2022-2119

United States Court of Appeals for the Federal Circuit

W.J., by his parents and legal guardians, R.J. and A.J.,

Petitioner-Appellant

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent-Appellee

Appeal from the United States Court of Federal Claims in 21-1342-V Judge Kathryn C. Davis

BRIEF OF APPELLANT W.J., by his parents and legal guardians, R.J. and A.J.

RECEIVED

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October 24, 2022

(2 of 397)

TABLE OF CONTENTS

 \mathbb{C}

(

Tat	ble of Authoritiesv
Uni	ited States Constitutionv
	Articlesv
	Amendmentsv
Cou	urt Casesv
Fed	leral Lawvii
Fed	leral Rules of Civil Procedureviii
Rul	es of the U.S. Court of Federal Claimsviii
	Appendix B (Vaccine Rules)viii
PR	ELIMINARY STATEMENT1
STA	ATEMENT OF RELATED CASES1
JUI	RISDICTIONAL STATEMENT1
STA	ATEMENT OF THE ISSUES2
STA	ATEMENT OF THE CASE AND FACTS
	Our Petition
	W.J.'s Injuries4
	W.J.'s Underlying Chromosomal Aberration4
	The MMR Vaccine Warnings and Contraindications5
	The Special Master Ordered the Secretary to Move to Dismiss Our Petition

(

Our Equitable Tolling Claims7
Fraudulent Concealment7
Extraordinary Circumstance10
The Secretary's Motion to Dismiss Was Granted11
We Filed Our Motion for Review11
Judge Davis Affirmed the Special Master's Dismissal of Our Petition11
Judge Davis Rejected Our Separation-of-Powers Claim13
Judge Davis Rejected Our Extraordinary Circumstances Claim14
Judge Davis Rejected Our Fraudulent Concealment Claim15
Judge Davis Rejected Our Disability Discrimination Claim16
SUMMARY OF THE ARGUMENT16
The Six Issues We Present for Review16
The Court's Rule 12(b)(6) Jurisdiction Issue17
The Separation-of-Powers Issue18
The U.S. Supreme Court's Twombly/Iqbal Plausibility Standard Issue19
The Matters Outside the Pleadings Issue20
The Equitable Tolling Issue21
Extraordinary Circumstance21
Fraudulent Concealment22
The Fourteenth Amendment and Section 504 Discrimination Issue24

(

THE ARG	UMENT	25
12(b)	e Special Master Entertained and Ruled on the Secretary's Rule)(6) Motion to Dismiss Our Petition Without Any Authority from gress to Do So	25
Twor	he Special Master Deviated from the U.S. Supreme Court's <i>mbly/Iqbal</i> Plausibility Standard for Rule 12(b)(6) Motions When She hissed Our Petition	29
Matt	The Special Master, and Then Judge Davis, Improperly Considered ers Outside the Pleadings in Assessing the Rule 12(b)(6) Motion to hiss Our Petition	31
	The Special Master's Order to the Secretary to File a Motion to thiss Our Petition Breaches the Separation-of-Powers Doctrine	33
	A. The Special Master Indeed Ordered the U.S. Justice Department to File a Motion to Dismiss Our Petition	34
	B. The Special Master's Order Is Clearly Contrary to the U.S. Constitution's Separation-of-Powers Doctrine	37
	C. The Special Master's Violation of the Separation-of-Powers Doctrine Necessitates the Reversal of Judge Davis' Decision	41
V. E	quitable Tolling is Warranted in this Matter	42
	A. Extraordinary Circumstances	42
	B. The Federal Fraudulent Concealment Doctrine	44
	1. The Fraudulent Concealment Doctrine Applies to Claims Under the Vaccine Act	44
	2. We Submitted Ample Evidence in Support of Our Fraudulent Concealment Claim	44
	3. Intent to Defraud Is Not a Necessary Element of a Cause of Action for Federal Fraudulent Concealment	51

()	4. The Federal Fraudulent Concealment Doctrine Tolls a Statute of Limitations Until the Fraud Is Discovered by the Plaintiff/Petitioner
	5. Fraudulent Concealment Occurs When a Defendant/Respondent Makes Misleading Statements Which Mask the Existence of a Cause of Action Against It54
	6. Neither the Special Master nor Judge Davis Drew All Inferences from Our Fraudulent Concealment Evidence in Our Favor54
	VI. Judge Davis' Decision Violates W.J.'s Rights Under the Fourteenth Amendment and Section 504 of the Rehabilitation Act of 197357
	STANDARD OF REVIEW60
	CONCLUSION AND RELIEF SOUGHT
(ADDENDUM64
	Judgment, dated June 21, 2022, Fed. Cl. ECF No. 41 Appx001
	Memorandum Opinion and Order, the Order being appealed, dated June 21, 2022, revised July 7, 2022, Fed. Cl. ECF No. 43 Appx002-022
	Special Master's Decision, dated February 16, 2022, Fed. Cl. ECF No. 29 Appx023-043
	CERTIFICATE OF COMPLIANCE107
\mathbf{C}	PROOF OF SERVICE108

Table of Authorities

United States Constitution:

Articles:

(

 $\left(\begin{array}{c} \cdot \\ \cdot \end{array} \right)$

()

1	
2	
3	
Amendments:	
14	

Court Cases:

Advanced Cardiovascular Systems, Inc. v. Scimed Life Systems, Inc. 988 F.2d 1157 (Fed. Cir. 1993)61
<i>Althen v. HHS</i> 418 F.3d 1274 (Fed. Cir. 2005)62
Ashcroft v. Iqbal 129 S.Ct. 1937 (2009)2, 17, 19-20, 29-31, 55-56, 60-61
<i>Banks v. HHS</i> No. 02-0738V (Fed. Cl., July 20, 2007)
<i>Beck v. HHS</i> 924 F.2d 1029 (Fed. Cir. 1991)17, 27
<i>Bell Atlantic v. Twombly</i> 127 S.Ct. 1955 (2007)
Cleburne v. Cleburne Living Center, Inc. 473 U.S. 432 (1985)

<i>Glidden Co. v. Zdanok</i> 370 U.S. 530 (1962)26
Hobson v. Wilson 737 F.2d 1 (D.C. Cir. 1984)
Holmberg v. Armbrecht 327 U.S. 392 (1946)
<i>In re Bill of Lading Transmission</i> 681 F.3d 1323 (Fed. Cir. 2012)
<i>K.G. v. HHS</i> 951 F.3d 1374 (Fed. Cir. 2020)
<i>Kisor v. Shulkin</i> 880 F.3d 1378 (Fed. Cir. 2018)
<i>Knudsen v. HHS</i> 35 F.3d 543 (Fed. Cir. 1994)62
<i>Kreizenbeck v. HHS</i> 945 F.3d 1362 (Fed. Cir. 2020)
K-Tech Telecommunications v. Time Warner Cable 714 F.3d 1277 (Fed. Cir. 2013)
Loving v. United States 517 U.S. 748 (1996)
<i>Paluck v. HHS</i> 786 F.3d 1373 (Fed. Cir. 2015)9, 23, 49-51
<i>Poling v. HHS</i> No. 02-1466V (Fed. Cl., January 28, 2011)9, 47-48, 50-51
<i>Redding v. District of Columbia</i> 828 F.Supp.2d 272 (D.D.C. 2011)61-62

