# IN THE UNITED STATES COURT OF FEDERAL CLAIMS

## OFFICE OF SPECIAL MASTERS

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| JOHN DOE 67 and<br>JANE SMITH, parents of<br>CHILD, a minor,<br><br>Petitioners,<br><br>v.<br><br>SECRETARY OF HEALTH<br>AND HUMAN SERVICES,<br><br>Respondent. | * | No. XX-XXXV<br>Special Master Christian J. Moran<br><br>Filed: May 3, 2010<br>Reissued: May 21, 2010<br><br><br>Autism, Statute of Limitations,<br>Support for Allegation of<br>Significant Aggravation |

*William Marc Graham,* Wallace & Graham, P.A., Salisbury, NC., for petitioners;
*Heather L. Pearlman*, United States Dep't of Justice, Washington, D.C. for respondent.

**PUBLISHED DECISION DISMISSING PETITION**[*]

John Doe and Jane Smith filed a petition on behalf of their son, Child, who has autism. Mr. Doe and Ms. Smith assert two alternative theories of recovery – either that various vaccines caused Child to develop autism, or that various vaccines significantly aggravated Child's autism. They seek compensation pursuant to the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa–10 et seq. (2006).

For the reasons explained below, the petition is DISMISSED. For the theory that the vaccines caused Child's autism, Mr. Doe and Ms. Smith filed their petition after the expiration of the time set in the statute of limitation. For the theory that the vaccines significantly aggravated Child's autism, Mr. Doe and Ms. Smith have failed to provide an adequate factual allegation that Child's autism worsened.

[*] After this decision was issued, Mr. Doe and Ms. Smith filed a motion to redact their names. This motion is GRANTED. See Vaccine Rule 18(b).

## I. Factual and Procedural History

The relevant factual events are not disputed. They are set forth below with the notation that the operative date for determining whether the petitioners filed the case within the time provided by the statute of limitations is July 23, 1999. See 42 U.S.C. § 300aa–16(a)(2).

Child was born in August 1994. He received various vaccinations between August 8, 1994 and September 9, 1999. Exhibit 3 at 1; exhibit 4 at 1.

On July 9, 1997, when Child was approximately 3 years old, his parents were concerned about his speech development. On August 12, 1997, his parents reported that Child "has very little time around other children and whenever he is around peers, he beats them up. . . . Parents note that he really says nothing as far as language. He grunts and screams to get what he wants. He jabbers some but really nothing intelligible." Exhibit 4 at 22-23. On October 15, 1997, Child was diagnosed with severe developmental delays and possible autism. Exhibit 7 at 4, 8.

On January 23, 1998, Mr. Doe and Ms. Smith completed a medical history form for Child's Occupational Therapy Evaluation stating their concerns that Child was "not talking" and that he had "developmental delays." Exhibit 8 at 1. An April 1, 1998 progress note from Child's speech pathologist states that Child's "self injurious behavior is more secretive now, subtle pinching, scratching himself." Exhibit 8 at 6. The events described in this paragraph and the previous paragraphs describe Child's history before the operative date for the statute of limitations.

Child received another round of vaccinations on August 9, 1999. Exhibit 4 at 1. A progress note from that visit states that Child's behavior had improved after he had been on Prozac for a month. The note also states that Child had been "pretty much nonverbal but now he is starting to say a few words. He is also starting to make eye contact . . . He actually seems to be doing well." Exhibit 4 at 29.

On February 10, 2000, a progress note from Dr. Mange at the Davidson Clinic stated that Child has had "a good response with social interaction." His dosage for Prozac was increased from 2cc daily to 2.5cc and then 3cc daily. Exhibit 4 at 29.

A March 22, 2000 progress note from Dr. Mange references a report from Child and Family Developmental Occupational Therapy Treatment Plan states that Child is "significantly delayed in postural development, ocular motor skills and fine motor skills. Goals are established and he should receive[] [occupational therapy] 2-3 times/wk."

A progress note by Dr. Mange from April 14, 2000, again references a note from Child and Family Development which states that Child "has been in occupational therapy for apraxia. He is able to self-regulate a little bit better. He seems to crave vestibular input. He still has tactile defensiveness. He is still significantly apraxic." Exhibit 4 at 30.

A July 23, 2001 progress note from Dr. Mange states that Child "has had increasing aggressiveness and hyperactivity over the last 4 years. He was on Risperdal January until May, which was initially helpful but then lost its effectiveness. Adderall was tried with increased hyperactivity and aggressiveness. He continues on Prozac 4ml qd and has been on that for the last 2 yrs." Exhibit 4 at 31. Dr. Mange's progress note from October 19, 2001, states that "Prozac has been helpful in decreasing anxiety and helping with language . . . With too much Prozac he gets aggressive." Id.

