me to review a proposed study that was attached to that Motion and to comment on considerations raised by that proposal from the standpoint of the VSD Project. These considerations include the feasibility of using VSD Project data for the proposed study, whether the study would require chart review, whether it would require MCO resources, the estimated time to complete it, and its estimated cost.

5. In the following paragraphs, I will describe the VSD Project and the data used in VSD Project research. I will also describe the component of the CDC Data Sharing Program through which access to well-defined VSD Project data is provided to external researchers who are not affiliated with the VSD Project. These descriptions should make apparent key distinctions between the VSD Project and the Data Sharing Program, particularly with respect to access to VSD data.

6. The VSD Project, established in 1990, is a collaborative research project among investigators at eight MCOs and the Immunization Safety Office ("ISO") at the CDC. The primary focus of the VSD Project is to conduct vaccine safety studies of importance to public health using patient data collected by the MCOs. The VSD Project conducts planned vaccine safety studies and emergent investigations. Research is led by investigators at one of the participating MCOs or the CDC, and is conducted in collaboration with investigators at the participating MCO sites.

7. The MCOs collect data from their computerized administrative and medical data systems and put it in a standard format that permits comparison with data from other VSD Project participating MCOs. Initially, the MCOs participating in the VSD Project provided CDC with a complete dataset on an annual basis as a contract deliverable. These data are owned and maintained by CDC. The annual datasets were delivered each year containing VSD Project data through December 31, 2000. For datasets containing data after December 31, 2000,, VSD Project data remain with the respective MCO. The only datasets received by CDC containing data after December 31, 2000, are those providing specific data for approved VSD Project studies. In addition to the routine computerized data, many VSD Project studies require the collection of additional data from patient medical charts, patient surveys/interviews, other computerized sources, and other data collection instruments. At all

times, Institutional Review Board (IRB) approval by participating MCOs has been required by those organizations for use of the data they contributed to the VSD Project. This approval requirement applies to studies proposed by CDC, as well as those proposed by any MCO.

8. In addition to providing data, each MCO provides scientists who work on VSD Project studies, which is in keeping with the collaborative nature of the VSD Project. It is likely that compensation provided to participating MCOs for contributing data to the VSD Project does not fully defray the cost of extracting patient data, formatting it for VSD Project use, updating the individual MCO's VSD Project database, and maintaining scientific and technical staff for the VSD Project.

9. As discussed above, the VSD Project is a government conceived and managed research program. The CDC has oversight responsibility for the VSD Project. Most aspects of the administration of the VSD Project have been turned over to a contractor, America's Health Insurance Partners (AHIP), pursuant to a ten year contract that became effective in 2002. AHIP provides the CDC with a monthly activity report, as required by the contract. The activity report includes updates from each of AHIP's subcontractors to the VSD, i.e., the MCOs. The updates include information such as any changes to staff made during the month, and financial information regarding how much money and time is being billed by an MCO to AHIP. The billing information is an important way in which the CDC monitors the progress of a study. The activity reports are not scientific in nature, nor do they require or include information regarding any data. AHIP coordinates a monthly VSD Project conference call among AHIP, CDC, and the MCOs. Proposed and ongoing studies are discussed among the participants. VSD data are not discussed.

10. Because the VSD Project is a collaboration between the CDC and the participating MCOs, investigators for both the MCOs and CDC propose potential VSD Project studies for consideration. Although the CDC VSD Project Team Lead has the final authority to approve a VSD Project study proposal, the MCOs retain final authority to approve their participation in a VSD Project study and to approve the provision of their data for a VSD Project study. Of the current studies being conducted, eighty-two percent of the time, the lead VSD Project investigator is from one of the MCOs and not CDC. In addition, the VSD Project considers input from numerous sources to determine potential research topics, as well as methods to conduct the studies. Since the VSD Project has finite resources, the CDC and MCOs designate "priority studies" to be done utilizing the VSD Project. The participating MCOs are expected to

allocate their resources to complete the priority studies in an efficient and timely manner. Each year, AHIP, the CDC, and the MCOs review the list of priority studies, and modify it as necessary.