	Seila Law LLC v. Consumer Financial Protection Bureau 140 S.Ct. 2183 (2020)
	Smith v. West 214 F.3d 1331 (Fed. Cir. 2000)26, 62
	Supermarket of Marlinton v. Meadow Gold Dairies 71 F.3d 119 (4th Cir. 1995)8
	<i>U.S. v. Brown</i> 381 U.S. 437 (1965)
	Federal Law:
	28 U.S.C. § 516
	28 U.S.C. § 1295(a)(3)1, 27
(Tucker Act (1988) 28 U.S.C. § 149117, 26-27
	Section 504 of the Rehabilitation Act of 1973 29 U.S.C. § 794
	National Vaccine Injury Compensation Program ("Vaccine Act") 42 U.S.C. § 300aa-10, et seqPassim
	42 U.S.C. § 300aa-10(c)50
	42 U.S.C. § 300aa-11(a)(1)1
	42 U.S.C. § 300aa-11(b)(1)(A)43
	42 U.S.C. § 300aa-1227
	42 U.S.C. § 300aa-12(a)1
	42 U.S.C. § 300aa-12(c)(6)(A)29
C	42 U.S.C. § 300aa-12(d)(2)(C)17, 27

(

 \mathbb{C}

42 U.S.C. § 300aa-12(f)1
42 U.S.C. § 300aa-16(a)(2)12
Federal Courts Improvement Act of 1982 96 Stat. 25
Camp Lejeune Justice Act of 2022 Public Law No: 117-16850
Federal Rules of Civil Procedure:
8
12(b)(6)
Rules of the U.S. Court of Federal Claims:
8(a)(2)
12(b)(6)2-3, 12, 16-20, 22, 25-33, 36, 42, 51, 60-61
12(c)20, 32
12(d)2, 20, 32-33
56
56(a)
56(b)
56(c)(4)
Appendix B (Vaccine Rules):
1(h) 28

1(b)	
4(c)	

Cas	e: 22-2119	Document: 17	Page: 10	Filed: 10/26/2022	(11 of 397
8(d)					27
21					
		ix			

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PRELIMINARY STATEMENT

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R.J. and A.J. (hereinafter "us," "we" or "our"), appearing pro se on behalf of Petitioner-Appellant W.J., respectfully submit this memorandum of law in support of our appeal from U.S. Court of Federal Claims Judge Kathryn C. Davis' Memorandum & Order, dated June 21, 2022 (hereinafter "Judge Davis' Decision"), for this Honorable Court's review.

Respondent-Appellee in this matter is the Secretary of Health and Human Services (hereinafter "the Secretary" or "the Government").

STATEMENT OF RELATED CASES

We hereby certify that no other appeal from the underlying proceeding in this matter before the U.S. Court of Federal Claims was previously before this or any other appellate court.

JURISDICTIONAL STATEMENT

The U.S. Court of Federal Claims has subject matter jurisdiction over, and is the proper venue for, our vaccine injury petition under 42 U.S.C. §§ 300aa-11(a)(1) and 300aa-12(a).

This Court has jurisdiction over this appeal under 28 U.S.C. § 1295(a)(3) and 42 U.S.C. § 300aa-12(f). Judge Davis' June 21, 2022 Memorandum & Order finally disposed of the matter. Appx002. Judgment was entered on June 21, 2022.

Appx001. We filed a timely notice of appeal with this Court on August 12, 2022.

Appx179.

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STATEMENT OF THE ISSUES

Whether it was arbitrary, capricious, an abuse of discretion, clearly erroneous, or otherwise not in accordance with the law for:

- Judge Davis to uncritically accept that the Special Master had the authority to entertain and rule on the Secretary's Rule 12(b)(6) motion even though Congress specifically refrained from granting the special masters any authority to do so in proceedings under the Vaccine Act. *Infra*, pp. 26-29.
- the Special Master, then Judge Davis, to consider evidence or the lack thereof as a basis for deciding on the Rule 12(b)(6) motion in deviation from the U.S. Supreme Court's *Twombly/Iqbal* plausibility standard and Rule 12(d) of the Rules of the Court of Federal Claims (RCFC). *Infra*, pp. 29-33.
- Judge Davis to find that the Special Master did not breach the U.S. Constitution's separation-of-powers doctrine by ordering the Secretary to file a motion to dismiss our Petition. *Infra*, pp. 33-42.
- Judge Davis to dismiss our extraordinary circumstance equitable tolling claim based solely upon a purported law which she did not pinpointedly cite or quote, and which does not in fact exist. *Infra*, pp. 42-44.

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- Judge Davis to find that our Petition did not contain sufficient well-pleaded factual allegations to find that our fraudulent concealment equitable tolling claim is a claim upon which relief can be granted under Rule 12(b)(6). *Infra*, pp. 44-51.
- Judge Davis to find that we do not have standing to bring a discrimination claim under the Fourteenth Amendment and Section 504 on behalf of W.J. *Infra*, pp. 57-60.

STATEMENT OF THE CASE AND FACTS

W.J. is a now 18-year-old young man who was born on February 8, 2004. Appx045. We, Petitioners-Appellants, R.J. and A.J., are his parents. Appx044. We, R.J. and A.J. are also W.J.'s legal guardians. Appx126.

Our Petition

Our Petition for vaccine injury compensation on behalf of W.J. was filed on May 7, 2021. Appx044. In our Petition, we request compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10, *et seq.* (the "Vaccine Act") for a Table Injury of chronic encephalopathy or, in the alternative, a "cause-in-fact injury" for the chronic encephalopathy and all other injuries described in our Petition, resulting from a Measles, Mumps, and Rubella (MMR) vaccination administered to W.J. on February 24, 2005. Appx044.

(14 of 397)

In addition to our injury claims, our Petition also includes our equitable tolling claims. Appx055-062.

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W.J.'s Injuries

We allege that, due to the administration of the MMR vaccine, W.J. has chronic encephalopathy and immunodeficiency issues which persist to this day. Appx045.

On March 7, 2006, about a year after receiving his MMR shot, W.J. was diagnosed with speech delay. Appx053. Based on his autism-like symptoms and behaviors, W.J. was diagnosed by his physician, at around the age of two, as having autism. Appx058. W.J.'s autism diagnosis resulted in his receiving treatment, therapies, and special education accordingly. Appx058.

In the years that followed his reception of the MMR vaccine, W.J. suffered greatly with several bouts of immune-related blood disorders including a disorder resembling mumps which resulted in hospitalization. Appx047-053.

W.J.'s Underlying Chromosomal Aberration

On March 19, 2019, after genetic testing, we were informed that W.J. was born with a chromosomal aberration known as an Xq28 duplication. Appx060. The Xq28 duplication is known to cause immune system impairment and mental

(16 of 397)

incapacities. Id. We allege that the Xq28 duplication caused W.J. some congenital cerebral injury and immunodeficiency impairment. Id.