The petitioners filed their short-form petition on July 23, 2002. They did not file any medical records with their petition. When this petition was filed, the Office of Special Masters was attempting to manage the numerous petitions that were claiming various vaccines caused autism. A history of these efforts is provided in Cedillo v. Sec'y of Health & Human Servs., No. 98-916V, 2009 WL 331968, at *7 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), motion for review denied, 89 Fed. Cl. 158, 182 (2009), appeal docketed, No. 2009-5004 (Fed. Cir. Oct. 7, 2009). Development of this case was stayed.

The petitioners' case resumed in 2008, when a special master ordered the petitioners to file medical records. The petitioners filed exhibits 1 through 11 on April 11, 2008. Mr. Doe and Ms. Smith later presented additional factual information about Child. In informal status conferences, the parties discussed whether the petition was filed within the time permitted by the statute of limitations.

Respondent filed a motion to dismiss arguing that the petition was untimely because Child manifested the first sign or symptom of autism by July 9, 1997. Respondent argued that the statute of limitations barred the action. Resp't Mot. to Dismiss, filed May 27, 2008.

Mr. Doe and Ms. Smith filed a response. Mr. Doe and Ms. Smith did not dispute that Child was diagnosed with autism in 1997.[1] Rather, Mr. Doe and Ms. Smith noted that Child received his last round of vaccinations in August 1999. Mr. Doe and Ms. Smith argued that "there is a chance Child suffered an aggravation of his vaccine related autism injury after August 1999. As such, his statute of limitations would not have run until August of 2002, several months after his claim was filed." Pet'r Resp., filed July 23, 2008, at 2 (citation omitted). Pursuant to an order, Mr. Doe and Ms. Smith filed a supplemental response that summarized Child's medical condition before the August 1999 vaccinations and after the August 1999 vaccinations. Pet'r Supp. Resp., filed Oct. 29, 2008.

Respondent filed a reply brief, addressing the petitioners' assertion that the vaccinations significantly aggravated Child's autism. Respondent addressed each of the factual assertions that, according to Mr. Doe and Ms. Smith, demonstrate a worsening. Resp't Reply, filed Jan. 15, 2009, at 3-7.

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[1] Essentially, Mr. Doe and Ms. Smith conceded that the statute of limitations barred their theory that vaccines caused Child's autism.

Mr. Doe and Ms. Smith were given an opportunity to support the allegation that the August 1999 vaccination significantly aggravated Child's autism. In support of their claim, Mr. Doe and Ms. Smith anticipated filing a report from an occupational therapist, Linda Catlin, who was to review Child's records and to state whether certain symptoms exhibited by Child worsened. See Order, dated May 5, 2009. During a January 26, 2010 status conference, Mr. Doe and Ms. Smith stated that they were not filing an expert report from Ms. Catlin and requested that the undersigned issue a ruling on respondent's motion to dismiss based on the record as it currently stands.[2] Thus, this case is ready for adjudication.

## II. Analysis

As noted previously, Mr. Doe and Ms. Smith are asserting two different theories. First, they assert that various vaccines caused Child to develop autism initially. Second, they assert that the August 1999 vaccinations may have significantly aggravated Child's autism. These theories are addressed separately below.

### A. Initial Causation

Respondent maintains that Mr. Doe and Ms. Smith may not receive compensation based upon the theory that vaccines initially caused Child's autism because the case was not filed within the time permitted. For cases in the Vaccine Program, the statute of limitations requires a petition to be filed within 36 months "after the date of the occurrence of the first symptom or manifestation of onset . . . of such injury." 42 U.S.C. § 300aa–16(a)(2).

Child manifested signs and symptoms of autism outside of the period set by the statute of limitations. Child's parents had concerns about his development by July 1997. A doctor diagnosed Child with severe developmental delay and possible autism in August 1997.

Regardless of whether the triggering date is July 1997 or August 1997, Mr. Doe and Ms. Smith filed their petition beyond the time permitted by the statute of limitations. Pursuant to 42 U.S.C. § 300aa–16(a)(2), they were required to file their petition within 36 months of the first manifestation of autism. The petition was actually filed on July 23, 2002, meaning that the petition was out of time by approximately two years. Consequently, Mr. Doe and Ms. Smith cannot prevail on a theory that vaccines caused Child's autism. This portion of the petition is dismissed for failure to file within the time permitted by the statute of limitations.