11. While external research was not the purpose for which the VSD Project was established, nor was the VSD Project designed to accommodate external research, in 2002, CDC launched the Data Sharing Program because of heightened interest in public access to the data generated by the VSD Project. The Data Sharing Program allows external researchers public access to certain VSD Project data under specified conditions. Two categories of data are currently available. First, external researchers may analyze final datasets generated for VSD Project studies published from August 2002 to the present. Second, external investigators may investigate new hypotheses using VSD Project data containing data through December 31, 2000, that is, the VSD data in the possession of CDC. The Data Sharing Program requires the external researcher to submit a research proposal and secure IRB approval from each MCO that will contribute data to the proposed research. Once approved by the relevant MCO IRBs, external researchers access VSD datasets for the proposed analyses at the Research Data Center in Hyattsville, Maryland, to ensure confidentiality and privacy protections. The Data Sharing Program is administered by the National Center for Health Statistics, a component of the CDC. One aspect that differentiates the Data Sharing Program from the VSD Project is that the Data Sharing Program does not require external researchers to collaborate with a VSD Project investigator as a precondition to research.

12. External investigators neither affiliated with the CDC nor a participating MCO can participate in VSD Project studies by establishing a formal collaboration with one of the participating MCOs or CDC. Such collaborative relationships are at the discretion of each MCO. CDC places no limitations on the formation of such collaborative relationships.

13. The Motion seeks access to post-2000 VSD Project data to conduct the research outlined in the proposed study, so I will describe the nature of those data and how those data are used in the VSD Project.

14. There is no one database or dataset for post-2000 data that contains all VSD Project data from participating MCOs. Instead, discrete datasets are prepared containing only the specific data responding to a particular approved study. Each MCO owns and manages its data, and only has access to its own data. Each MCO is responsible for safeguarding its data, which are securely kept at each MCO site. For the data to be used effectively in a VSD Project study, the MCOs and the CDC have developed a standard format for coding and storing the data at each MCO

site. In addition, the MCOs actively monitor access to their data. Each MCO may suspend use of its data at any time without prior notice.

15 No VSD Project study may be conducted without first obtaining the approval of the IRB at each MCO that contributes data to that study. The Health Insurance Portability and Accountability Act ("HIPAA") also generally requires that Data Use Agreements be established for each proposed study before the study may commence.

16. The CDC does not have unrestricted access to post-2000 VSD Project data. Rather, the CDC only receives from the MCOs completed, analytical data files for specific VSD Project studies which have been previously approved by the MCOs. Those data files contain only the minimum information necessary to conduct a particular study. The Acting Project Officer of the Vaccine Safety Datalink Project and the CDC Data Manager for VSD Project are permitted to conduct quality control reviews of the MCOs' data to ensure that appropriate data elements are expressed in the standard format or conduct inquiries into data suitability for study planning purposes. Any quality control review or data suitability inquiries undertaken by the CDC are monitored by the MCOs. The CDC has no authority to grant external researchers access to post-2000 VSD Project data.

17. I have reviewed the proposed study attached to the Motion. The proposal is vague in critical aspects of study design and shows a lack of understanding of VSD Project data and the complexities particular to study design using that data. Comparison groups, exposure assessment, outcome assessment, and confounder assessment are unclear, all areas that would have to be resolved before the study could be undertaken or the proposal even adequately reviewed.

18. Most of the diagnosis codes proposed for examination are congenital diagnoses. The proposal does not state how incident cases will be distinguished from prevalent ones.

19. The proposal does not identify how changes in MCO membership, patterns of care, variations in the use of diagnostic codes, and temporal changes will be accounted for in the analysis. The proposal states that proportional hazard models will be used to estimate relative risk at each MCO, stratified in part for "clinic most often visited." This is not always the most reliable VSD Project data field and could be problematic to use in the manner proposed.

20. Seventy potential associations are proposed for investigation. The proposal does not state how many positive associations would be

expected by chance alone, contrary to standard practice in study proposals.

21. IRB approval is ethically mandated for studies using data of this nature, but that is not addressed in the proposal. Typically IRB approval for a complicated, multi-site study takes 3 to 6 months. The current proposal is not sufficiently clear to proceed to an IRB review. HIPAA requires Data Use Agreements for studies of this nature, a matter that is also not addressed in the proposal. Data Use Agreements can also take 3 to 6 months to complete.

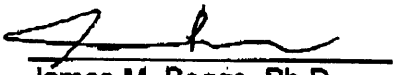
22. Deriving the data sought would require expenditure of MCO resources. The proposal does not address how the study will be funded.

23. The cost of doing a study of this nature is likely very high, particularly if additional data collection is necessary, as it appears it will be. A VSD Project study requiring chart review, standardized subject testing, and other clinical data, but using a much smaller population than that proposed here, cost more than $5,000,000.00.

24. The PSC's proposed study likely would require additional data collection to complete, including, but not limited to, chart review, subject interviews, and additional automated data (not routinely collected by the VSD Project). Based on experience with other VSD Project studies, requiring additional data collection, the size of the proposed study population, and the number of diagnoses investigated, my best professional assessment is that the proposed study would take three to five years to complete.