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The MMR Vaccine Warnings and Contraindications

The MMR vaccine warnings state in relevant part that "[d]ue caution should be employed in administration of M-M-R II to persons with a history of cerebral injury," and the MMR vaccine contraindications include individuals with "[p]rimary and acquired immunodeficiency states." Appx046. We therefore allege, in our Petition, that the MMR vaccine was administered to W.J. in contravention to the vaccine's warnings. Appx047. We allege that, as a result of the administration of the MMR vaccine, W.J. has chronic encephalopathy and immunodeficiency issues caused either directly by the vaccine, or by its significant aggravation of the pre-existing damage caused by his chromosomal abnormality. Appx054. We further allege that the injuries from the vaccine led to the several bouts of immunerelated blood disorders and the disorder resembling mumps that resulted in his hospitalization. Appx047-053.

The Special Master Ordered the Secretary to Move to Dismiss Our Petition

On June 3, 2021, the Special Master held an initial status conference which dealt largely with our equitable tolling claims. Appx065.

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(17 of 397)

At the outset of the conference, the Special Master raised the statute of limitations issue, making reference to our Petition. Appx068. The Special Master stated that "there is a statute of limitations issue that we will need to address since that's a threshold issue." Telegraphing her inclination regarding our equitable tolling claims, she told us, "I just don't want to lead you to have any unrealistic expectations about how the case may proceed." Id.

During the initial conference, the Special Master indicated that she wished to order the Secretary to file a motion to dismiss our Petition based on the statute of limitations issue. She said, "Okay, we will issue an order asking Ms. Rifkin, on behalf of Respondent to file a Rule 4 and a motion to dismiss based on the statute of limitations or any other legal issue." Appx070-071. In her Decision, the Special Master wrote: "The undersigned ordered respondent to file a Rule 4(c) Report and Motion to Dismiss, and to set a briefing schedule for petitioners to file a response." Appx024.

At no point during the conference did the Special Master ask the Secretary if it had any motions it wished to make. At no point during the conference did the Secretary request leave to file a motion to dismiss, nor did it indicate a desire to do so. Moreover, the Special Master advised the Secretary on how to best proceed to move to dismiss our Petition. She said to the U.S. Department of Justice attorney

representing the Secretary:

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So I think the best course of action, Ms. Rifkin, is probably for the Government to file a Rule 4 report with any motion to dismiss or any other legal filing with regard to the statute of limitations. And then I can ask [R.J.] to file any reply or response which he may wish to do so, and then I can rule on that issue.

Appx068-069.

On August 2, 2021, the Secretary filed its motion in which it stated: "Respondent files this Motion in accordance with the Court's June 3, 2021 Scheduling Order." Appx073.

Our Equitable Tolling Claims

In response to the Secretary's motion to dismiss, Appx073, we argued that equitable tolling in our case is warranted because (1) the Government has engaged in the fraudulent concealment of our cause of action due to its minimalization of the judicially-determined connection between the MMR vaccine and autism, or autism-like symptoms, in some Vaccine Act petitioners, Appx101-112, and (2) that W.J.'s lifelong mental incapacity is an "extraordinary circumstance" within the meaning of this Court's 2020 *K.G.* Decision, 951 F.3d 1374, warranting equitable tolling in this matter, Appx112-123.

Fraudulent Concealment

(19 of 397)

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We cited to *Holmberg v. Armbrecht*, 327 U.S. 392, 396-397 (1946); *Hobson v. Wilson*, 737 F.2d 1, 33-36 (D.C. Cir. 1984); and *Supermarket of Marlinton v. Meadow Gold Dairies*, 71 F.3d 119, 122 (4th Cir. 1995) which explain and define the Federal Fraudulent Concealment Doctrine. Appx101-102.

We submitted evidence of judicially-determined links between vaccines and autism, and the Government's fraudulent concealment of that link, by showing that the Secretary lost a vaccine injury compensation case – involving a child with autism named Bailey Banks – on the merits. Appx105-106. That case was decided a month after the Omnibus Autism Proceedings began. The petitioners proved a causal link between the MMR vaccine and autism, according to the standards of the Vaccine Act. It is unclear if the Government brought this case to the attention of the special masters of the Omnibus Autism Proceedings.

The administration of the MMR vaccine to Bailey Banks resulted in him getting Pervasive Developmental Disorder Not Otherwise Specified (PDD-NOS). Appx105. The *Banks* Decision masks the link between the MMR vaccine and autism by describing the Banks child's PDD-NOS injury as "Non-autistic

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(20 of 397)

developmental delay," Appx105, even though PDD-NOS is part of the Autism Spectrum, Appx166.

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We submitted more evidence of a judicially-determined link between vaccines and autism by showing that the now much-publicized Hannah Poling case, Fed. Cl. No. 02-1466V, was one of the over five thousand cases involving a child classified as autistic that was not selected as a "test case" for the Omnibus Autism Proceedings. Appx131-136. The Hannah Poling case was secretly settled by the Secretary in November of 2007. Appx137. This was some five months after the Omnibus Autism Proceedings hearings commenced. Appx132.

Both of these cases were contemporaneous with the Omnibus Autism Proceedings.

We submitted yet more evidence of a judicially-determined link between vaccines and autism by showing that the Paluck family ultimately won their vaccine injury compensation case because one of their expert witnesses "presented a plausible medical theory explaining how vaccination could aggravate an underlying mitochondrial disorder." *Paluck v. HHS*, 786 F.3d 1373, 1377 (Fed. Cir. 2015). Id. at 1379 (K.P. won a favorable judgment based on his parents' amply supported allegation that he was a child "suffering from both a mitochondrial disorder and autism who experienced developmental regression following

vaccination."). The Paluck child was found, by this Honorable Court on the Government's appeal, to have established that he had been harmed by the MMR vaccine and two other vaccines. Id.

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The Government ignores these cases, which include a binding and precedent-setting Decision from this Court, in favor of the decisions of a handful of carefully selected "test cases" in the Omnibus Autism Proceedings.

Extraordinary Circumstance

In our opposition to the motion to dismiss we argued, based on this Court's 2020 *K.G.* Decision, that W.J.'s mental incapacity warranted equitable tolling. We argued that, unlike K.G., W.J.'s mental incapacity has spanned his entire lifetime and that, therefore, his extraordinary circumstance period spanned his whole life. Appx113. We argued that

[t]he K.G. court did not list claimant's age as one of the relevant facts to be considered in deciding if equitable tolling is available. On the contrary, the court held that "mental incapacity is a basis for equitable tolling in any context." K.G. at 1380. Respondent fails to establish why the age of someone with mental incapacity matters under K.G.

Appx114. We noted that the Secretary failed to show how or why K.G.'s refusal to communicate warranted equitable tolling while W.J.'s inability to do so does not. Id. We argued that the Secretary failed to show why K.G.'s temporary drug and

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(22 of 397)

alcohol induced mental incapacity warranted equitable tolling while W.J.'s permanent congenital mental incapacity does not. Id. We argued that granting equitable tolling because of K.G.'s temporary drug and alcohol induced mental incapacity, but not because of W.J.'s permanent mental incapacity, amounts to unlawful discrimination on the basis of permanent disability under the Fourteenth Amendment and Section 504 of the Rehabilitation Act. Appx114-116.