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[2] The present case, therefore, is in a different procedural posture from Emkey v. Sec'y of Health & Human Servs., No. 08-160V, 2009 WL 3683390, at *16 (Fed. Cl. Spec. Mstr. Oct. 20, 2009), in which the special master refrained from dismissing a significant aggravation theory to allow the petitioners "additional time in which to submit evidence supporting their claim to entitlement under the significant aggravation provision of the Act." Here, in contrast, Mr. Doe and Ms. Smith have investigated all avenues that they sought to explore in looking for support for their theory that Child's autism worsened after the 1999 vaccinations.

### B. Significant Aggravation

In the Vaccine Program, petitioners may assert that a vaccine "significantly aggravated" an underlying condition. 42 U.S.C. § 300aa–11(c)(1)(C)(ii)(I). Mr. Doe and Ms. Smith have presented this theory – that the August 1999 vaccinations may have significantly aggravated Child's autism.[3] To prevail upon this theory, Mr. Doe and Ms. Smith must establish that Child's condition changed. See 42 U.S.C. § 300aa–33(4) (defining "significant aggravation"); Loving v. Sec'y of Health & Human Servs., 86 Fed. Cl. 135, 143-44 (2009) (setting forth six part test for cases alleging significant aggravation of off-Table injuries).

The standards for pleading a significant aggravation case have not been extensively litigated. Generally, Vaccine Rule 2(c)(1)(A) requires that the petition set forth "a short and plain statement of the grounds for an award of compensation, including . . . (iii) a specific description of the injury alleged." These pleading requirements are comparable to the pleading requirements set forth in the Federal Rules of Civil Procedure[4] and in the Rules of the Court of Federal Claims.[5] Because Vaccine Rule (2)(c)(1)(A), Rule 8(a)(2) of the Fed. R. Civ. Proc., and Rule 8(a)(2) of the Rules of the Court of Federal Claims share common language, cases interpreting the pleading requirements from Rule 8 of the R.C.F.C. and Rule 8 of the Fed. R. Civ. Proc. are instructive in evaluating the pleadings pursuant to Vaccine Rule 2(c)(1)(A).

The "plain statement" provision of Rule 8 of the Fed. R. Civ. Proc. was interpreted by the United States Supreme Court to require "allegations plausibly suggesting (not merely consistent with)" the theory that the plaintiff is entitled to relief. Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 557 (2007). The Supreme Court explained that "a plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." Id. at 555.

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[3] Mr. Doe and Ms. Smith have not amended their petition to allege the specific facts on which they rely for their legal conclusion that a vaccine significantly aggravated Child's autism. This lack of amendment is not fatal to their position because the Vaccine Program requires less formality in pleading. See 42 U.S.C. § 300aa–12(d)(2). Thus, the factual allegations made in the briefs submitted by Mr. Doe and Ms. Smith will be considered as if they were set forth in an amended petition.

[4] Rule 8(a)(2) of the Federal Rules of Civil Procedure provides that a document seeking relief sSmith provide "a short and plain statement of the claim showing that the pleader is entitled to relief."

[5] Rule 8(a)(2) of the Rules of the Court of Federal Claim requires that a pleading that states a claim for relief to contain "a short and plain statement of the claim showing that the pleader is entitled to relief."

Two years later, the Supreme Court stated that "Our decision in Twombly expounded the pleading standard for 'all civil actions.'" Ashcroft v. Iqbal, ___ U.S. ___, 129 S.Ct. 1937, 1953 (2009). In Iqbal, the Supreme Court reiterated the two foundations of Twombly:

> First, the tenet that a court must accept as true all the allegations contained in a complaint is inapplicable to legal conclusions. Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice. . . . Second, only a complaint that states a plausible claim for relief survives a motion to dismiss.

Id. at 1949-50.

Twombly and Iqbal have been followed by the two courts that exercise appellate review of decisions of special masters: the United States Court of Appeals for the Federal Circuit and the United States Court of Federal Claims. E.g. Acceptance Ins. Companies, Inc. v. United States, 583 F.3d 849, 853 (Fed. Cir. 2009) (affirming trial court's dismissal of the case pursuant to a motion to dismiss for failure to state a claim); Cary v. United States, 552 F.3d 1373, 1376 (Fed. Cir. 2009) (affirming trial court's dismissal of the case on the pleadings pursuant to Rule 12(c) of the Rules of the Court of Federal Claims); Dobyns v. United States, 91 Fed. Cl. 412, 422-28 (2010).