Pursuant to 28 U.S.C.A. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Executed on this 19th day of January, 2007.



James M. Baggs, Ph.D.
Centers for Disease Control and Prevention
Atlanta, Georgia

B

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.	AUTISM MASTER FILE Special Master Hastings

DECLARATION OF ROBERT S. KRASOWSKI, M.A., M.S.
RESEARCH DATA CENTER, NATIONAL CENTER FOR HEALTH STATISTICS
CENTERS FOR DISEASE CONTROL AND PREVENTION

I, Robert S. Krasowski, declare that:

1. I am a statistician at the Research Data Center ("RDC"), at the National Center for Health Statistics ("NCHS"), Centers for Disease Control and Prevention ("CDC"). I have served in this capacity for over eight years, since 1998. Before that, I spent approximately ten years working as a statistician/analyst with government agencies, including the NCHS and the Food and Drug Administration. I also spent six years working in the Department of Biostatistics at the University of North Carolina Chapel Hill's School of Public Health. I earned a Master of Science degree in Computer Systems Management at the University of Maryland, College Park, in 1989. I also earned a Master of Arts degree in Sociology from the University of North Carolina Chapel Hill in 1971, a discipline that involves significant work with statistics.

2. The RDC's mission is to provide a mechanism for researchers to access to statistical data without jeopardizing the confidentiality interests at stake. The RDC maintains data on several statistical databases including the National Health Survey, the National Survey of Family Growth, and the Third National Health and Nutrition Examination Survey (1988-1994). In 2005, the Vaccine Safety Datalink ("VSD") Data Sharing Program was moved to the RDC.

3. My job responsibilities include generally acting as the coordinator for researchers using the RDC and providing them with assistance as requested. More specific responsibilities include aiding in the modification and enhancement of proposals, writing programs that extract data from multiple data sources, tracking projects to completion, maintaining databases, upgrading computer resources (both hardware and software) for the RDC, and monitoring compliance with rules of access to RDC data.

4. I am submitting this Declaration in response to a request from the United States Department of Justice to describe the RDC's procedures for handling access to data made available through the VSD Data Sharing Program, and to address certain events regarding researchers who were initially granted access to data through the Data Sharing Program but ultimately had their research terminated due to violation of the terms of use of the Data Sharing Program.

5. The RDC has specific guidelines that describe the Data Sharing Program requirements. In particular:

> [p]roposals requesting use of VSD data through the Data Sharing Program undergo a review by the [Managed Care Organizations ("MCOs")]' Institutional Review Board(s) ["IRBs"] . . . in addition to a review by RDC staff. After approval of their research proposal and payment of fees for the associated costs, researchers are able to independently analyze VSD data through the VSD Data Sharing Program.

See CDC/NCHS, Research and Development, Procedures and Costs for Use of the Research Data Center, Appendix IV ("Project-Specific Requirements[:] Vaccine Safety Datalink (VSD) Data Sharing Program").

6. IRB approval for proposed research is a critical aspect of Data Sharing Program use. IRB review is a method of safeguarding the confidentiality of patient information. The Data Sharing Program requirements provide that:

> The MCO IRBs have the responsibility to protect the confidentiality and privacy of their members' medical records and to adhere to the rules and regulations applicable to their respective institution(s). Consequently, each of the MCO IRBs must review any request for access to the VSD data files that contain information on its MCO members.

CDC has no involvement in the IRB approval process.

7. In "Petitioners' Motion to Compel and for Issuing Third-Party Subpoenas" ("Motion"), the Petitioners' Steering Committee ("PSC") states:

> Between April 2005 and August 2006, petitioners sought access to the VSD by working directly with researchers who had already initiated a series of vaccine safety studies pursuant to approval by the . . . [IRBs] of some of the . . . [MCOs] participating in the VSD. Those studies, however, were not explicitly designed to investigate an association between thimerosal exposure and pediatric neurological or developmental injuries, as is the case with the proposed study in this Motion. The CDC and the MCOs refused to allow the researchers involved in those ongoing studies to combine datasets for multiple vaccines, and in August 2006 the CDC terminated the ongoing research by those investigators, seized work product already generated, and barred ongoing access to the VSD by the researchers.

Motion at 3, n.2. I recognize the incident described above because, under my duties at the RDC, I was personally involved in some of the events. The "researchers" to whom the PSC refers are Dr. Mark R. Geier and his son, David A. Geier.

