the TOXIC TORT newsletter

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We Make The Complex Simple

Science On Trial: An Analysis Of Alleged Vaccine-Related Autism Claims

By Cameron D. Turner and Melissa M. Fallah

Introduction

Autism is one of the most increasingly diagnosed disorders in children in the United States. The Centers for Disease Control reported in 2003 that as many as one in 166 children falls within the spectrum of autistic disorders and that autism disorder diagnoses have increased nearly 1,000 percent in the past twenty years.[1] This apparent increase in autism, or at least its diagnosis, begs the question "why?" and there are numerous hypotheses posited in response. Some experts suggest that doctors and parents have become increasingly aware of the symptoms and diagnostic criteria of autism-spectrum disorder (ASD) and further, that the diagnostic criteria are rather broad and vague to encompass an array of developmental issues.[2] [3] Others suggest that the increase in diagnoses is real and

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Welcome

In this edition of the Toxic Tort Newsletter, we report on some interesting state decisions favorable to defendants. We also bring you up-to-date on the status of the epidemiology and lawsuits relating to the use of Bisphenol in plastics (primarily used in plastic bottles). Our lead article relates to one of the most discussed conditions affecting children—autism. The article reviews known causes and suspected causes resulting from exposure to environmental influences and hazards. The emerging new area in toxic tort litigation is explored in detail.

Feel free to contact us regarding any of these articles.

- Edward J. McCambridge

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an accurate reflection of children's increased exposure to environmental influences and hazards.[4]

Naturally, the heightened awareness and diagnosis of ASD has led to much research on what causes autism, and lawmakers and lawyers have become involved. In December 2006, Congress passed and President Bush signed into law Public Law No. 109-416, dubbed "The Combating Autism Act of 2006." The Act authorized $950 million in research on ASD, including epidemiological studies to be performed by the Centers for Disease Control in conjunction with research overseen by the National Institutes of Health.

And yet, despite all of this uncertainty about the causes of ASD, there is a movement in the plaintiffs' bar to bring claims alleging that some cases of autism are caused by specific environmental factors, particularly vaccines and vaccine additives, such as thimerosal. Thimerosal (more properly spelled "thiomersal") is an antiseptic and antifungal agent developed in the 1920's and registered by Eli Lilly under the trade name Merthiolate.[5] It is an "organomercury compound" that is comprised of approximately 49 percent mercury by weight.[6] Thimerosal was originally used as an antiseptic in ointments and sprays to prevent contamination, but soon was used by Eli Lilly as a preservative in vaccines to allow for the use of multi-dose vials of vaccines instead of more expensive single dose vials.[7] It is used less frequently today for this purpose in the western world.[8] Some scientists have suggested that childhood exposures to thimerosal and other additives in vaccines cause at least some cases of autism, and that theory has led to approximately 4,900 lawsuits claiming that the plaintiffs' autism disorders were caused by vaccine-related exposures. Presently, these claims are being adjudicated in the Congressionally-established "Vaccine Court" to evaluate the causation issue (i.e. is there enough evidence that vaccines and vaccine additives can cause ASD to allow the plaintiffs to advance these claims?).

This article will examine the status of these autism claims, outline the general procedures in the Vaccine Court and the proceedings specific to these claims, and evaluate the future and defense of the vaccine-related autism claims, if and when they are allowed to proceed.

What Is The Vaccine Court?

Congress passed the National Childhood Vaccine Injury Act (NCVIA) of 1986 to address the public's concerns regarding vaccines supply, safety and liability.[9] Beginning in the 1970's, there was an increase in lawsuits filed on behalf of individuals who alleged injury from the diphtheria, tetanus, and pertussis (DTP) vaccine.[10] As a result of this litigation, prices soared for vaccines and some manufacturers halted their production, thereby causing shortages.[11] In the interest of public policy, Congress passed the NCVIA to create the National Vaccine Injury Compensation Program (VICP).[12] VICP protects manufacturers from civil liability and encourages vaccines to be used, administered and developed. Furthermore, the VICP system was designed to provide a fair, just and speedy compensation program for children who have adverse reactions to vaccines.[13]

VICP's objective is to compensate those injured by all childhood vaccines on a no-fault basis.[14] The program became effective on October 1, 1998.[15] This no-fault system is an alternative to the traditional forum of filing a tort cause of action and tries to ensure that there is an adequate supply of vaccines while allowing those who are injured from a vaccine easy and effective monetary relief.[16] The National Vaccine Injury Compensation Program has a $2.5 billion fund built up from a 75-cent-per-dose tax that is placed on vaccines.[17]

The Vaccine Court, as the federal VICP is commonly called, is adjudicated by a special master.[18] The special master's role can be differentiated from that of a judge in traditional litigation in that the special master is to be more "inquisitorial" than a traditional judge and may question witnesses, ask for documentary evidence, and hire his or her own expert witnesses to resolve difficult medical issues.[19] There is no discovery as a matter of right in a vaccine proceeding, and the special master is not bound by formal rules of evidence.[20] Petitioners' burden is to prove that a link between the injury and the vaccine is more likely than not, based on a preponderance of evidence.[21]

