

IN THE UNITED STATES COURT OF FEDERAL CLAIMS

OFFICE OF SPECIAL MASTERS

NANCY ANGIELLO and
WILLIAM GILLETT, Parents of
SOPHIA-GABRIELLA GILLETT,
a Minor,

Petitioners,

v.

SECRETARY OF HEALTH
AND HUMAN SERVICES,

Respondent.

No. 07-552V
Special Master Christian J.
Moran

Filed: April 10, 2012

Autism; dismissal;
statute of limitations;
significant aggravation.

Patricia Ann Finn, Patricia Finn Esq., Piermont, NY, for petitioners;
Lynn Elizabeth Ricciardella, United States Dep't of Justice, Washington, D.C. for
respondent.

DECISION GRANTING MOTION TO DISMISS¹

Nancy Angiello and William Gillett filed a petition on behalf of their
daughter, Sophia-Gabriella Gillett ["Gabriella"]. Gabriella has autism. In this
litigation, the petitioners are attempting to link Gabriella's autism with vaccines
that she received. They seek compensation pursuant to the National Vaccine
Injury Compensation Program, 42 U.S.C. § 300aa-10 et seq. (2006).

¹ The E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899,
2913 (Dec. 17, 2002), requires that the Court post this decision on its website.
Pursuant to Vaccine Rule 18(b), the parties have 14 days to file a motion proposing
redaction of medical information or other information described in 42 U.S.C.
§ 300aa-12(d)(4). Any redactions ordered by the special master will appear in the
document posted on the website.

Initially, Ms. Angiello and Mr. Gillett claimed that vaccines caused Gabriella's autism. However, during this lengthy litigation, Ms. Angiello and Mr. Gillett changed their legal claim. They have conceded that they filed their petition after the expiration of the time set in the statute of limitations. This concession means that Ms. Angiello and Mr. Gillette may not recover upon a theory that the vaccines caused Gabriella to develop autism. See Cloer v. Sec'y of Health & Human Servs., 654 F.3d 1322 (Fed. Cir. 2011) (en banc).

In light of the effective withdrawal of the theory that vaccines caused Gabriella's autism, petitioners are now pursuing a different theory. Ms. Angiello and Mr. Gillette argue that a dose of the measles, mumps and rubella ["MMR"] vaccine, which was given to Gabriella when she had autism, made her autism worse. The Vaccine Act authorizes compensation to petitioners who show that a vaccine "significantly aggravated" an illness. 42 U.S.C. § 300aa—11(c)(1)(C)(ii)(I). For a "significant aggravation" theory, Ms. Angiello and Mr. Gillette must show that a vaccination caused a "change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health." 42 U.S.C. § 300aa-33(4) (defining significant aggravation).

Ms. Angiello and Mr. Gillette filed an amended petition setting forth the significant aggravation theory. The Secretary filed a motion to dismiss that petition. For the reasons explained in more detail below, this motion is granted because the petitioners have failed to provide an adequate factual allegation that Gabriella's autism worsened after receiving the MMR vaccine.

I. Facts

The relevant factual events are not disputed. Gabriella was born August 31, 2001. She received various vaccinations between March 26, 2002, and July 19, 2004.²

Before July 19, 2004, Gabriella was displaying symptoms of autism. For example, in an evaluation on July 22, 2004, Gabriella's parents reported that they became concerned about her poor progression in communication skills when she was approximately two and a half years old, or in February 2004. Exhibit 6 at 46. At this time, she experienced a regression, losing words she had previously

² July 19, 2004 is the operative date for the statute of limitations. See 42 U.S.C. § 300aa-16(a)(2).

acquired and exhibiting decreased eye contact. Exhibit 6 at 53. She also “tuned out” family members, such as her grandparents, and stopped responding to her name. Id.

On July 15, 2004, Gabriella was examined by a psychologist due to her parents’ concerns that she was not ready for preschool. Exhibit 12 at 2. Ms. Angiello reported that Gabriella had stopped progressing in speech. Additionally, Gabriella had recently become inconsolable and uncooperative, threw frequent tantrums, and bit her mother on one occasion. During an interview regarding Gabriella’s enrollment in preschool, the preschool informed Ms. Angiello it “was not comfortable taking [Gabriella] without an aide assigned to her.” Id. at 2-3 (notes dated July 15, 2004).