8. The Geiers had initiated research through the Data Sharing Program before the NCHS had any role in administering the Program.

9. Initially, the Geiers presented a protocol for thirteen vaccine safety studies, each searching for various outcomes (medical conditions) expressed by ICD-9 diagnostic codes. The proposed research projects were divided by vaccine received, with thirteen different vaccines investigated. That protocol eventually received IRB approval. Therefore, thirteen separate datasets were prepared, each specific to the vaccine research project proposed.

10. The Geiers subsequently requested to modify their protocol to expand the number of vaccines searched, proposing four additional vaccines. In addition, they also requested to add new ICD-9 codes to be searched. In their modification request, they also described linking the separate datasets so that they could search across multiple vaccines. The MCOs' IRBs approved modifying the protocol to permit the search of additional vaccines and ICD-9 diagnostic codes, but did not approve deviating from protocol to search across datasets.

11. Approximately late June, 2006, a SAS programmer hired by a law firm began working with the Geiers on their research. After completing some work at the RDC in July, 2006, that programmer described to one of my colleagues the

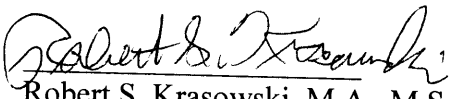
analyses she was performing on the datasets. When that colleague told me about the analyses being performed, I recognized that searches across datasets were being conducted. I spoke with the programmer about the work she was performing, and she indicated that she had specifically requested a copy of the protocol from the Geiers and they had stated that there was none. Rather, they had informed her that there were no restrictions on the analyses she could do. Finally, she stated that, had she known of the parameters of the protocol, she would have never attempted analyses across datasets.

12. The programmer's comments prompted me to examine the dataruns that she had generated for the Geiers' research project. The right to inspect these dataruns is specifically outlined in the Data Sharing Program procedures, and agreed to in advance by researchers seeking to utilize the Data Sharing Program. The dataruns revealed that outcomes were being searched across datasets – a procedure not originally proposed in the Geiers' protocol, and a deviation from protocol expressly prohibited by the MCOs when the Geiers subsequently proposed it. This was a clear violation of the MCO-approved protocol, so I sought guidance from the MCOs. Ultimately, the MCOs determined that the Geiers' access to the datasets should be terminated. This occurred on August 17, 2006.

13. The Geiers violated the terms of the IRB-approved protocol for their analysis of VSD data at the RDC. Consequently, their access and investigations were terminated. Although the PSC alleges that the CDC simply "terminated the ongoing research by [the Geiers], seized work product already generated, and barred ongoing access to the VSD by the researchers" (Motion at 3, n.2), these actions were taken in response to the Geiers' violation of the MCO-approved protocol and the express conditions of their access to Data Sharing Program data.

Pursuant to 28 U.S.C.A. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Executed on this 19 day of January, 2007.



Robert S. Krasowski, M.A., M.S.
Research Data Center
National Center for Health Statistics
Hyattsville, Maryland

C

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.	AUTISM MASTER FILE Special Master Hastings

DECLARATION OF JOANNE C. BINKLEY

I, Joanne C. Binkley, declare that:

1. I am the Director of the Division of Disclosure and Oversight Management (DDOM) at the Center for Biologics Evaluation and Research (CBER) of the United States Food and Drug Administration (FDA) in Rockville, Maryland. I have served in this capacity since May 1999.

2. DDOM is comprised of two branches, the Access Litigation and Freedom of Information Branch (ALFOI) and the Congressional and Oversight Branch (COB). Before assuming my current duties as Division Director, I served in an acting capacity and then officially as the Branch Chief of the COB from July 1997 to May 1999.

3. My responsibilities as DDOM Director include overseeing the development and coordination of CBER's responses to Congressional requests, including comments on proposed legislation and responses to Congressional oversight inquiries. DDOM serves as CBER's liaison with FDA's Office of Legislation. DDOM is also responsible for coordinating CBER's

responses to discovery in cases brought under the Federal Food, Drug, and Cosmetic Act (FDCA) and the Federal Tort Claims Act, responding to third-party subpoenas, and serving as CBER's liaison to FDA's Office of General Counsel and the Department of Justice for these activities. DDOM also prepares, develops, and coordinates CBER's responses to requests under the Freedom of Information Act (FOIA), including the Electronic Freedom of Information Act (EFOIA) amendments, and, in that capacity, reviews CBER-generated documents prior to their posting on various agency websites. DDOM also reviews CBER's advisory committee briefing packages for privileged information prior to their posting on FDA's website.