Since 1998, the Vaccine Court has reviewed approximately 7,000 non-autism-related claims, including nearly 4,000 cases alleging injury or death from the DTP vaccine.[22] Nearly a third of the non-autism cases have won an average settlement of $850,000.[23] The key issue falls on the science behind each case. A scientific advisory panel creates a table listing the medical conditions attributable to each vaccine. The table currently lists roughly fourteen vaccines with medically recognized adverse effects and a time period.[24] The side effect must appear within the allotted time period in order for it to be presumed the vaccine was the cause of the injury (unless another cause is found).[25] Notably, autism is not listed as a potential adverse condition for any of the vaccines listed on the table. If the vaccine or cause of the injury is not found on the table, then the petitioner must prove the vaccine caused the injury through medical records and expert opinions.[26] Once a decision has been

rendered, petitioners may exercise their opt-out rights under the VICP by rejecting the Vaccine Court judgment; withdrawing from the VICP if the special master fails to make a decision on their petition within 240 days; or withdrawing from the VICP if the court fails to enter judgment on a petition within 420 days.[27]

In the spring of 2002, the special masters began receiving a large number of petitions alleging that vaccines caused ASD in children. Additionally, in courtrooms across the country, parents were bringing civil lawsuits against vaccine manufacturers, alleging that the thimerosal ingredient in the vaccines caused their child's autism. The court in *Owens v. American Home Products Corp.*, (2002) WK 992094 S.D. Tex. May 7, 2002, stated that as a matter of law such claims must first be brought in the Vaccine Court.[28] The Office of Special Masters, working with counsel for both sides, developed a special procedure, known as the Omnibus Autism Proceeding, for dealing with these types of claims.[29]

The Office of Special Masters then established a two-step guideline for handling the influx of cases. First, the Office of Special Masters, through the Omnibus Autism Proceedings, would inquire into the general causation issues in the cases – i.e. whether the vaccines in question could cause ASD, and if so, under what circumstances.[30] Second, the conclusions reached from these Omnibus Autism Proceedings would be applied to individual cases.[31]

Omnibus Autism Proceedings — The Test Cases

The Omnibus Autism Proceedings "Test Cases"

At this time, about 4,900 autism claims remain pending in the Vaccine Court.[32] The cases are stayed, at the petitioners own request, until the conclusion of the Omnibus Autism Proceedings (OAP).[33] The Petitioners Steering Committee stated its desire to present three different theories of "general causation" in the OAP.[34] There are nine total tests cases comprised of three test cases for each of the three theories being advanced. The Special Masters will hear expert medical and scientific testimony on each of the three theories within the context of the individual cases. To date, the OAP has conducted evidentiary hearings on three of the test cases relating to the first "general causation" theory that the measles, mumps and rubella (MMR) vaccine and thimerosal-containing vaccines can combine to cause autism.[35] Specifically, in June of 2007, the OAP heard its first test case, *Cedillo v. Secretary of Health and Human Services* (98-916V). The second test case is *Hazlehurst v. Secretary of Health and Human Services* (03-654V). The third case is *Snyder v. Secretary of Health and Human Services* (01-162V). A report on each of these cases is included below. The additional two theories of causation that will eventually be heard are (a) that thimerosal-containing vaccines alone can cause autism, and (b) that MMR vaccines alone can cause autism.[36] The second theory will begin its evidentiary hearings on May 12-30, 2008 in Washington, D.C. with the *Mead v. HHS*, *Krakow v. HHS* and *King v. HHS* cases.[37] The OAP expects the evidentiary hearings in each of the three test cases on the additional two theories to be completed by September 30, 2008.[38]

Cedillo v. Secretary of Health and Human Services (98-916V)

On June 11, 2007, the court began its evidentiary hearing in the case of *Cedillo v. Secretary of Health and Human Services* (98-916V).[39] The case was heard by Special Master George Hastings on the causation theory that thimerosal-containing vaccines and the MMR vaccine could combine to cause ASD.[40] More specifically, the theory presented in *Cedillo* is that thimerosal vaccines cause immune system suppression making certain children vulnerable to viral infections which, in turn, cause neurological injuries including autism.[41]

The *Cedillo* case involves Michelle Cedillo of Yuma, Arizona, whose family alleges that she suffered five days of high fever after receiving an MMR vaccination at the age of fifteen months.[42] They claim that Michelle was born healthy but today suffers from inflammatory bowel disease, glaucoma, epilepsy and autism.[43] Michelle received all her vaccines as recommended by her physicians from the day of her birth.[44] However, after the MMR vaccine was administered, Michelle allegedly became silent, engaged in repetitive behavior and would not respond to her name.[45] Furthermore, she allegedly developed diarrhea and vomited for almost thirty-two weeks continuously. In July of 1999, a doctor diagnosed her with autism.[46]

Petitioners argue that the vaccines Michelle Cedillo received from birth contained unsafe levels of mercury.[47] They argue, in turn, that the presence of the mercury and thimerosal in Michelle's vaccines compromised her immune system and made her nervous system susceptible to the measles virus.[48] Ultimately, the Cedillos claim that this caused Michelle to develop autism.[49]