On July 22, 2004, Gabriella was referred to Dr. William Levinson, who specializes in neurodevelopmental pediatrics. Exhibit 6 at 44. Ms. Angiello again raised concerns regarding Gabriella’s poor progression in communication, stating that Gabriella “now communicates needs more by pointing and pulling, does not respond to question[s], ‘rarely’ responds to her name, [and] does not really respond to commands.” Id. at 46. Dr. Levinson described Gabriella’s behavior as “consistent with Pervasive Developmental Disorder.” Id. at 47. Less than one month later, on August 18, 2004, Dr. Levinson confirmed Gabriella’s diagnosis of Pervasive Developmental Disorder. Id. at 44.

Although Dr. Levinson’s diagnosis of pervasive developmental disorder occurred within 36 months of the petition’s filing, the date of diagnosis does not trigger the accrual of the statute of limitations. Instead, the statute of limitations begins to run upon the “first symptom or manifestation of onset.” 42 U.S.C. § 300aa—16(a)(2). As previously noted, Gabriella was not communicating and not maintaining eye contact --- two symptoms of autism --- in February 2004. Thus, the statute of limitations bars Ms. Angiello and Mr. Gillette from recovering on a theory that vaccines given relatively early in Gabriella’s life caused her autism. Ms. Angiello and Mr. Gillette do not dispute this conclusion. See Pet’r Opp’n, filed Sept. 10, 2010, at 4-5 (“Petitioners acknowledge that the 2002 and 2003 vaccines, by themselves, would result in an untimely filing.”).

After the accrual date for the statute of limitations (July 19, 2004), Gabriella received another vaccination. On August 25, 2004, she received her first and only MMR vaccine. Exhibit 4 at 23. Ms. Angiello and Mr. Gillett claim this vaccination significantly aggravated her autistic condition.

Nearly two months later, on October 18, 2004, her parents reported that she was coughing, with a “crackling” in her chest and nasal drip. Id. at 24. The coughing persisted for approximately one month. Id. at 25-27. On November 17, 2004, her pediatrician indicated that Gabriella had a “red rash in [her] vaginal area,” as well as a sore throat. Id. at 26. She was diagnosed with an upper respiratory infection. Id.

Gabriella was frequently seen by her pediatrician following the November 17, 2004 visit. See Exhibit 4 at 27-36. She experienced persistent coughing and congestion, occasional vomiting and diarrhea, decreased appetite, and some difficulty sleeping. See id. at 28-36. On April 1, 2005, Ms. Angiello and Mr. Gillett reported that Gabriella exhibited a rash on her belly, back, and face. Her pediatrician diagnosed her with B19 virus,³ but did not prescribe medication. Id. at 34.

A little bit more than one year after the MMR vaccination, on November 25, 2005, Gabriella was referred to Dr. Claudia Chiriboga of Columbia Child Neurology Associates. Ms. Angiello and Mr. Gillett reported that Gabriella was “normal until 2 years of age.” Exhibit 6 at 5. However, following her vaccinations, she “developed language regression, losing many of the words she had previously acquired” and became “more aloof and less interested in others,” leading to her diagnosis of Pervasive Developmental Disorder. Id.⁴ During the examination, Gabriella suddenly lashed out, striking both Dr. Chiriboga and her father. Id. at 6. Dr. Chiriboga diagnosed Gabriella with Autism Spectrum Disorder, which she described as “mild and improving.” Id. at 2.

³ B19 virus, also known as human parvovirus B19, is a virus which can cause fever, headache, and gastrointestinal distress such as nausea and vomiting. Gerald L. Mandell et al., Principles and Practices of Infectious Diseases (7th ed. 2010) at 795. It also causes erythema infectiosum, a three-stage rash beginning with a “streak facial rash” and progressing to a more variable rash usually occurring on the upper extremities. Id.

⁴ Gabriella turned two on August 31, 2003. Dr. Chiriboga’s history that Gabriella started to regress after turning two is consistent with the notation that she had regressed by February 2004.

Dr. Chiriboga’s mention of vaccinations refers to vaccines given to Gabriella outside of the period established by the statute of limitations. Dr. Chiriboga is not discussing the August 25, 2004 MMR vaccination. See Ex. 6 at 2, 5.

The next year, Gabriella began school in the Bronxville Elementary School's special kindergarten class. Exhibit 12 at 41. Her placement was evaluated on January 25, 2007. Id. Susan Medonis conducted the evaluation, and indicated that Gabriella presented with "many emotional and behavioral issues." Exhibit 12 at 42. Although Gabriella progressed well academically, the teacher expressed concern regarding how Gabriella's emotional and behavioral problems affected other children in the class. Id. Gabriella remained in a self-contained class, but received occupational therapy services individually twice per week. Exhibit 13 at 31.