The Secretary's Motion to Dismiss Was Granted

On February 16, 2022, the Special Master decided against us on the motion to dismiss. Appx023. The Special Master granted the Secretary's Motion to Dismiss finding that we failed to file a timely action under the Vaccine Act. Appx043. Although the Special Master discussed the merits of our claims throughout the decision, Judge Davis found that she dismissed our Petition solely on the basis of the statute of limitations. Appx005.

We Filed Our Motion for Review

On March 14, 2022, we filed a Motion for Review of the Special Master's Decision with the U.S. Court of Federal Claims. Appx179.

Judge Davis Affirmed the Special Master's Dismissal of Our Petition

On June 21, 2022, Judge Davis affirmed the Special Master's Decision to dismiss our Petition in its entirety. Appx002. Based on W.J.'s speech delay

(23 of 397)

diagnosis in March 2006, and the 36-month statute of limitations provided for in the Vaccine Act, 42 U.S.C. § 300aa-16(a)(2), Judge Davis concurred with the Special Master's finding that we needed to have filed a petition on W.J.'s behalf by March 2009. Appx005.

The Special Master's Decision discusses our factual allegations regarding our specific injury claims even though the motion to dismiss does not concern those allegations. Neither the Special Master nor Judge Davis made any dispositive findings or rulings regarding any of the vaccine injuries. The Special Master's Decision is essentially a Rule 12(b)(6) dismissal for failure to state a claim because of the statute of limitations.

At one point, the Special Master said that she found that even if all of our injury claims were to be proven to have merit, those claims would fail "for failure to timely file the petition within the statute of limitations." Appx043. In regard to the scope of the Special Master's Decision, Judge Davis stated:

The Court agrees with Respondent that to the extent the Special Master made rulings on the merits of Petitioners' underlying claims, those rulings did not serve as a basis for her dismissal decision. ... Rather, the decision repeatedly held that – even if Petitioners were able to establish their claims – the Petition was time-barred and that no equitable tolling applied.

Appx021.

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(24 of 397)

Judge Davis summed up the nine objections in our Motion for Review by narrowing them down to three categories. Appx009. Judge Davis stated that (1) "Petitioners contend the Special Master violated separation-of-powers principles by sua sponte ordering Respondent to file a motion to dismiss at the initial status conference," (2) "they allege the Special Master erred in rejecting their equitable tolling arguments because she allegedly applied the wrong legal standard for reviewing a motion to dismiss," and (3) "Petitioners contend the Special Master's decision went beyond the scope of Respondents' dismissal request and improperly ruled on the merits of Petitioners' claims." Id.

We disagree with Judge Davis' findings with regard to the first and second of these three categories. We consider the third category of our objections, that the Special Master went beyond the scope of the Secretary's dismissal motion, to be moot because Judge Davis said that the merits of our injury claims did not factor into the decisions of either the Special Master or Judge Davis. There appear to be no dispositive findings regarding our underlying claims. Therefore, the underlying claims are not part of this appeal.

Judge Davis Rejected Our Separation-of-Powers Claim

Judge Davis rejected our separation-of-powers claim because, despite the fact that the Special Master clearly and unambiguously stated in her decision, in

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(25 of 397)

plain language, that "[t]he undersigned ordered respondent to file a Rule 4(c) Report and Motion to Dismiss," Appx024, Judge Davis came to the erroneous factual conclusion that the Special Master did not actually order the Secretary to do anything. Moreover, Judge Davis minimized the Special Master's unlawful order by stating that she was simply "addressing the threshold issue before the merits," Appx011, that she "efficiently used judicial resources to save the parties time, energy, and money," Id., and that the transcript of the June 3, 2021 conference does not "reflect that the Special Master ordered Respondent to take a particular position on the statute of limitations," Appx012. All of which, we argue, is false.

We argue herein that Judge Davis' factual finding that the Special Master did not actually order the Secretary to file a motion to dismiss, or that her order was harmless error that did not breach the separation-of-powers doctrine is arbitrary, capricious, an abuse of discretion, and not in accordance with the law.

Judge Davis Rejected Our Extraordinary Circumstances Claim

Judge Davis rejected our extraordinary circumstances claim based on W.J.'s mental incapacity solely "because – as a minor – the law required W.J.'s parents to file a claim on his behalf regardless of his mental capacity." Appx017. However, Judge Davis never quoted or cited the specific provision of the law to which she referred. This is probably because there is no provision, in the Vaccine Act or

(26 of 397)

anywhere else, that "required" us to file a claim on W.J.'s behalf "regardless of his mental capacity." We argue herein that Judge Davis' decision to reject our extraordinary circumstance claim based on a non-existent provision of law was arbitrary, capricious, an abuse of discretion, and not in accordance with the law.

Judge Davis Rejected Our Fraudulent Concealment Claim

Judge Davis rejected our fraudulent concealment claim, in large part, because she found that we had failed to prove that the Government had made any misleading statements with intent to defraud. Appx019-020. However, the U.S. Supreme Court has held that a cause of action for fraudulent concealment can be brought "though there be no special circumstances or efforts on the part of the party committing the fraud to conceal it from the knowledge of the other party." *Holmberg* at 397. (Internal citations omitted). The *Holmberg* Court did not mention intent as a necessary element of a fraudulent concealment claim. We argue herein that Judge Davis' decision to reject our fraudulent concealment claim based on her factual finding that we had failed to prove fraudulent intent against the Government, and that fraudulent intent is a necessary element of a federal fraudulent concealment claim, was arbitrary, capricious, an abuse of discretion, and not in accordance with the law.

Judge Davis Rejected Our Disability Discrimination Claim

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Judge Davis rejected our disability discrimination claim on behalf of W.J., under the Fourteenth Amendment and Section 504, by again referring to the imaginary uncited provision of law which she used to reject our extraordinary circumstances claim. Appx020. In a very brief and somewhat unclear finding, Judge Davis seems to suggest that since we purportedly had a legal responsibility to bring a Vaccine Act claim on W.J.'s behalf, that this somehow bars us from claiming that W.J. was discriminated against. Judge Davis implied that we would need to show that we, his parents, were discriminated against, rather than W.J. Then she found that we "did not demonstrate [we] were members of a protected class of persons," Id., and denied our claim on that basis. We argue herein that Judge Davis' decision to reject our discrimination claim on W.J.'s behalf, based upon a non-existent provision of law, was arbitrary, capricious, an abuse of discretion, and not in accordance with the law.

SUMMARY OF THE ARGUMENT

The Six Issues We Present for Review

We present argument on the following issues for this Honorable Court's review: (1) The jurisdiction of the Special Master to entertain and rule upon Rule 12(b)(6) motions to dismiss in the first instance, (2) the separation-of-powers issue,

(3) the U.S. Supreme Court's *Twombly/Iqbal* plausibility standard issue, (4) the matters outside the pleadings issue, (5) the equitable tolling issue, and (6) the discrimination issue under the Fourteenth Amendment and Section 504 of the Rehabilitation Act.