The crux of the government's argument is that the Cedillos' claim is unsupported by the science and does not satisfy the *Daubert* criteria.[50] The government cites the Centers for Disease Control's statement that no conclusive evidence exists that any vaccine or vaccine additive increases the risk of developing ASD.[51] Furthermore, the government attacked studies performed by Dr. Andrew Wakefield, upon which the Cedillos heavily relied, as

biased and influenced by financial gain.[52]

Hazlehurst v. Secretary of Health and Human Services (03-654V)

The evidentiary hearing in *Hazlehurst*, the second test case, began on October 15, 2007 before Special Master Patricia Campbell-Smith.[53] Like *Cedillo*, this case examined the general causation theory that the combination of thimerosal containing vaccines and the MMR vaccine can cause autism.[54] This claim was brought under the Vaccine Act by Mr. and Mrs. Rolf Hazlehurst on behalf of their seven-year-old son, Yates.[55] The Hazlehursts claim that Yates developed normally during the first year of his life but began to develop symptoms of autism after receiving MMR, HIB, Hep. B and Prevnar vaccines. They assert that the timing of the onset implicates thimerosal and the MMR vaccination as the cause of Yates' autism.

Dr. Jean-Ronel Corbier testified for the Hazlehursts and opined that autism is a result of genetic predisposition and environmental exposure.[56] He testified that exposure to thimerosal may cause a genetically predisposed child to develop autism.[57] Dr. Corbier's opinion echoed the science in *Cedillo* that mercury in the thimerosal may affect those children who are less able to excrete the mercury from their systems.[58]

As in *Cedillo*, the government responded that the theory posited by the Hazlehursts is based on "bad science" that cannot be considered in determining whether the Hazelhursts have satisfied their burden of proof.[59] To illustrate its point, the government noted that the theory that Yates' persistent measles caused his autism defies even common logic, as no study or epidemiology has ever demonstrated an increased incidence of autism following a measles epidemic.[60]

Snyder v. Secretary of Health and Human Services (01-162V)

In this case, the Snyders claim that their son, Colton, now a ten-year-old boy, was born healthy and developing normally until some time after April 23, 1998, when he received the MMR vaccine. Within one month of the MMR, he became withdrawn, did not interact with others and was engaging in repetitive behaviors.[61] The Snyders claim that a persistent vaccine strain of the measles virus caused Colton's neurological injuries.[62]

The government presented testimony via two experts, Drs. Wade and Rima, that Colton's clinical picture was different from the conditions that are typically attributed in the medical literature to a measles-infected brain.[63] Furthermore, the government disputed underlying evidence from a laboratory that concluded that Colton's cerebral spinal fluid contained the measles virus, arguing: 1) that the lab's methodology was improper; 2) that there were potential contamination issues; and 3) that the lab's results could not be replicated.[64]

In all three of these test cases on the first general causation theory, the parties are now in the process of preparing written briefs analyzing the evidence in each case. After the last of those briefs are filed in each case, the presiding special master will issue a written ruling.[65] Again, all three test cases on each theory are expected to be heard by September 30, 2008.[66]

In what was to have been one of the next test cases, the claim of 9-year-old Hannah Poling recently received media attention. On March 6, 2008, the government conceded that in Poling's very narrow instance, a vaccine may have worsened her underlying condition, triggering autism-like symptoms.[67] The Polings, on behalf of their daughter, filed a claim under the National Vaccine Injury Compensation Program in 2002.[68] The government conceded this case before there was an evidentiary hearing or any expert reports were filed before a Special Master in the Vaccine Court.[69] This appears to be an isolated case. Hannah has an underlying condition known as mitochondrial disease.[70] This disease affects cells' mitochondria and their ability to completely burn food and oxygen in order to generate energy.[71] About one in 4,000 children in the United States will develop mitochondrial disease by the age of 10, and between 1,000 to 4,000 children per year in the United States are born with a type of mitochondrial disease.[72]

The Polings advanced two theories to support their claim that a vaccine caused Hannah's autism-like symptoms.[73] First, they asserted that she was born with mitochondrial disorder and the vaccines caused stress to her body which in turn worsened her pre-existing condition.[74] Second, they claimed thimerosal attacked the mitochondria, thereby causing her mitochondrial disorder.[75] The government has agreed to pay the Polings from the federal vaccine fund, but the amount has not yet been determined.[76] Notably, the government maintains that vaccines do not cause autism, instead citing this as a rare case where the vaccine may have worsened an underlying disorder that led to autism-like symptoms.[77] The Health Resources and Services Administration (HRSA) issued a statement on March 3, 2008 stating:

> HRSA has reviewed the scientific information concerning the allegation that vaccines cause autism and has found no credible evidence to support the claim. Accordingly, in every claim submitted under the Act, HRSA has maintained and continues to maintain the position that vaccines do not cause autism, and has never concluded in any case that autism was caused by vaccination.[78]

The Poling case appears to be exceptional and likely provides very little precedential benefit to the remaining cases pending before the Vaccine Court.