On May 10, 2007, Gabriella was referred to Dr. Lawrence Shapiro due to Ms. Angiello's and Mr. Gillett's concern about an "underlying cause" of Gabriella's autism. Exhibit 13 at 10. After numerous genetic tests, Dr. Shapiro concluded that Gabriella's autism lacked any specific etiology. He suggested Gabriella visit a pediatric psychiatrist to ameliorate her behavioral problems. Id. at 12.

Prior to the next school year, the school district assessed Gabriella's condition again to determine if she should remain placed at Bronxville Elementary School. Exhibit 23 at 1. According to the school district's report, Gabriella continued to "make steady progress" in her speech and language skills. Id. at 3. Although Gabriella's ability to initiate social interaction was limited, she would share with other students and participate in a simple card game. Id. At school, Gabriella would not participate in the general education program, but would instead receive special instruction in an environment with minimal distractions and a smaller student-to-teacher ratio. Id. at 4.

Beginning in November 2008, Gabriella was seen by Dr. Alice Siegel, a pediatric psychiatrist.⁵ Exhibit 20 at 1. In her report, dated August 7, 2009, Dr. Siegel described Gabriella as manifesting "many related Autistic difficulties, including a narrow range of interests, perseverative and obsessive thinking, and catastrophic reactions to the ordinary changes and vicissitudes of daily life." Id. at 3. Dr. Siegel recommended Gabriella continue to participate in regular psychiatric visits and suggested medication might improve her behavioral problems. Id.

⁵ In a report dated August 7, 2009, Dr. Siegel indicates she has treated Gabriella since November 2008. Exhibit 20 at 1. However, petitioner filed no records from Dr. Siegel except for the August 7, 2009 report.

On August 13, 2009, Gabriella was also examined by Dr. Stephen Cowan, a developmental pediatrician.⁶ Dr. Cowan recorded a history of Gabriella's development. Dr. Cowan stated that in her second year, Gabriella "began losing milestones, stopped recognizing her grandparents, and stopped acquiring new language." Dr. Cowan continued that "[d]uring this time [referring to her second year], she received the MMR vaccine and shortly after this her parents and the teachers at the Alcott school noted a significant regression in her developmental skills." Then, Dr. Cowan wrote, "By her 3rd birthday she was no longer using language appropriately." Exhibit 18 at 1. Dr. Cowan reviewed Gabriella's current condition. He concluded that Gabriella "fits the criteria for Autism Spectrum Disorder, which by history seems linked to a post-vaccination encephalopathy." *Id.* at 3. Dr. Cowan's report is the most recent evidence of Gabriella's condition filed to date.

II. Procedural History

The procedural history is set forth in some detail below to show how the change from a "causation" theory to a "significant aggravation" theory affected the case. Evidence that showed that early vaccinations caused Gabriella's autism became irrelevant after the petitioners began to claim that the August 24, 2004 MMR vaccination aggravated her autism.

The petitioners filed a short-form petition on July 19, 2007. They did not file medical records with their petition. Shortly thereafter, the presiding special master ordered petitioners to file medical records and a statement regarding timely filing within sixty days. *Order*, filed July 30, 2007. After the sixty days had passed, respondent filed a report pursuant to Vaccine Rule 4(c) indicating that Ms. Angiello and Mr. Gillett failed to provide any evidence in support of their claim. *Respt. Rep't.*, filed October 19, 2007, at 3. The special master granted Ms. Angiello and Mr. Gillett additional time to file the requisite medical records.

⁶ Dr. Cowan's report notes that he evaluated Gabriella on three separate occasions: September 25, 2008; March 12, 2009; and August 13, 2009. Exhibit 18 at 1. His report is dated August 13, 2009. *Id.* No records pertaining to the previous examinations were filed.

Ms. Angiello and Mr. Gillett filed a single exhibit on March 10, 2008, which contained 55 pages of medical records.⁷ Respondent then filed a motion to dismiss, arguing that the petition was untimely filed because Gabriella manifested the first sign or symptom of autism as early as August 31, 2003, when she was two years old, and no later than the end of February 2004. Respondent argued that the statute of limitations barred the action. Resp't Mot. to Dismiss, filed April 3, 2008.