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<u>The Court's Rule 12(b)(6) Jurisdiction Issue</u>

Congress has not authorized the special masters of the Court of Federal Claims to entertain or rule upon Rule 12(b)(6) motions to dismiss. The Special Master ruled on the Secretary's motion and dismissed our Petition without any authority from Congress to do so.

The Tucker Act (1988), 28 U.S.C. § 1491, the Vaccine Act, and other statutes give the Claims Court certain limited equitable powers, but "its power is limited to that which Congress has expressly given to it." *Beck v. HHS*, 924 F.2d 1029, 1036 (Fed. Cir. 1991).

Given the circumscribed power granted to the claims court by the Tucker Act, we point out that even though Congress explicitly granted special masters the power to "include the opportunity for summary judgment" under the Vaccine Act, 42 U.S.C. § 300aa-12(d)(2)(C), Congress did not make any provision for Rule 12(b)(6) dismissals. This Court should infer from this that Congress did not intend for petitioners' cases to be dismissed under Rule 12(b)(6). Judge Davis' uncritical acceptance that the Special Master had the authority to entertain and rule upon the Secretary's Rule 12(b)(6) motion was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law.

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The Separation-of-Powers Issue

In regard to the separation-of-powers issue, we point out to this Court that the Special Master, in breach of the separation-of-powers doctrine, ordered the Secretary to file a motion to dismiss our Petition. In her Decision, the Special Master clearly states: "The undersigned ordered respondent to file a Rule 4(c) Report and Motion to Dismiss, and to set a briefing schedule for petitioners to file a response." Appx024. However, in her Decision, Judge Davis rejects the plain meaning of this statement by the Special Master, preferring instead her own strained interpretations of what the Special Master said at our initial conference on June 3, 2021.

A glaring example of one of Judge Davis' strained interpretations of the transcript is when she stated: "Nor does the transcript reflect that the Special Master ordered Respondent to take a particular position on the statute of limitations." Appx012. This is clearly not true. By her own account in her decision, the Special Master said she ordered the Secretary to file a motion to dismiss based on the statute of limitations. Appx097. This clearly indicates that the Special

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(30 of 397)

Master ordered the Secretary to take the position that our claims are barred by the statute of limitations. Moreover, in the June 3, 2021 transcript, the Special Master stated: "Okay, we will issue an order asking Ms. Rifkin, on behalf of Respondent to file a Rule 4 and a motion to dismiss based on the statute of limitations or any other legal issue." Appx070-071. Here, the Special Master orders the Secretary to file a motion to dismiss our Petition based on the statute of limitations or any other legal issue that it can dig up. We argue that this is untenable under the U.S. Constitution.

Based on this and other incorrect interpretations of the June 3, 2021 transcript, Judge Davis came to the clearly erroneous conclusion that the Special Master didn't actually order the Secretary to file any motion to dismiss at all. Judge Davis' finding that the Special Master did not make that order and thereby breach the separation-of-powers doctrine is arbitrary, capricious, an abuse of discretion, clearly erroneous, and otherwise not in accordance with the law.

The U.S. Supreme Court's Twombly/Igbal Plausibility Standard Issue

Even assuming that the Special Master had the authority to entertain and rule on the Rule 12(b)(6) motion, which she did not, she still abused her discretion and authority by dismissing our Petition under Rule 12(b)(6) in disregard of the U.S. Supreme Court's *Twombly/Iqbal* plausibility standard. In contravention to this standard, the Special Master drew inferences from the available evidence as part of the process of ruling on the Rule 12(b)(6) motion, and used evidence, or the purported lack thereof, as a basis for granting the motion to dismiss. Appx032.

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In fact, in her Decision, Judge Davis stated that the Special Master rejected our fraudulent concealment claim, and therefore granted the Secretary's Rule 12(b)(6) motion, "due to lack of evidence." Appx016. This is not in accordance with the Supreme Court's *Twombly/Iqbal* plausibility standard.

The Matters Outside the Pleadings Issue

Determinations on Rule 12(b)(6) motions are supposed to consider only the pleadings, i.e., in the instant matter, our Petition only.

If, on a motion under RCFC 12(b)(6) or 12(c), matters outside the pleadings are presented to and not excluded by the court, the motion must be treated as one for summary judgment under RCFC 56. All parties must be given a reasonable opportunity to present all the material that is pertinent to the motion.

Rule 12(d) RCFC. However, in the instant matter, evidence or the lack thereof was weighed in the determination of the court to dismiss our Petition. The motion was not treated as one for summary judgment under RCFC 56 as required. Id. The disregard of Rule 12(d) by the court was arbitrary, capricious, an abuse of discretion, and not in accordance with the law.

(32 of 397)

The Equitable Tolling Issue

There are two elements to our equitable tolling claims: Extraordinary Circumstance and the Federal Fraudulent Concealment Doctrine.

Extraordinary Circumstance

Our extraordinary circumstance claim involves W.J.'s mental incapacity. We base our claim on this Court's 2020 *K.G.* decision. Our argument is essentially that equitable tolling should apply to W.J. just as it did for K.G.

Judge Davis' finding against us rests on the fact that W.J. was a child with two parents during the time we claim as his period of extraordinary circumstance whereas K.G. was an adult without a guardian at all during her extraordinary circumstance period. Judge Davis' Decision, however, is fatally flawed because her entire rationale for dismissing our Petition is based on a non-existent provision of law which "required W.J.'s parents to file a claim on his behalf regardless of his mental capacity." Appx017. Judge Davis does not quote or cite this law because it does not exist. We argue below that this Court should not abide the dismissal of our Petition based on a law that does not exist. We ask this Court to reverse Judge Davis' finding on this issue under the arbitrary, capricious, abuse of discretion, clearly erroneous, or otherwise not in accordance with the law standard.

Fraudulent Concealment

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Our Federal Fraudulent Concealment claim alleges that, for many years now, the Government has been making false and/or misleading statements to the public in a largely successful effort to conceal the judicially-determined connection between vaccines and autism, or autism-like symptoms, in children who receive these vaccines – the MMR vaccine in particular.

The Special Master stated that "the petitioners did not file any evidence to suggest that the government was fraudulently concealing the connection between vaccines and autism." Appx039. Then Judge Davis concurred "that the fraudulent concealment claim failed due to lack of evidence." Appx016. The finding that we did not present the court with enough evidence on this issue to defeat a Rule 12(b)(6) motion is clearly erroneous.

What is concealed under the Federal Fraudulent Concealment Doctrine is the existence of a cause of action against a defendant/respondent. *Hobson* at 34-35. We provided evidence that in at least three cases of which we are aware, compensation was awarded to petitioners who were able to establish, according to the standards of the Vaccine Act, that the MMR vaccine caused, or probably caused, autism or autism-like symptoms in a child.