The Future And Defense Of The Claims

So, what happens to these cases if any of them proceed outside of the Vaccine Court pursuant to any of the opt-out provisions? A rather stringent statute of limitations, discussed further below, that applies to vaccine-related injury claims discourages potential claimants who have yet to file their claims from waiting and seeing how the test claims play out in the Vaccine Court. That, coupled with the fact that thimerosal is used rarely these days in vaccines in the United States, suggests that thimerosal-related autism claims probably will not turn into the next wave of litigation. Nevertheless, the imprimatur of the Vaccine Court would likely encourage additional filings and would certainly be a significant concern for the defendants who are being named in this litigation. Any lawsuit involving a child claiming permanent injury, of course, has significant verdict potential.

The threshold issue in defending vaccine-related autism claims is whether the claim has been filed within the statute of limitations. Section 16(a)(2) of the Vaccine Act provides:

> [I]f a vaccine-related injury occurred as a result of the administration of such a vaccine, no petition may be filed for compensation…for such injury after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury….[79]

Naturally, neither the Vaccine Act nor the section within it addressing the statute of limitations for vaccine-related claims was written with vaccine-related autism claims in mind. The challenge in interpreting the statute of limitations in vaccine-related autism claims is determining when "the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury" arises.

The United States Court of Federal Claims was faced with this very issue in *Setnes v. United States*.[80] The minor claimant, A.J. Setnes, was born on June 10, 1997 subsequent to a normal pregnancy and uncomplicated birth, and by all accounts developed normally during the early part of his infancy.[81] Approximately fourteen months after he was born, A.J. received his fifteen-month vaccinations, including MMR, DTaP-Hib, Varicella and OPV immunizations.[82] Subsequent to that, his parents began to notice changes in A.J.'s behavior, as outlined in an affidavit submitted as part of the record to the Federal Claims court.[83] Shortly after the immunizations, A.J.'s parents claimed that A.J. started making a humming noise, babbled, was slow to develop words and stopped responding to his name.[84] Soon after that, A.J. began to have temper tantrums, would run around the kitchen table and stare at the corner of it and the counter and started eating cardboard boxes.[85] By A.J.'s second birthday (June 10, 1999), his parents stated that A.J. was no longer happy, did not interact with others, did not follow directions, could not be controlled in public places, had stopped developing speech skills and had developed a vacant stare.[86] On July 16, 1999, A.J.'s pediatrician noted that A.J. had developmental delays and suggested that they might be a result of pervasive developmental disorder.[87] The pediatrician also noted that A.J. had abnormal physical findings, speech delay and poor social skills.[88] Finally, on January 7, 2000, A.J.'s doctors first suggested that A.J. had "probable PDD/autism", and A.J. was officially diagnosed with autism on March 3, 2000.[89] The petitioners filed their claim on July 15, 2002.

The respondents argued that the 36-month statute of limitations had begun to run between September 1998 and A.J.'s second birthday in June 1999 based on the statements in the petitioners' affidavit.[90] Petitioners asserted that the statute of limitations began to run no sooner than July 16, 1999, or alternatively, that they were entitled to equitable tolling of the statute of limitations.[91] Notably, the Court rejected the equitable tolling argument and insisted that the 36-month limitations period would apply to claims such as this.[92] Instead, the Court focused its analysis on whether, under these facts, petitioners had timely filed their petition within the 36-month limitations period.

The Court rejected the application of the "occurrence of the first symptom" standard to claims such as this, noting that "the beginning stage of autism cannot be reduced to a single, identifiable symptom."[93] The Court focused instead on when the "manifestation of onset" of symptoms occurred. The Court declined to adopt a standard that abnormal behavior that might be associated eventually

with autism commenced the running of the statute of limitations.[94] Instead, the Court noted that the fact that A.J.'s own doctors did not suggest until July 16, 1999 that A.J.'s behavior might be connected to autism indicated that A.J.'s behavior was not "manifest" of a vaccine-related injury until that date at the earliest.[95] Thus, the court held that the petitioners had filed their claim within the statute of limitations.[96]

This opinion, while very fact-specific, will nevertheless provide courts with a lot of guidance in evaluating statute of limitations issues in vaccine-related autism claims. While the 36-month limitations period itself is not flexible, the date the courts will choose to begin the running of the limitations period is. The *Setnes* opinion recognizes the difficulty in diagnosing ASD and the need for doctors to see a pattern of different behaviors over a period of time before they will conclude that a child has an ASD. As outlined above, the diagnostic criteria for autism indeed includes several different types of behavior and requires that a child demonstrate a certain number of them before an autism diagnosis is even proper. At the same time, it is noteworthy that neither the petitioners argued nor did the Court suggest that the limitations period would not begin to run until the petitioners associated or should have associated A.J.'s autism diagnosis with his immunizations. The *Setnes* opinion implicitly holds that the date that a disorder that one could link to a vaccination develops, regardless of when the petitioners actually realize that the disorder might be connected to a vaccination, is the trigger date.

The rather stringently-applied statute of limitations should effectively reduce the claimant pool for vaccine-related autism cases. For those claims that do actually proceed, though (assuming the Vaccine Court permits them to, again), the potential defenses certainly do not end with the statute of limitations.