4. The Department of Justice provided me with a discovery request from the plaintiffs in this litigation, which seeks information about the thimerosal content for each lot of vaccine distributed in the United States from 1999 onward. The request further seeks production of the dates on which thimerosal-preserved vaccine brands were first licensed for use in a thimerosal preservative-free formulation. These vaccine brands include: Aventis Diphtheria-Tetanus-acellular Pertussis (DtaP); Aventis Diphtheria-Tetanus-Pertussis (DTP); Aventis Haemophilus influenza b Conjugate (Hib Conj.); Aventis Diphtheria-Tetanus (DT); Aventis Tetanus (T); Merck Hepatitis B (Hep B); Merck Hib Conj.; North American DtaP; GSK Hep B; Wyeth DTP; Wyeth T; Wyeth DT; Lederle DtaP; Lederle DTP; Lederle DTP/Hib Conj.; Lederle T; and Lederle DT.

5. It is my understanding that the plaintiffs in this litigation have requested this data for purposes of determining the distribution of thimerosal-preserved and preservative-free vaccines among patients receiving vaccinations administered in the United States from 1999 onward. As explained further below, it is not possible to use the information in FDA's possession to

determine the administration of thimerosal-preserved versus preservative-free vaccines to a particular patient population.

6. FDA records contain the dates on which various vaccine formulations were first licensed for use, as well as the approval dates for product license application (PLA) supplements, including supplements for manufacturing changes such as a change to a preservative-free formulation of a brand previous preserved with thimerosal. Many of these dates are publicly available on FDA's website [http://www.fda.gov/cber/vaccine/thimerosal.htm]. Moreover, PLA supplements and corresponding approval letters are normally incorporated into PLAs, which have already been provided in discovery to the plaintiffs in this litigation.

7. At the time preservative-free supplements were approved, thimerosal-preserved vaccines were not recalled, and therefore, physicians may have continued to administer thimerosal-preserved vaccines until package lots were expended or reached their expiration dates. Thus, the supplement approval date for preservative-free vaccines or the date FDA released the first lot of preservative-free vaccine likely are not the actual dates a physician stopped administering thimerosal-preserved vaccines. Likewise, the supplement approval date cannot be assumed to be the date on which manufacture of the preservative-free vaccine began or on which manufacture of the thimerosal-preserved vaccine ceased, because there may be some lag time between the approval and the implementation of the new production process. Finally, the supplement approval date has no bearing on whether thimerosal-preserved vaccine remained in inventory, and thus, in use at the time the preservative-free vaccine was distributed.

8. Accordingly, because physicians used both preserved and preservative-free vaccines during the time period in question, in order to determine the actual use of thimerosal-preserved or

preservative-free vaccine within a specified population since 1999, one would have to identify each particular lot of vaccine administered to each patient. The only way to get the lot number administered to each patient would be to examine each patient's medical record, which should contain the name of the manufacturer and package lot number of the particular vaccine administered. Only by matching the manufacturer's bulk product number with the package lot number identified in the patient's medical record could someone determine the actual amount of thimerosal-preserved versus preservative-free vaccine received by a particular patient population.

Pursuant to 28 U.S.C.A. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Executed on this 12th day of January, 2007.

JOANNE C. BINKLEY
Director
Division of Disclosure and Oversight Management
United States Food and Drug Administration
Center for Biologics Evaluation and Research

D

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

LISA SYKES and SETH SYKES, Individually and as Parents and Natural Guardians of WESLEY ALEXANDER SYKES, a minor child,

Plaintiffs,

v.

GLAXO-SMITHKLINE, Individually and as successor-in-interest to Smith Kline Beecham Corporation; WYETH, Inc., f/k/a AMERICAN HOME HOME PRODUCTS CORPORATION, d/b/a WYETH, INC., WYETH LABORATORIES, WYETH-AYERST, WYETH-AYERST, LABORATORIES, WYETH LEDERLE, WYETH LEDERLE VACCINES, and LEDERLE LABORATORIES, and BAYER PHARMACEUTICALS CORPORATION, f/k/a Bayer Corporation, Individually and as Successor-In-Interest to Miles, Inc.,

Defendants.

CASE No. 06-CV-1111

30(b)6 DEPOSITION OF America's Health Insurance Plans BY AND THROUGH ITS DESIGNEE

BARBARA LARDY
Washington, D.C.
Tuesday, October 10, 2006
10:14 a.m.