Ms. Angiello and Mr. Gillett filed a response. In a conclusory fashion, they rejected respondent's contention that the developmental delay recorded when Gabriella was two and a half years old was the first symptom or manifestation of onset. Pet'r Opp'n, filed June 6, 2008, at 2. Petitioners also claimed that even if the first symptom or manifestation of onset occurred more than 36 months prior to the filing of the petition, Gabriella suffered "vaccine related neurological injuries beyond autism," such as a "seizure disorder," as a result of vaccinations she received *after* the July 19, 2004 deadline. *Id.* To support this claim, petitioners referred to Dr. Chiriboga's records, dated November 28, 2005, noting Gabriella suffered "a pronounced episode in June 2005 of high fever and lethargy following multiple vaccinations, including DTP and HIB hepatitis injection."⁸ Exhibit 6 at 3.

On August 25, 2008, the chief special master reassigned the case to the undersigned. On September 24, 2008, Ms. Angiello and Mr. Gillett were ordered to file an amended petition along with any outstanding medical records. Order, filed Sept. 24, 2008. Following a series of telephonic status conferences and status reports updating the court on their progress, Ms. Angiello and Mr. Gillett filed additional medical records on April 9, 2009.⁹ They filed their amended petition on

⁷ Although the medical records were filed as one exhibit, it appears Ms. Angiello and Mr. Gillette intended the records to be separated into multiple exhibits. At certain points throughout the exhibit, pages labeled "Exhibit A," "Exhibit B," and so forth, divide sections of the exhibit. This exhibit was re-filed, in its entirety, as Exhibit 6.

⁸ According to the vaccine record, Gabriella received her final DTP and Hib vaccines on July 22, 2002 and February 3, 2003, respectively. Ex. 10 at 6.

⁹ These medical records were incorrectly numbered exhibits 1 and 2. Ms. Angiello and Mr. Gillette were consequently ordered to re-file the exhibits with proper exhibit numbers and page numbers. Order, filed May 19, 2009. They complied with this order on June 1, 2009. On September 3, 2009, Ms. Angiello and Mr. Gillett were also ordered to re-file the exhibits filed on March 10, 2008,

September 3, 2009, after numerous extensions. The amended petition claimed that Gabriella's vaccinations caused her autism or, alternatively, that her autism was "substantially aggravated" by the MMR vaccine she received on August 25, 2004.

On December 30, 2009, Ms. Angiello and Mr. Gillett filed an expert report from Dr. Richard Layton, a pediatrician specializing in allergies. According to Dr. Layton, Gabriella was "adversely affected by vaccines she received her first three years of life." Exhibit 24 at 9. Although he described Gabriella as suffering from a "documented Vaccine Injury," Dr. Layton failed to state Gabriella's autism was caused by her vaccinations explicitly. Id. However, he acknowledged the "proximate temporal relationship" between her vaccinations and her condition, as well as a "logical sequence of cause and effect between receiving multiple vaccines and developing [r]egressive [a]utism." Id. Dr. Layton also indicated that, based on her parents' reports, Gabriella's regression occurred at eighteen months. Id. at 1.

Dr. Layton's report did not assist the petitioners because he effectively placed the onset of Gabriella's autism around the end of February 2003, when Gabriella reached 18 months. The statute of limitations prevents Ms. Angiello and Mr. Gillett from relying on Dr. Layton's initial report. Ms. Angiello and Mr. Gillett were then ordered to file a supplemental report from Dr. Layton focusing on the theory of significant aggravation. Order, filed Jan. 13, 2010.

In his supplemental report, Dr. Layton stated his belief that children can demonstrate acute regression following a vaccine such as MMR. Ex. 25 at 1. However, although he stated that Gabriella was "adversely affected" by the MMR vaccination, it was "impossible" for him to provide further detail since he was not involved in Gabriella's care. Id. at 1-2. According to Dr. Layton, "the best that [he could] do" was state that Gabriella did receive an MMR vaccine and was later diagnosed by Dr. Cowan as suffering from vaccine encephalopathy secondary to the vaccination. Id.

The parties discussed Dr. Layton's supplemental expert report during a May 4, 2010 status conference. Respondent maintained that both the initial causation and the significant aggravation claims should be dismissed. Respondent was ordered to memorialize her views in a second motion to dismiss. Order, filed May 7, 2010.

April 9, 2009, and August 31, 2009. They complied with these orders on September 4, 2009.