The approval of the Vaccine Court does not and certainly would not amount to a declaration that vaccines absolutely cause ASD or that a particular vaccine or vaccine additive caused the specific disorder at issue in a given case. In other words, each case will still, of course, require an independent evaluation of whether there is sufficient evidence to support the plaintiff's theory that his or her ASD was more likely than not caused by exposure from a vaccine. When one considers the weak epidemiology generally connecting vaccines to autism disorders and the fact that numerous other theories abound as to what causes autism in children, one can easily imagine how the causation defense of these cases can be developed through discovery and put on at trial.

Discovery in these cases must include an analysis of all the potential "causes" of a plaintiff's alleged autism. Some experts suggest that certain foods and types of diets can cause autism.[97] Exploring a child's diet thoroughly, as odd as it might sound, would be a crucial defense tactic. Many other environmental factors have been suggested as possible causes of autism, including heavy metals and pesticides.[98] Thus, a defense attorney will need to develop a full exposure profile for a child and become armed with that in cross-examining plaintiff's experts to evaluate how the experts were able to rule out these other potential causes in favor of another very weakly-linked cause - i.e. vaccines.[99] And, of course, no one seems to rule out the simple possibility that autism just happens for biological and/or genetic reasons in some people and that no single environmental trigger can definitively be linked to every current case of ASD diagnoses. As is evident from this very brief discussion, a thorough survey of the epidemiology and a detailed approach to discovery will be essential in testing the causation issue in defending vaccine-related autism claims.

Finally, of course, the issue of damages will likely be significant in these cases. The threshold damages issue, naturally, is whether the plaintiff even has an ASD as alleged in his or her complaint. As discussed above, many experts believe that the increase in diagnoses of ASD is a reflection of both the broad diagnostic criteria for the disorders and increased awareness of the disorders and diagnostic criteria. This would suggest that autism is both defined too broadly (and that perhaps the diagnosis needs to be more specifically defined to the various disorders within the spectrum), and further, that it is possibly over-diagnosed and misdiagnosed. Thus, logically, in evaluating damages issues, defense attorneys in these cases must be sure to ask first whether the alleged injury is even accurately diagnosed.

The damages defense analysis certainly does not end there, though. Almost instinctively in cases involving injury to children, attorneys fear and expect significant potential damages verdicts. But one must keep in mind that even properly diagnosed autism varies in degrees of severity and that research suggests that, in many cases, early intervention and treatment can very effectively permit a child to lead a normal life. Defense attorneys will need to ask tough questions (and ask juries to ask these tough questions, too) like: 1) does this child's autism diagnosis really mean that he or she will not and cannot lead a normal, healthy and fulfilling life; 2) what really is a "normal" life? (For example, if a child proves to be an average or slightly below average student, is the child entitled to damages because he or she may never be in honors courses or valedictorian of the class?); 3) what

have the parents and child's doctors done to mitigate damages and get the child the appropriate treatment and intervention to "head off" any long-term potential effects of the child's autism?

Conclusion

The probable conclusion, based on the present state of the epidemiology, is that vaccine-related autism claims will fail either within the Vaccine Court or soon thereafter in courts of common law. The science just does not seem to be there, at the time at least, to link vaccines and/or vaccine additives (or, for that matter, other environmental factors), to ASD. If there is an upside to the litigation, it is that it has brought attention to a legitimate concern about a disorder that seems to be arising more in more in our nation's children. Ultimately, our focus should be on reversing this trend and working on a solution rather than pointing the finger, which can be done later, if and when the science warrants it.

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[1] Neimark, Jill, "Autism: It's Not Just in the Head," *Discover*, March 2007.
[2] *Id.*
[3] The definition of "ASDs," at least as set forth by the current DSM-IV criteria, is as follows:

A. A total of six (or more) items from (1), (2), and (3), with at least two from (1), and one each from (2) and (3)
(1) qualitative impairment in social interaction, as manifested by at least two of the following:
a) marked impairments in the use of multiple nonverbal behaviors such as eye-to-eye gaze, facial expression, body posture, and gestures to regulate social interaction
b) failure to develop peer relationships appropriate to developmental level
c) a lack of spontaneous seeking to share enjoyment, interests, or achievements with other people, (e.g., by a lack of showing, bringing, or pointing out objects of interest to other people)
d) lack of social or emotional reciprocity (the following are examples: not actively participating in simple social play or games, preferring
solitary activities, or involving others in activities only as tools or "mechanical" aids)
(2) qualitative impairments in communication as manifested by at least one of the following:
a) delay in, or total lack of, the development of spoken language (not accompanied by an attempt to compensate through alternative modes of communication such as gesture or mime)
b) in individuals with adequate speech, marked impairment in the ability to initiate or sustain a conversation with others
c) stereotyped and repetitive use of language or idiosyncratic language
d) lack of varied, spontaneous make-believe play or social imitative play appropriate to developmental level
(3) restricted repetitive and stereotyped patterns of behavior, interests and activities, as manifested by at least two of the following:
a) encompassing preoccupation with one or more stereotyped and restricted patterns of interest that is abnormal either in intensity or focus
b) apparently inflexible adherence to specific, nonfunctional routines or rituals
c) stereotyped and repetitive motor mannerisms (e.g. hand or finger flapping or twisting, or complex whole-body movements)
d) persistent preoccupation with parts of objects
B. Delays or abnormal functioning in at least one of the following areas, with onset prior to age 3 years:
(1) social interaction
(2) language as used in social communication
(3) symbolic or imaginative play
C. The disturbance is not better accounted for by Rett's Disorder or Childhood Disintegrative Disorder. American Psychiatric Association.
Diagnostic and Statistical Manual of Mental Disorders, 4th edition. Washington, DC: American Psychiatric Association, 1994, pp. 70-71.