Job No.: 176897
Pages 1 -
Reported by: Tristan-Joseph, RPR

CERTIFIED COPY

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A. Yes.
Q. And was AHIP's response to that was a step in ultimately getting that VSD administration contract or --
MR. THOMASCH: Objection to form.
MR. HOLLOWAY: Join.
MS. MARTINEZ: I assume one objection is good for all, Tom?
MR. POWERS: Yeah.
THE WITNESS: We submitted a proposal. We had -- it was a competitively bid process. We submitted a proposal sometime in June of 2002.
BY MR. POWERS:
Q. And when was the contract awarded?
A. It was awarded in September.
Q. Of '02?
A. Yes.
Q. Can you describe what the terms of the contract were just as best as you know them sitting there.
MR. THOMASCH: Object to the form.
MR. HOLLOWAY: I object to the extent

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that it calls for a legal conclusion.
BY MR. POWERS:
Q. For how many --
A. I'm not sure what you mean by terms of the contract.
Q. For how many years is the contract enforced?
A. Oh, okay.
It's a ten-year contract and it is funded every year. We wait -- we await a funding document every year. We do not have ten years of funding to divide up over the years. We are funded each year as funds that are available.
Q. And where does the money for the contract come from?
Is this something that something that the CDC pays?
MR. HOLLOWAY: Object to the form of the question. Calls for speculation.
BY MR. POWERS:
Q. Do you know where the funding that AHIP receives for performance under the contract comes

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from?
A. We have a contract with the CDC, and we submit invoices to the CDC so.
Q. So when the payments are made, it would be the CDC making payments on those invoices?
A. That's right.
Q. Okay.
A. Well, that's my assumption.
Q. Okay. Aside from the CDC making payment on invoices that AHIP submits, are you aware of any other entities that make payments to AHIP under the terms of the contract with the CDC?
A. I'm not aware of any, but I -- since we submit invoices only to one entity, I don't -- I doubt that there would be any other source of funding.
Q. All right. What does -- what are AHIP's responsibilities in terms of the VSD under the contract with the federal government?
MR. HOLLOWAY: You're talking about the 2002 contract?
MR. POWERS: The 2002, yeah. The 2002

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contract.
THE WITNESS: AHIP has purely an administrative role under the contract. We work with -- we monitor the work of the sites. We receive monthly reports and annual reports from the sites. We receive monthly invoices. We generally oversee the work of our subcontracts.
And as I said, AHIP's deliverables under the contract all fall into the administrative arena. We arrange conference calls. We schedule meetings, that sort of thing.
BY MR. POWERS:
Q. You mentioned as one of the administrator roles overseeing the work of subcontracts.
What were you referring to when you were saying subcontracts?
A. The research organizations. Maybe that's a better way to refer to them. The HMO research centers that are part of the Vaccine safety data.
Q. In that role does AHIP participate in

the design of study protocols at all?
A. No, we don't -- we did not have a scientific role in the contract.
Q. In the administrative role that AHIP does have does AHIP receive any data from the VSD itself?
MR. HOLLOWAY: Object to the form of the question.
THE WITNESS: We don't receive any data. We only receive monthly reports that would -- and invoices that do not contain any data.
BY MR. POWERS:
Q. The first thing you mentioned under AHIP's administrative role was that you monitor the work at the sites.
Can you describe with a little more detail what sort of monitoring that AHIP does of the work of the sites?
What tasks would AHIP do in monitoring the work at the sites?
A. We -- basically, what we monitor is the -- their compliance with the deliverables under

the contract. So submitting monthly reports, submitting invoices on time, participating in calls, and work groups, and those kinds of thing.
We also do an annual evaluation of the sites. There are two portions to that. One is a administrative and one is scientific. And we have no role in the scientific evaluation. That's all done by CDC.
Q. So I want to make sure, if you evaluate the sites and there are two things, one that AHIP does -- what was the one that AHIP does?
A. The administrative aspects.
Q. Okay. And those are the things you were just describing in --
A. Yes.
Q. -- detail a --
A. Yes.
Q. -- moment ago?
Okay. And then the other part of the site evaluation is the scientific evaluation?
A. Yes, sir.
Q. And that's something that CDC does and

not AHIP. Correct?
A. That's right.
Q. So does AHIP archive any data from the VSD, any data generated by the VSD?
A. No, we don't get any data. So we don't -- that's not our responsibility of AHIP.
Q. For studies that are being conducted using the VSD, does AHIP receive progress reports or any sort of reports about ongoing studies?
A. The only kind of information that sites include in their monthly or annual reports is progress in terms of what stage of a study -- are they -- are they collected -- you know, are they identifying -- in the study design, are they identifying patients? Are they doing data collection? Are they in the analysis phase?
There's never any mention of data in the reports in terms of any real data. It's just here's where we are, our study is on track. We basically just do -- study tracking and monitoring a time line.
Q. You mentioned some of the things that