On August 11, 2010, respondent filed a renewed motion to dismiss, addressing both the causation and significant aggravation theories. Respondent again contended that petitioners' claim of initial causation was untimely, as the first symptom or manifestation of onset of Gabriella's autism occurred when she was two-and-a-half years of age, or around February 2004. However, Ms. Angiello and Mr. Gillett did not file their claim until July 19, 2007, approximately five months beyond the time permitted by the statute of limitations. Resp't Ren. Mot. to Dismiss, filed Aug. 11, 2010, at 5-6. Additionally, in regard to the significant aggravation claim, respondent contended that Ms. Angiello and Mr. Gillette merely stated legal conclusions, without alleging any specific facts in support of their claim. Id. at 7.

Ms. Angiello and Mr. Gillett filed their response on September 10, 2010. Despite their belief that the earlier vaccinations caused Gabriella's autism, they conceded that any claim arising from vaccines administered in 2002 or 2003 would be time-barred. Pet'r Opp'n, filed Sept. 10, 2010, at 5. They also argued, however, that the MMR vaccine administered on August 25, 2004, significantly aggravated Gabriella's autistic condition. Id. at 5-6. As evidence of significant aggravation, Ms. Angiello and Mr. Gillett pointed to the fever, congestion, and rash Gabriella experienced intermittently between November 29, 2004 and April 1, 2005. Id. at 7.

Respondent filed a reply to Ms. Angiello's and Mr. Gillett's response to the renewed motion to dismiss. Because petitioners conceded their claim that the vaccinations caused Gabriella's autism was untimely, respondent addressed only the significant aggravation claim. Resp't Reply, filed Sept. 22, 2010, at 1. According to respondent, although Gabriella did experience fever, congestion, and a rash, each of these conditions occurred months after she received the MMR vaccine. Id. at 2. Secondly, even if these symptoms were linked to the MMR vaccine, no evidence suggests Gabriella's autism was significantly aggravated as a result. Id. at 3-6.

No further activity occurred in this case until September 8, 2011, after the en banc Federal Circuit decided Cloer. During a status conference on September 8, 2011, Ms. Angiello and Mr. Gillett were advised to consider the implications of Cloer on their claim and to determine if they wished to proceed in the Vaccine Program. Order, filed Sept. 8, 2011. Approximately one month later, during a second status conference, Ms. Angiello and Mr. Gillette contended that Gabriella suffered from not only autism, but also a seizure disorder. However, they failed to

identify any medical records in support of this allegation. They were thus ordered to file any additional evidence of Gabriella's seizure disorder.

On January 5, 2011, Ms. Angiello and Mr. Gillett filed a status report indicating no other evidence would be filed. Thus, the case is ready for adjudication.¹⁰

III. Analysis

In the Vaccine Program, petitioners are entitled to compensation when they establish, by a preponderance of the evidence, that a vaccine "significantly aggravated" an underlying condition. 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(I). Ms. Angiello and Mr. Gillett have presented this theory – that the August 2004 MMR vaccine may have significantly aggravated Gabriella's autism. Amended Pet., filed Aug. 31, 2009. To prevail upon this theory, Ms. Angiello and Mr. Gillett must establish that Gabriella'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 a 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 Procedure¹¹ and the Rules of the Court of Federal Claims.¹²

¹⁰ The present case, therefore, is in a different procedural posture from Emkey v. Sec'y of Health & Human Servs., No. 080-160V, 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 petitioners "additional time in which to submit evidence supporting their claim to entitlement under the significant aggravation provision of the Act." Here, in contrast, Ms. Angiello and Mr. Gillett have investigated all avenues that they sought to explore in looking for support of their theory that Gabriella's autism worsened after the 2004 MMR vaccination.

¹¹ Rule 8(a)(2) of the Federal Rules of Civil Procedure provides that a document seeking relief shall provide "a short and plain statement of the claim showing that the pleader is entitled to relief."

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 RCFC 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.

Two years later, the Supreme Court stated that “[o]ur decision in Twombly expounded the pleading standard for ‘all civil actions.’” Ashcroft v. Iqbal, 556 U.S. 662, 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.

The pleading standards announced in Twombly and Iqbal have been followed by the two courts that exercise appellate review of decisions by special masters: the United States Court of Appeals for the Federal Circuit and the United States Court of Federal Claims. E.g., Acceptance Ins. Co. v. United States, 583 F.3d 849, 853 (Fed. Cir. 2009) (affirming the 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 the 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). Additionally,

¹² Rule 8(a)(2) of the Rules of the Court of Federal Claims requires that a pleading that states a claim for relief contain “a short and plain statement of the claim showing that the pleader is entitled to relief.”

these standards have been used to evaluate petitions in the Vaccine Program. See Richard v. Sec’y of Health & Human Servs., No. 02-877V, 2010 WL 2766742, at *4 (Fed. Cl. Spec. Mstr. May 3, 2010). Consequently, Ms. Angiello and Mr. Gillett must allege sufficient facts to “plausibly suggest” that Gabriella was worse after the August 2004 MMR vaccination. They have failed to do so.