[4] *Id.*
[5] *See*, http://en.wikipedia.org/wiki/Thiomersal.
[6] *Id.*
[7] Baker, JP. "Mercury, Vaccines and Autism: One Controversy, Three Histories." *Am J Public Health*, February 1, 2008, 98(2): 244-53.
[8] Global Advisory Committee on Vaccine Safety (July 14, 2006). Thiomersal and Vaccines. World Health Organization.
[9] U.S. Department of Health and Human Services, National Vaccine Injury Compensation Program, (January 28, 2008), http://www.hrsa.gov/vaccinecompensation.
[10] Interlandi, Jeneen, "A Neverending Story," *Newsweek*, January 27, 2007.
[11] *Id.*

[12] See *supra* note 9.
[13] *Cedillo v. Secretary of Health and Human Services*, 98-916V (2007).
[14] U.S. Department of Health and Human Services. (January 28, 2008), http://www.hrsa.gov/vaccinecompensation
[15] *Id.*
[16] *Id.*
[17] Fox, Maggie. "Washington court will hear autism-vaccine suits" *Reuters.* June 10, 2007.
[18] See *supra* note 10.
[19] The Office of Special Masters, United States Court of Federal Claims, "Guidelines for Practice under the National Vaccine Injury Compensation Program", Revised July 2002, page 8.
[20] *Id.*
[21] "Court investigates vaccine link to autism", *MSNBC*, June 11, 2007.
[22] See *supra* note 10.
[23] See *supra* note 10.
[24] See *supra* note 9.
[25] See *supra* note 9 at http://www.hrsa.gov/vaccinecompensation/table.htm
[26] See *supra* note 9.
[27] See *supra* note 19, page 17.
[28] See *supra* note 9, Autism General Order Number 1 at www.usfc.uscourts.gov/OSM/AutismDocket.htm
[29] See *supra* note 19.
[30] See *supra* note 9.
[31] See *supra* note 9.
[32] Office of Special Masters, January 17, 2008 Autism Update. http://www.uscfc.uscourts.gov/OSM/Autism/update.
[33] See *supra* note 9.
[34] *Id.*
[35] Id.
[36] See *supra* note 9.
[37] *Id.*
[38] *Id.*
[39] See *supra* note 13.
[40] See *supra* note 13, at 10.
[41] See *supra* note 13, at 10.
[42] See *supra* note 13, at 32.
[43] See *supra* note 13.
[44] See *supra* note 13, at 34.
[45] See *supra* note 13, at 37.
[46] See *supra* note 13, at 37.
[47] See *supra* note 13, at 47.
[48] See *supra* note 13, at 50.
[49] See *supra* note 13, at 48.
[50] See *supra* note 13, at 60.
[51] See Centers for Disease Control Website, http://www.cdc.gov/od/science/iso/concerns/thimerosal_faqs_thimerosal.htm.
[52] See *supra* note 13, at 2899.
[53] *Hazlehurst v. Secretary of Health and Human Services*, 03 – 654V, October 15, 2007.
[54] *Id.* at 5.
[55] *Id.* at 4.
[56] *Id.* at 270.
[57] *Id.* at 280.
[58] *Id.* at 286.
[59] *Id.* at 585.
[60] *Id.* at 688-9.
[61] *Id.* at 53-54.
[62] *Id.* at 213.
[63] *Id.* at 842 and 941.
[64] *Id.* at 927.
[65] See *supra* note 32.
[66] *Id.*
[67] "Parents Speak out on Vaccine Settlement." *New York Times*, March 6, 2008.
[68] "Analysis: Vaccine –Autism Link Unproven." *New York Times*, March 7, 2008.
[69] *Id.*
[70] *Id.*
[71] The Cleveland Clinic Health Information Center. http://www.clevelandclinic.org/health/health-info/docs/1600/1678.asp?index=6957 (March 7, 2008)
[72] *Id.*
[73] "Analysis: Vaccine –Autism Link Unproven." *New York Times*, March 7, 2008.
[74] *Id.*
[75] *Id.*
[76] "Parents Speak out on Vaccine Settlement." *New York Times*, March 6, 2008.
[77] *Id.*
[78] U.S. Department of Health and Human Services, Health Resources and Services Administration, http://newsroom.hrsa.gov/releases/2008/vaccinestatement.htm, (March 8, 2008).
[79] 42 U.S.C.A § 300aa-16(a)(2).
[80] 57 Fed.Cl. 175 (2003).
[81] *Id.* at 176.
[82] *Id.*
[83] *Id.*
[84] *Id.*
[85] *Id.* at 177.
[86] *Id.*
[87] *Id.*
[88] *Id.*
[89] *Id.*
[90] *Id.*
[91] *Id.*
[92] *Id.* at 178.
[93] *Id.* at 179.
[94] *Id.* at 181.
[95] *Id.*
[96] *Id.*
[97] See *supra* note 1.
[98] See *supra* note 1.
[99] On December 2, 2007, in *Blackwell v. Sigma-Aldrich* in the Circuit Court of Baltimore City, Judge Stuart Berger issued a Memorandum Opinion in which he concluded that the Plaintiff's expert opinions failed to satisfy the "generally accepted" standard for expert testimony. Following a Frye-Reed hearing on Defendant Wyeth's motion to preclude plaintiff's expert testimony, the Judge issued his opinion, stating, "the court finds that it is generally accepted in the relevant scientific community that autism is genetic in origin." Pamela and Ernest Blackwell, Individually and as Parents and Next Friends of *Jamarr Blackwell v. Sigma Aldrich, et al.*; Case Number 24-C-04-00489; Circuit Court of Baltimore City, Maryland, page 54. The court further opined that, "it is generally accepted in the relevant scientific community that thimerosal in vaccines does not cause or contribute to neurodevelopmental disorders such as autism." *Id.* at pages 54-55.