might be included in a report on a study and data -- the progress of data collection was one of the things that you mentioned.
Does AHIP -- I think I know what the answer is going to be but I do want to ask this.
Does AHIP at any point participate in data collection on any one of these studies based on a report that you get about a study?
A. No, we don't -- our people don't have any role in the scientific part of the work.
Q. And so AHIP would not participate in any analysis of data either?
A. That's right.
Q. AHIP wouldn't participate in the peer review process or the publication process. Correct?
A. That's correct.
Q. For the HMOs that participate in the VSD, are all of those considered subcontractors of AHIP?
A. Yes.
Q. When researchers at one of those

included in their Monthly Activity Report?
A. No.
Q. That would be a separate thing that they would deliver to AHIP?
A. Yes.
Q. And based on those invoices, AHIP would compile those and sent a quarterly report to the CDC; is that right?
A. That's right.
Q. Okay. Then in Item No. 3 it says Conference Call Minutes.
What conference calls are being described here in this deliverable item?
A. It's not specified which conference calls we -- in -- I mean, this, what you see is what it is. In practice, we do minutes on the -- primarily the monthly network call and then the working group calls that go on throughout the minutes so.
Q. Would any of the conference calls be discussing ongoing studies in progress that are using the VSD as a resource?

MR. HOLLOWAY: Object to the form of the question.
THE WITNESS: The minutes would -- as I think when you were talking earlier about minutes, the minutes would talk about the tracking or the stage of the study. It would not -- there's no data revealed in the minutes.
BY MR. POWERS:
Q. So no data revealed. Would it be fair to say that no substantive discussion about the scientific work is discussed during these conference calls?
A. Well, the -- they would talk about what -- on a conference call we talk about what the goal of the study was, which sites were participating, what, you know, what the elements were that they were looking at. So to the extent -- I don't know if that's getting at what you're asking.
Q. Right.
A. But there's no -- there's no data that's discussed in the calls.

Q. Okay. And then for item -- oh, I'm sorry. Then the conference call minutes, these are calls that AHIP coordinates. Correct?
A. Yes.
Q. And then AHIP compiles these minutes and sends them periodically to the CDC?
A. Yes, on the schedule specified here.
Q. Right. And then on Item No. 4, it says, "Reports on data collection procedures, numbers and results of validation procedures performed."
Who is delivering that particular item to the CDC?
A. That's provided by the sites, by the research -- the participating HMOs.
Q. Now do the HMOs send, this deliverable Item No. 4, do they send it directly to the CDC?
A. Yes.
Q. Do they send a copy to AHIP also?
A. No.
Q. So does AHIP ever see the reports on data collection as described in Item No. 4?
A. No.

Q. Does CDC ever send copies of those reports back to AHIP after receiving them from the HMOs?
A. No.
Q. Does AHIP have any record on what -- understanding that your testimony is they don't have the reports themselves, does AHIP have any record of what reports the individual sites would have sent to the CDC?
MR. THOMASCH: Objection to form.
THE WITNESS: The only thing that the sites would say in their monthly report to us would be, you know, completed data files and sent to the CDC. That would be the extent. It would just be, you know, that they were meeting the deliverable specified here.
BY MR. POWERS:
Q. Okay. But they wouldn't send you a copy of a deliverable --
A. No.
Q. -- in Item No. 4?
Okay. Again, Item No. 5, Access to

E

AWARD/CONTRACT

THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 350) ▶ | TING | PAGE OF PAGES

CONTRACT (Proc. Inst. Ident.) NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQUEST/PROJECT NO.
200-2002-00732	09/20/2002	ESD3

SSUED BY	CODE 27	6. ADMINISTERED BY (If other than Item 5)	CODE 27
nters for Disease Control and Prevention (PGO) ntracts Management Branch 20 Brandywine Rd, Rm 3000 lanta, GA 30341-5539 C: Cheryl Stauss/770-488-2685		Centers for Disease Control and Prevention (PGO) Contracts Management Branch 2920 Brandywine Rd, Rm 3000 Atlanta, GA 30341-5539 Approved as to Form and Legality: OMB 0990-0115/9000-0008	

NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code)	8. DELIVERY
erican Association of Health Plans 29 20th Street NW ite 600 shington, DC 20036 N/TIN:	☐ FOB ORIGIN ☒ OTHER (See below)
	9. DISCOUNT FOR PROMPT PAYMENT Net 30
	10. SUBMIT INVOICES (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN: ▶ ITEM
DE 207 FACILITY CODE	