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(34 of 397)

In one of these cases the Vaccine Court found that the petitioner had established that his autistic injuries were the result of having received the MMR vaccine. The Secretary appealed that decision. Then, this Court affirmed the findings of the special master and the judge of the Court of Federal Claims. *Paluck* at 1377. This binding and precedential case means that every family that is similarly situated, i.e., they have a child with an underlying condition who began to display autism-like symptoms after having received the MMR vaccine, may likely have a cause of action under the Vaccine Act.

We provided ample evidence that the Government has concealed, and in fact is still concealing, the existence of a cause of action under the Vaccine Act on the part of autistic children. This evidence includes (1) a Vaccine Court decision which describes the child's injury as "[n]on-autistic developmental delay" even though the child's condition is under the umbrella of Autism Spectrum Disorder, *infra* pp. 46-47, (2) a case that was secretly settled with an autistic child, wherein the Secretary agreed to confidentially award compensation for her vaccine injuries while the Omnibus Autism Proceedings were getting underway, *infra* pp. 47-48, (3) a misleading and unclear statement to the press by the Secretary that the administration of the MMR vaccine didn't *cause* the aforementioned child's autism but merely *resulted* in it, *infra* p. 48, and (4) the fact that even today, the Omnibus

(35 of 397)

Autism Proceedings are used by the Government to convince the public that autistic children do not have a cause of action under the Vaccine Act, *infra* p. 57.

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Links to the decisions of the selected cases of the Omnibus Autism Proceedings are still featured prominently on the U.S. Court of Federal Claims website.¹ The obvious purpose of the webpage is to convey to anyone with an autistic child, who is thinking about filing a vaccine injury petition, that it has been conclusively proven by the Omnibus Autism Proceedings that there is no link between vaccines and autism and that, therefore, there is no cause of action for such a claim. Notably absent (or concealed) from the court's webpage is any mention of the cases cited herein wherein compensation was awarded to petitioners who successfully proved a link, according to Vaccine Act standards, between the MMR vaccine and their injuries which manifested as autism or autism-like symptoms.²

The Fourteenth Amendment and Section 504 Discrimination Issue

Our Fourteenth Amendment/Section 504 claim is that Judge Davis' Decision unjustly discriminates against W.J. based on his disability, in arbitrary and capricious fashion. Judge Davis stated:

¹ http://www.uscfc.uscourts.gov/autism-decisions-and-background-information ² Ibid.

(36 of 397)

Petitioners claim that denying equitable tolling in this case would be discriminatory against W.J. on the basis of his disability because courts have not denied such relief to other individuals who suffered from drug- and alcohol-based mental incapacity (for example, in K.G.).

Appx020. Judge Davis justifies the disparate treatment, however, by falling back on the imaginary law in which we had the "responsibility to seek compensation on [W.J.'s] behalf," Id., and that the discrimination laws do not apply in our case because we "did not demonstrate [we] were members of a protected class of persons." Id. It is unclear why we need to be "a protected class of persons" in order to vindicate the rights of our son, W.J., who is clearly protected by antidiscrimination laws because of his disability. We ask this Court to reverse Judge Davis' finding on this issue under the arbitrary, capricious, abuse of discretion, clearly erroneous, or otherwise not in accordance with the law standard.

Based on these arguments, which are presented in full below, we respectfully ask this Court to reverse Judge Davis' Decision and order that this matter be remanded to the U.S. Court of Federal Claims.

THE ARGUMENT

I. <u>The Special Master Entertained and Ruled</u> on the Secretary's Rule 12(b)(6) Motion to Dismiss Our Petition Without Any Authority from Congress to Do So $\left(\right)$

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(37 of 397)

We raise this issue for the first time on appeal here. However, this Court has held that it has jurisdiction over matters first raised on appeal if "the issue raised relate[s] to the validity of a statute or regulation, or an interpretation thereof, *and* that it have been relied on by the [] court in its decision." *Smith v. West*, 214 F.3d 1331, 1333 (Fed. Cir. 2000). We herein challenge the Special Master's interpretation that the Vaccine Act and the Vaccine Rules provide for the dismissal of our Petition under Rule 12(b)(6) of the Rules of the Court of Federal Claims.

The U.S. Court of Federal Claims traces its origins directly back to 1855, when Congress established the United States Court of Claims to provide for the determination of private claims against the United States government. *Glidden Co. v. Zdanok*, 370 U.S. 530, 552 (1962). The court today has nationwide jurisdiction over most suits for monetary claims against the government and sits, without a jury, to determine issues of law and fact. The general jurisdiction of the court, described in The Tucker Act (1988), 28 U.S.C. § 1491, is over claims for just compensation for the taking of private property, refund of federal taxes, military and civilian pay and allowances, and damages for breaches of contracts with the government. The Federal Courts Improvement Act of 1982, 96 Stat. 25., created the modern court.
Appeals from the Court of Federal Claims are taken to the United States Court of Appeals for the Federal Circuit and a judgment there is conclusive unless reviewed by the Supreme Court on writ of certiorari. 28 U.S.C. § 1295(a)(3).

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The National Childhood Vaccine Injury Act of 1986 gave the court the authority to create an Office of Special Masters to receive and hear certain vaccine injury cases, and the jurisdiction to review those cases. 42 U.S.C. § 300aa-12.

The Tucker Act (1988), 28 U.S.C. § 1491, and other statutes give the Claims Court certain limited equitable powers, "but the Claims Court has no *general* equitable power ... other than those in which such power has explicitly been granted." *Beck* at 1036.

Given the circumscribed power granted to the claims court by the Tucker Act, we point out that even though Congress explicitly granted special masters the power to "include the opportunity for summary judgment" under the Vaccine Act, 42 U.S.C. § 300aa-12(d)(2)(C), Congress did not make any provision for Rule 12(b)(6) dismissals. This Court should infer from this that Congress did not intend for petitioners' cases to be subject to Rule 12(b)(6) motions.

Vaccine Rule 8(d) permits motions for summary judgment, in which RCFC 56 applies. Vaccine Rule 21 permits petitioners to voluntarily request that their cases be dismissed. However, the Vaccine Rules do not provide any mechanism for a Rule 12(b)(6) motion to dismiss. The lack of a provision for Rule 12(b)(6) motions in the Vaccine Rules stems from the lack of same in the Vaccine Act.

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The Special Master acknowledges the lack of authority for Rule 12(b)(6) motions in Vaccine Act proceedings. She goes on to explain, though, how she justifies the dismissal of our Petition under Rule 12(b)(6) despite the lack of provision from Congress to do so. The Special Master explained that, based on Vaccine Rule 1(b), which states that "the special master may regulate applicable practice consistent with the rules and the purpose of the Vaccine Act," Appx031, "there is a well-established practice of special masters entertaining motions to dismiss in the context of RCFC 12(b)(6)," Id. She further stated that

[i]n assessing motions to dismiss in the Vaccine Program, special masters have concluded that they need only assess whether the petitioner could meet the Act's requirements and prevail, drawing all inferences from the available evidence in petitioner's favor.