State Law Updates

LOUISIANA – Victoria Ott Keith

***Thibodeaux, et al. v. Asbestos Corp. Ltd. et al.*, No. 2007-CA -0617 (La. Ct. App., 4th Cir.)**

The Louisiana Fourth Circuit Court of Appeals affirmed Summary Judgment in favor of an insulation manufacturer, Eagle Asbestos & Packing Co., on the grounds that there was no evidence that Plaintiff was exposed to asbestos by any product supplied or used by Eagle. While Eagle did sell, install and remove asbestos containing products at two sites at which Plaintiff worked, there was no evidence that Eagle did so during the time in which Plaintiff actually worked at those job sites. Plaintiff cited *Torrejon v. Mobil Oil Co.* (03-1426, La. App. 4th Cir., June 2, 2004) for the premise that "any" exposure to asbestos was sufficient to prove causation. The Court distinguished *Torrejon*, however, as being a Jones Act claim with a different level of causation than in other tort cases and held that Plaintiff offered no actual proof of exposure to asbestos from any Eagle product or action. Thus, the Court affirmed the district court's ruling granting summary judgment.

TEXAS – John LaBoon

***BIC Pen Corp. v. Carter* (Tex. April 18, 2008)**

In this case, a 6 year-old girl was injured when her younger brother accidentally caught her dress on fire while playing with a lighter. Plaintiffs filed suit alleging design and manufacturing defects. A Matagorda County jury awarded $5 million in damages, including $2 million in punitive damages. BIC appealed the verdict and argued that Federal law (the Consumer Product Safety Act (CPSA) of 1972, 15 U.S.C. §§2051-2084) pre-empted Plaintiffs' claims.

The Consumer Product Safety Commission is an independent regulatory commission created under the CPSA. The Commission adopted regulations that require disposable lighters to be child-resistant and establish the protocol for testing a lighter's child resistance. Plaintiffs contended pre-emption did not apply, because the savings clause in the CPSA 'specifically retains common law actions.' Under 15 U.S.C. §2074(a), 'Compliance with the consumer product safety rules or other rules or orders under this chapter shall not relieve any person from liability at common law or under State statutory law to any person.' In *Carter*, the Court noted that the CPSA also includes a pre-emption clause, 15 U.S.C. §2075(a). Under that provision, no state has authority to establish or to continue in effect any safety standard or regulation that sets requirements for a consumer product 'unless such requirements are identical to the Federal standard.' The Court further noted that the U.S. Supreme Court held in 2000's *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000) that saving clauses do not supersede conflicts pre-emption. Finally, the Texas Supreme Court disagreed with BIC's argument that the CPSA regulations pre-empt the plaintiff's manufacturing-defect claim as a mere restatement of the design-defect claim. Citing the Court's decision in *Cooper Tire & Rubber Co v. Mendez*, 204 S.W.3d 797 (Tex. 2006), the Court wrote that a manufacturing defect exists if a product deviates in its construction or quality from the specifications for that product in a way that makes it "unreasonably dangerous."