SHIP TO/MARK FOR CODE	12. PAYMENT WILL BE MADE BY	CODE 434
	Centers for Disease Control and Prevention (FMO) PO Box 15580 Atlanta, GA 30333	

AUTHORITY FOR OTHER THAN FULL AND OPEN COMPETITION:	14. ACCOUNTING AND APPROPRIATION DATA
☐ 10 U.S.C. 2304 (c)( ) ☐ 41 U.S.C. 253 (c)( )	See Section B

5A. ITEM NO.	15B. SUPPLIES/SERVICES	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT
	"See Continuation Page"				

15G. TOTAL AMOUNT OF CONTRACT → $190,871,967.00

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CONTRACTING OFFICER WILL COMPLETE ITEM 17 OR 18 AS APPLICABLE

☒ CONTRACTOR'S NEGOTIATED AGREEMENT (Contractor is required	18. ☐ AWARD (Contractor is not required to sign this document.)
sign this document and return One (1) copies to issuing office.) ntractor agrees to furnish and deliver all items or perform all the services set forth or erwise identified above and on any continuation sheets for the consideration stated ein. The rights and obligations of the parties to this contract shall be subject to and verned by the following documents: (a) this award/contract, (b) the solicitation, if any, d (c) such provisions, representations, certifications, and specifications, as are ched or incorporated by reference herein. (Attachments are listed herein.)	Your offer on Solicitation Number 2002-N-00408 including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the items listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your offer, and (b) this award/contract. No further contractual document is necessary.
A. NAME AND TITLE OF SIGNER (Type or print)	20A. NAME OF CONTRACTING OFFICER William J. Ryan, Jr.
B. NAME OF CONTRACTOR / (Signature of person authorized to sign)	19C. DATE SIGNED / 20B. UNITED STATES OF AMERICA BY (Signature of person authorized to sign) / 20C. DATE SIGNED

7540-01-152-8069
VIOUS EDITION UNUSABLE

26-107

STANDARD FORM 26 (REV. 4-85)
Prescribed by GSA
FAR (48 CFR) 53.214(a)

Section F - Deliveries Or Performance

FAR SOURCE	TITLE AND DATE
52.242-15	Stop-Work Order (Aug 1989)
52.242-15 Alternate I	Stop-Work Order (Alternate I) (Apr 1984)

F.1 Period of Performance (Jul 1999)

The period of performance shall be a period of ten (10) years from date of award, to be performed in ten annual phases of 12 months each.

F.2 Deliverable(s) Schedule (Jul 1999)

The Contractor shall deliver, within the time frames specified, the following items as identified to the Project Officers (PO) at the Centers for Disease Control and Prevention, National Immunization Program, 1600 Clifton Road, NE, M/S E-61, Atlanta, GA 30333; and/or the Contracting Officer (CO) at the address shown on the face page of the contract.

A. Delivery Schedule (Elective Activities A & B)

ITEM	DESCRIPTION	QUANTITY & RECIPIENT	DELIVERY DATE
1	Monthly activity .eport	1 to PO 1 to CO	Not later than 15th of each month
2	Quarterly Financial Report	1 to PO 1 to CO	Within 20 days after end of quarter.
3	Conference Call Minutes	1 to PO	Sent Electronically within 5 workings days after meeting
4	Reports on data collection procedures, numbers and results of validation procedures performed.	2 to PO	Semiannually, starting 180 days after contract award
5	Access to provisional limited data files containing the designated database files in Statistical Analysis System (SAS) format, with appropriate documentation	1 to PO	Starting 180 months after contract award.
6	Access to data files, containing the designated database files, with appropriate format as described in Elective Activity A	4 to PO	Starting 12 months after contract award.
7	Draft annual report containing the information as set forth in the SOW	4 to PO	Annually, 30 days before anniversary of contract award.
8	Annual report	10 to PO 1 to CO	Annually, on anniversary of contract award.

CERTIFICATE OF SERVICE

I certify that on this 19th day of January, 2007, a copy of the foregoing Respondent's Response to Petitioners' Second Motion to Compel and Motion for Issuance of Third-Party Subpoenas was served, by first-class mail, postage prepaid, upon:

Michael L. Williams
Williams Love, et al.
9755 SW Barnes Avenue
Suite 450
Portland, OR 97255-6681

and

Ghada A. Anis, Esq.
Petitioners' Steering Committee
105 North Alfred Street
Alexandria, VA 22314