Therefore, the pleading standard announced in Twombly — allegations must plausibly suggest that the pleader is entitled to compensation — will be used to evaluate petitions in the Vaccine Program. Two overlapping reasons support this holding. First, as noted above, Iqbal stated that Twombly sets the pleading standard for "all civil actions." It seems reasonable to consider a petition in the Vaccine Program to be a "civil action." See Schindler v. Sec'y of Health & Human Servs., 29 F.3d 607, 609 (Fed. Cir. 1994) (discussing the phrase "civil action"); cf. Sullivan v. Hudson, 490 U.S. 877 (1989) (holding that the Equal Access to Justice Act, which authorizes awards of attorneys' fees in "any civil action," permitted an award of attorneys' fees for work before the Social Security Administration after a remand from district court). Second, even if proceedings in the Vaccine Program were not considered a type of "civil action," proceedings in the Vaccine Program have the same pleading standards. As discussed above, the phrase "short and plain statement" is used in Vaccine Rule 2(c)(1)(A) and in Rule 8. The Supreme Court's interpretation of what a "short and plain statement" requires may be transferred to the Vaccine Program. See United Keetoowah Band of Cherokee Indians of Okla. v. United States, 480 F.3d 1318, 1323 n.2 (Fed. Cir. 2007) (noting appropriate reliance on case law under "virtually identical" federal rule).

Here, although respondent actually does not cite any cases discussing the standards for pleading, respondent is essentially arguing that the allegations made by Mr. Doe and Ms. Smith fail to satisfy the standard for pleadings set forth in Twombly. Respondent argues that the significant aggravation theory offered by Mr. Doe and Ms. Smith is "unsubstantiated by the

medical records and lack[s] the support of an expert medical opinion." Resp't Resp., filed Jan. 15, 2009, at 7.

Mr. Doe and Ms. Smith have not presented facts that "plausibly suggest" that Child was worse after the August 1999 vaccinations. For example, approximately one month after the August 1999 vaccinations, a medical record stated that "He has been on prozac for a month and actually some improvements have been noted." Exhibit 4 at 29 (entry for Sept. 9, 1999). This statement – the accuracy of which the petitioners have not questioned – contradicts the significant aggravation theory. At best, Mr. Doe and Ms. Smith argue that "there is a chance Child suffered an aggravation of his vaccine related autism injury after August 1999." Pet'r Resp., filed July 23, 2008, at 2. This assertion does not "plausibly suggest" significant aggravation.

Twombly and Iqbal make clear that Mr. Doe and Ms. Smith may not survive a motion to dismiss by merely asserting the "formulaic" elements of a cause of action. The assertion by Mr. Doe and Ms. Smith that Child "suffered an aggravation of this vaccine related autism injury" is a legal conclusion, not a factual assertion. As a legal conclusion, it is not presumed to be true. Instead of relying upon this conclusion, Mr. Doe and Ms. Smith were obligated to present facts that "plausibly suggest" that Child worsened. See also 42 U.S.C. § 300aa–13(a) (stating that special masters may not award compensation "based upon the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.") They have been given sufficient opportunity to present facts plausibly suggesting their theory and have not done so. Thus, their significant aggravation theory must be dismissed.

## III. Conclusion

There is no controversy that Child experienced the "first symptom or manifestation of onset" of autism more than 36 months before Mr. Doe and Ms. Smith filed their petition. Therefore, the statute of limitations bars recovery on a theory that any vaccines initially caused Child's autism.

In terms of the alternative theory that vaccines significantly aggravated Child's autism, Mr. Doe and Ms. Smith have failed to present (either in a petition or in their briefs) facts that "plausibly suggest" that Child's autism worsened after August 1999 vaccinations. This failure means that this theory must be dismissed as well.[6]

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[6] If Mr. Doe and Ms. Smith seek attorneys' fees and costs pursuant to 42 U.S.C. § 300aa–15(e), they will be required to establish three things. The first is subject matter jurisdiction. Special masters may award attorneys' fees and costs only if there is subject matter jurisdiction. Brice v. Sec'y of Health & Human Servs., 358 F.3d 865, 868 (Fed. Cir. 2004); Kay v. Sec'y of Health & Human Servs., 80 Fed. Cl. 601, aff'd without decision, ____F.3d ___, 298 Fed. Appx. 985 (Nov. 10, 2008), cert. denied, ___ U.S. ___, 129 S.Ct. 1933 (2009). The second and third are a reasonable basis and good faith. 42 U.S.C. § 300aa–15(e). The present decision

The Clerk's Office is instructed to enter judgment in favor of respondent unless a motion for review is filed.

IT IS SO ORDERED.

S/ Christian J. Moran
Christian J. Moran
Special Master

should not be interpreted as suggesting a result, one way or the other, on any of these three issues.