***Exxon Mobil Corp. v. Altimore* (Tex.App. – Houston [14th Dist.] April 3, 2008)**

The Court of Appeals issued its first opinion in this case on August 1, 2006. (*See: Toxic Tort Newsletter* Vol. 6, Issue 1). In the original opinion, the Court focused on duty and held that Exxon could not have been aware of "take-home risk of asbestos exposure until 1972." That opinion was withdrawn and this new opinion was issued. In the revised opinion, the Court noted that since the Texas Supreme Court had not addressed duty and take-home exposures, they would focus on the "legal sufficiency of the evidence to support imposition of punitive damages." The Court was guided by a two-prong test requiring objective and subjective evidence of gross negligence. The Court only focused on the objective prong, which requires that the Defendant's conduct involve "an extreme degree of risk," measured by the magnitude and probability of the anticipated injury. After reviewing the evidence including corporate documents, general state-of-the-art literature, and testimony by Dr. Lemen and Dr. Hammar, the Court held,

> After viewing all of the evidence in the light most favorable to the verdict, we cannot conclude that a reasonable trier of fact could form a firm belief or conviction, when viewed objectively from Exxon's standpoint, there was an *extreme* degree of risk of serious injury to appellee during the relevant period of time. Here, the magnitude of appellee's injury is disproportionate to the riskiness of Exxon's behavior. Even if Exxon's acts or omissions caused appellee's injury, when viewed prospectively and without benefit of hindsight, Exxon's conduct did not create an extreme degree of risk that appellee

would sustain serious injury.

Even after changing the issues reviewed, the Court reached the same outcome as it did when it originally focused on Exxon's duty to the spouses of employees, and the trial verdict was reversed.

New Report On Risks Of Bisphenol A (BPA) Spurs Lawsuit

By John A. LaBoon, Victoria Ott Keith and Scott W. Henry

Bisphenol A (BPA) is a ubiquitous chemical used in plastics to make the plastic stronger, clearer, and less prone to corrosion. It acts similar to the hormone estrogen, and a draft report by the National Toxicology Center, part of the National Institutes of Health (NIH), indicates that "there is some concern for neural and behavioral effects in fetuses, infants, and children at current human exposures," and that even low doses of exposure may cause changes in prostate glands, mammary glands and premature puberty in females. The NIH draft report was published on April 14, 2008. The peer-review process for the study closes on June 11, 2008.

A class action lawsuit was filed against Nalgene Nunc International Corp., a manufacturer of plastic sports bottles, in Federal court in Sacramento, California, on April 22, 2008. The plaintiff, Lani Felix-Lozano, filed the case on behalf of herself and two minor daughters, alleging that the company knew of the health risks associated with BPA but failed to disclose them and that she and her daughters used the plastic bottles for several years. No specific damages were alleged.

In 2007, a class action lawsuit was filed in Los Angeles County Superior Court against several retailers and leading manufacturers of plastic baby bottles, including Gerber, Evenflo, Playtex, Avent and Dr. Brown's, on the heels of studies indicating that even very low doses of BPA are harmful, especially to infants and children under six. The lawsuit, *Jack Ganjel, et al*, alleged intentional and negligent misrepresentation, violations of California Business and Professional Codes, violations of California Consumer Legal Remedies Act, and strict products liability, on behalf of five representative plaintiffs whose damages include genitalia defects, attention deficit hyperactive disorder, premature puberty and Down Syndrome allegedly resulting from BPA exposure *in utero* as well as after birth from plastic baby bottles and training ("sippy") cups. A similar class action lawsuit was filed by the same lead plaintiffs' counsel on April 30, 2008, in U.S. District Court for the Western District of Missouri, Western Division, *Maria Sullivan, et al*, No. 08-309-CV-W-RED.

Nalgene announced that it will phase out production of its products that contain BPA. Wal-Mart Stores said that it will remove baby bottles and other products with BPA from its Canadian stores immediately and phase out the items from its US stores over the next year. Toys "R" Us has also announced plans to stop selling BPA-containing baby bottles.

Senators Charles Schumer and Diane Feinstein recently introduced The BPA-Free Kids Act of 2008, which proposes

to ban BPA in all children's products and requires the Centers for Disease Control to study the risks of BPA to children and adults.

Canada recently completed a risk assessment of bisphenol A that focused on exposure for newborns and infants through the use of polycarbonate baby bottles. The risk assessment was published on April 19, 2008, which initiated a 60-day public comment period on whether to ban the importation, sale and advertising of polycarbonate baby bottles which contain bisphenol A.

An in-depth review of the final NIH study and other BPA related issues will be forthcoming in a future issue of the Toxic Tort Newsletter.

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Segal McCambridge Singer & Mahoney, Ltd. was founded in 1986 and has grown to having offices in Chicago, Illinois; Austin, Texas; Philadelphia, Pennsylvania; New York, New York; Baltimore, Maryland; Princeton, New Jersey and Brighton, Michigan. It represents a wide variety of clients in products liability, medical malpractice, professional liability, public official liability, construction litigation, general defense and toxic tort defense. The founding partners' experience in toxic tort cases dates back to the 1970's in pesticide and asbestos litigation. Today, the firm acts as national coordinating counsel in asbestos litigation to numerous companies including Garlock, Anchor Packing, Congoleum, Weil-McLain, Durametallic, DAP and Chicago Fire Brick. The firm also acts as national trial counsel for these and others in asbestos litigation. Segal McCambridge Singer & Mahoney, Ltd. also acts as national coordinating and trial counsel for Safeskin in the latex glove litigation. The philosophy of Segal McCambridge Singer & Mahoney, Ltd. has remained the same since its inception: provide state-of-the-art legal services with an extraordinary level of responsiveness and personalized attention to each client and each case.

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