Appx032. In the absence of any congressional authority upon which to rely, the Special Master cites the special masters themselves as the authority upon which Rule 12(b)(6) motions in Vaccine Act proceedings are administered.

This Court should find that the special masters did not simply "regulate [an] applicable practice," Vaccine Rule 1(b), but that they in fact added grounds for

dismissing a vaccine injury petition that Congress specifically refrained from including in the Vaccine Act.

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This Court should find that the special masters have no authority to unilaterally decide among themselves that they can dismiss vaccine petitions under Rule 12(b)(6) in the absence of any demonstrable congressional intent that they be authorized to do so. The special masters' goal of "providing for the efficient, expeditious, and effective handling of petitions," 42 U.S.C. § 300aa-12(c)(6)(A), cannot be achieved at the expense of petitioners' right to proceedings that are conducted in accordance with the relevant provisions of the law.

II. <u>The Special Master Deviated from the U.S. Supreme Court's</u> <u>Twombly/Iqbal Plausibility Standard for Rule 12(b)(6) Motions When</u> <u>She Dismissed Our Petition</u>

Even assuming that the Special Master had the authority to entertain and rule on the Rule 12(b)(6) motion, which she did not, she still abused her discretion and authority by dismissing our Petition under Rule 12(b)(6) in disregard of the U.S. Supreme Court's *Twombly/Iqbal* plausibility standard. In contravention to this standard, the Special Master drew inferences from the available evidence as part of the process of ruling on the Rule 12(b)(6) motion, and used evidence, or the purported lack thereof, as a basis for granting the motion to dismiss. Appx032. In fact, in her Decision, Judge Davis stated that the Special Master rejected our fraudulent concealment claim, and therefore granted the Secretary's Rule 12(b)(6) motion, "due to lack of evidence." Appx016. This is not in accordance with the Supreme Court's *Twombly/Iqbal* plausibility standard.

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Rule 12(b)(6) motions in all federal courts are governed by two U.S. Supreme Court Decisions: *Bell Atlantic v. Twombly*, 127 S.Ct. 1955 (2007) and *Ashcroft v. Iqbal*, 129 S.Ct. 1937 (2009). Together, these cases provide us with the Supreme Court's *Twombly/Iqbal* plausibility standard. *Iqbal* held that "*Twombly* interpreted and applied [FRCP] 8, which in turn governs the pleading standard in all civil actions." *Iqbal* at 1941 (Internal citation and quotations marks omitted). The *Twombly/Iqbal* standard applies in all civil actions.

RCFC 8(a)(2) says that "[a] pleading that states a claim for relief must contain a short and plain statement of the claim showing that the pleader is entitled to relief."

The *Twombly/Iqbal* standard does not countenance Rule 12(b)(6) dismissals based on lack of evidence. *K-Tech Telecommunications v. Time Warner Cable*, 714 F.3d 1277, 1282-1283 (Fed. Cir. 2013) ("The plausibility standard set forth in *Twombly* is met when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct C

(42 of 397)

alleged.") (Internal citation omitted). All that is required to defeat a Rule 12(b)(6) motion is that the complaint contain factual allegations that "plausibly suggest an entitlement to relief." *Iqbal* at 1951. *In re Bill of Lading Transmission*, 681 F.3d 1323, 1331-1332 (Fed. Cir. 2012) ("This plausibility standard is met when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. Although the standard asks for more than a sheer possibility that a defendant has acted unlawfully, it is not akin to a probability requirement. Of course, a well-pleaded complaint may proceed even if it strikes a savvy judge that actual proof of those facts is improbable, and that a recovery is very remote and unlikely.").

Our Petition contains several well-pleaded factual allegations which "plausibly suggest," *Iqbal* at 1951, that we were dissuaded from bringing our cause of action by misleading statements from the Government. Appx058-060.

The deviation from the *Twombly/Iqbal* plausibility standard by the Special Master, and then Judge Davis, in finding that the Special Master correctly dismissed our Petition under Rule 12(b)(6) is arbitrary, capricious, an abuse of discretion, and not in accordance with the law.

III. <u>The Special Master, and Then Judge Davis, Improperly Considered</u> <u>Matters Outside the Pleadings in Assessing the Rule 12(b)(6) Motion to</u> <u>Dismiss Our Petition</u>

Determinations on Rule 12(b)(6) motions are supposed to consider only the pleadings, i.e., in the instant matter, our Petition only.

If, on a motion under RCFC 12(b)(6) or 12(c), matters outside the pleadings are presented to and not excluded by the court, the motion must be treated as one for summary judgment under RCFC 56. All parties must be given a reasonable opportunity to present all the material that is pertinent to the motion.

Rule 12(d) RCFC.

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The Special Master dismissed our fraudulent concealment claim because "the petitioners did not file any evidence to suggest that the government was fraudulently concealing the connection between vaccines and autism." Appx039. In her Decision, Judge Davis stated that the Special Master rejected our fraudulent concealment claim, and therefore granted the Secretary's Rule 12(b)(6) motion, "due to lack of evidence." Appx016. Assessing evidence, or the purported lack thereof, is going to material outside the pleadings.

Judge Davis stated that, in deciding motions to dismiss under Rule 12(b)(6), the special master "need only assess whether the petitioner could meet the Act's requirements and prevail, *drawing all inferences from the available evidence* in petitioner's favor." Appx008 (Emphasis added). Judge Davis permits matters outside the pleadings to be assessed in Rule 12(b)(6) motions. This is a deviation from Rule 12(d) of the Court of Federal Claims. (

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(44 of 397)

The court rules require that if matters outside the pleadings are to be considered in whether to dismiss under Rule 12(b)(6), then "the motion *must* be treated as one for summary judgment under RCFC 56." Rule 12(d) (Emphasis added). This did not happen in the instant matter. The Secretary was not required to show, nor did it show, that that there was no genuine dispute as to any material fact. Rule 56(a). Summary Judgment motions are contemplated as being decided after the parties have had a reasonable opportunity to present all pertinent evidence to the motion. Rules 12(d) and 56(b). We were offered no such opportunity. No affidavits or declaration were required or sought to support or oppose the motion. Rule 56(c)(4). In short, the court adhered to neither Rule 12(b)(6) or 56 in its rush to dismiss our Petition.

The court's use of matters outside the pleadings in this matter was arbitrary, capricious, an abuse of discretion, and not in accordance with the law.

IV. <u>The Special Master's Order to the Secretary to File a Motion to Dismiss</u> <u>Our Petition Breaches the Separation-of-Powers Doctrine</u>

The federal question here is whether the Special Master violated the separation-of-powers doctrine by ordering the Secretary to file a motion to dismiss our Petition. This appears to be a case of first impression. We have not been able to find one case where a federal court ordered *any* respondent/defendant to file a

motion to dismiss, much less one where the respondent/defendant is the Executive Branch of the U.S. government.

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As a result of this appeal, this Court is in the position of deciding whether to let Judge Davis' Decision stand, thereby setting the precedent that it is legally permissible for the federal judiciary to order the Justice Department to file motions to dismiss the petitions of private citizens who bring claims against the United States government. It is untenable, however, that such a precedent should be set. The separation-of-powers concerns are glaring.