In support of their significant aggravation theory, Ms. Angiello and Mr. Gillett primarily rely on instances in which Gabriella intermittently experienced fever, congestion, and a rash beginning three months after the August 2004 MMR vaccination. Exhibit 9 at 26, 30, 33-34. However, Ms. Angiello and Mr. Gillett fail to address the large gap of time between the MMR vaccination and Gabriella’s symptoms, nor do they explain how these symptoms aggravated Gabriella’s pre-existing autistic condition.

Ms. Angiello and Mr. Gillett additionally rely on the supplemental expert report from Dr. Richard Layton. In his report, Dr. Layton stated that although he believes children can demonstrate acute regression following a vaccine such as MMR, it was “impossible” for him to provide more details since he was not involved in Gabriella’s care. Exhibit 25 at 1. According to Dr. Layton, “the best that [he could] do” was state that Gabriella did receive an MMR vaccine and was later diagnosed by Dr. Cowan as suffering from vaccine encephalopathy. Id. at 1-2.

Dr. Cowan’s report, however, does not assist Ms. Angiello and Mr. Gillett in showing that the August 25, 2004 MMR vaccination significantly aggravated Gabriella’s autism. Dr. Cowan’s report contains a critical mistake in chronology. He recorded that Gabriella received an MMR vaccine during her second year. Dr. Cowan also stated that she was having problems with language by her third birthday. Exhibit 18 at 1. Although the statement that Gabriella was having language problems when she was turning three is accurate, Dr. Cowan placed the MMR vaccine in the wrong year. Gabriella actually received the MMR vaccination shortly after she turned three years old and shortly after Dr. Levinson diagnosed her as having pervasive developmental disorder. Exhibit 4 at 23 (vaccination); exhibit 6 at 44 (diagnosis). Thus, Dr. Cowan’s conclusion, which he noted was “by history,” is based on a mistaken factual premise. When an expert assumes facts that are not supported by the record, the special master may find that report unpersuasive. Burns v. Sec’y of Health & Human Servs., 3 F.3d 415, 417 (Fed. Cir. 1993) (stating “The special master concluded that the expert based his opinion on facts not substantiated by the record. As a result, the special master properly rejected the testimony of petitioner’s medical expert.”).

Lastly, Ms. Angiello and Mr. Gillett allege Gabriella also suffered “other neurological injuries . . . resulting from vaccines administered” within the time frame permitted by the statute of limitations, namely, an unspecified “seizure disorder.” Pet’r Opp’n, filed June 6, 2008. Despite being afforded an opportunity to do so, Ms. Angiello and Mr. Gillett did not identify any medical records indicating Gabriella suffers from a seizure disorder of any kind.

Twombly and Iqbal instruct that Ms. Angiello and Mr. Gillett may not survive a motion to dismiss by merely asserting the “formulaic” elements of a cause of action. The assertion by Ms. Angiello and Mr. Gillett that Gabriella’s autism was “significantly aggravated” by her MMR vaccination 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, Ms. Angiello and Mr. Gillett were obligated to present facts that “plausibly suggest” that Gabriella’s condition 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.

IV. Conclusion

As originally pled, the petitioners claimed that vaccinations caused their daughter’s autism. Doctors who treated Gabriella, such as Dr. Chiriboga and Dr. Cowan, provide some support for this theory. However, there is no controversy that Gabriella experienced the “first symptom or manifestation of onset” of autism more than 36 months before Ms. Angiello and Mr. Gillett filed their petition. Therefore, the statute of limitations bars recovery on a theory that any vaccines initially caused Gabriella’s autism.

In response to the alternative theory that vaccines significantly aggravated Gabriella’s autism, Ms. Angiello and Mr. Gillett have failed to present, either in a petition or in their briefs or in the medical records, facts that “plausibly suggest” that Gabriella’s autism worsened after the August 2004 MMR vaccination. The reports of doctors that could have been useful in establishing a cause of action that vaccines caused Gabriella’s autism are not helpful in showing that the August 2004 MMR vaccination significantly aggravated Gabriella’s autism. This lack of factual allegations means that this theory must be dismissed as well.

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