A. <u>The Special Master Indeed Ordered the U.S. Justice Department</u> to File a Motion to Dismiss Our Petition

Judge Davis briefly acknowledged that "[i]n her decision, the Special Master noted that she 'ordered' Respondent to file a Rule 4(c) Report and Motion to Dismiss on the issue of the statute of limitations." Appx011. However, rather than accept the plain language of this statement in the Special Master's Decision, Judge Davis went on to mischaracterize the transcript of the initial conference so much that Judge Davis eventually came to the conclusion that the Special Master didn't actually order the Secretary to file any motion to dismiss.

During her discussion of our case, Judge Davis stated: "Nor does the transcript reflect that the Special Master ordered Respondent to take a particular (

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(46 of 397)

position on the statute of limitations." Appx012. We respectfully point out that this is patently untrue. During the initial conference, the Special Master said, "Okay, we will issue an order asking Ms. Rifkin, on behalf of Respondent to file a Rule 4 and a motion to dismiss based on the statute of limitations or any other legal issue." Appx070-071. The Special Master actually ordered the U.S. Justice Department to move to dismiss our Petition based on the statute of limitations <u>or</u> <u>any other legal issue</u>. Id. (Emphasis added). The Special Master appeared to telegraph that perhaps the Justice Department could find other legal bases to dismiss as well.

In her Decision, the Special Master acknowledged her order when she wrote: "The undersigned ordered respondent to file a Rule 4(c) Report and Motion to Dismiss, and to set a briefing schedule for petitioners to file a response." Appx024. Judge Davis seeks to mitigate the Special Master's unlawful order by:

- stating that the Special Master was simply "addressing the threshold issue before the merits," Appx011, and that she "efficiently used judicial resources to save the parties time, energy, and money," Id.
- stating that the transcript of the June 3, 2021 conference does not "reflect that the Special Master ordered Respondent to take a particular position on the statute of limitations." Appx012.

• minimizing the Special Master's order as simply a "briefing order" when, in fact, it was an order to the Secretary to move to dismiss our petition. Id.

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- pointing out that we did not object to the Special Master's order during the conference itself. Id.
- stating that the Special Master afforded each party "a full and fair opportunity to present its case and create a record sufficient to allow review" of the motion to dismiss. Id.
- stating that the Special Master "based her decision squarely on the pleaded facts and relevant law." Appx013.

However, none of these mitigations are relevant. Supreme Court precedent requires that, even if this Court finds that the decision on the Secretary's Rule 12(b)(6) motion would have been the same had there been no separation-of-powers breach, the decision must still be reversed because of the breach. *Seila Law LLC v. Consumer Financial Protection Bureau*, 140 S.Ct. 2183, 2196 (2020) ("We have held that a litigant challenging governmental action as void on the basis of the separation of powers is not required to prove that the Government's course of conduct would have been different in a 'counterfactual world' in which the Government had acted with constitutional authority.").

(47 of 397)

B. <u>The Special Master's Order Is Clearly Contrary</u> to the U.S. Constitution's Separation-of-Powers Doctrine

The law is clear that

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[e]xcept as otherwise authorized by law, the conduct of litigation in which the United States, an agency, or officer thereof is a party, or is interested, and securing evidence therefor, is reserved to officers of the Department of Justice, under the direction of the Attorney General.

28 U.S.C. § 516. It is well-settled that "one branch of the Government may not intrude upon the central prerogatives of another." *Loving v. United States*, 517 U.S. 748, 757 (1996). It was the Secretary's prerogative to decide whether to challenge the equitable tolling claims in our Petition. During the June 3, 2021 initial conference, the Special Master intruded on the Secretary's prerogative by ordering it to file a motion to dismiss our petition. The Special Master clearly has no authority whatsoever to order the Secretary to conduct its litigation in any particular way. 28 U.S.C. § 516. The Special Master's order to the Secretary to file a motion to dismiss our Petition clearly violates the separation-of-powers doctrine found laced within Articles I, II, and III of the United States Constitution.

Judge Davis cites this Court's 2020 *Kreizenbeck* decision, 945 F.3d 1362, in support of her decision to let the Special Master's order stand. Appx011. However,

the *Kreizenbeck* case is inapposite because that case did not involve an order from the court to the Secretary to move to dismiss the petition.

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Judge Davis does not cite one precedent from case law, or any provision from any rule or statute, indicating that any federal court ever has the authority to order any defendant or respondent to file a motion to dismiss a case, much less when the defendant or respondent is the Executive Branch of the U.S. government.

According to the Vaccine Rules, the Secretary is not required to state its position until it files its Respondent's Report, also known as the Rule 4(c) Report. The Special Master should have waited until the Secretary filed its Report to find out what it had to say in response to our Petition, including our equitable tolling claim. The court's vaccine rules provide that the Secretary was required to provide in their Report "a full and complete statement of its position as to why an award should or should not be granted" including "any legal arguments that respondent may have in opposition to the petition." Vaccine Rule 4(c). Instead of waiting for the Secretary's Report, the Special Master told the Secretary what to include in its Report during the June 3, 2021 initial conference. Appx070-071.

At no point during the June 3, 2021 status conference did the Secretary request to file a motion to dismiss of its own volition. Nor did the Special Master ask the Secretary what it thought of our equitable tolling claims. The Special Master told the Secretary to take a certain position and to employ a specific legal strategy. The Secretary simply complied with the Special Master's directive to file a motion to dismiss our Petition: "Yes, Special Master, that sounds like an appropriate plan." Appx069.

This Court has held, in the case of the separation-of-powers between the legislative and judicial branches, that "[h]e who writes a law must not adjudge its violation." *Kisor v. Shulkin*, 880 F.3d 1378, 1380 (Fed. Cir. 2018). By the same token in the instant case, which involves the separation-of-powers between the judicial and executive branches, it can be said that "she who orders the motion to be filed must not adjudge that motion's merit."

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Judge Davis correctly points out that a part of the Special Master's responsibility is to "efficiently use[] judicial resources to save the parties time, energy, and money." Appx011. However, such efficiency cannot be accomplished at the expense of the right of the people to our constitutional checks and balances. Neither governmental efficiency nor inefficiency is a just rationale for breaching the separation-of-powers doctrine. *U.S. v. Brown*, 381 U.S. 437, 442-443 (1965) ("The Constitution divides the National Government into three branches – Legislative, Executive and Judicial. This 'separation of powers' was obviously not

instituted with the idea that it would promote governmental efficiency. It was, on the contrary, looked to as a bulwark against tyranny.").

The fact that the Secretary accepted and obeyed the unlawful direction from the Special Master is immaterial. The purpose of the separation-of-powers doctrine is not to protect the rights of one branch of government from being infringed by another branch. The purpose of the doctrine is to protect the people from the tyranny that results when two or more branches of government collude in a way that infringes upon our rights. The Supreme Court reminds us that

James Madison wrote:

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"The accumulation of all powers, legislative, executive, and judiciary, in the same hands, whether of one, a few, or many, and whether hereditary, self-appointed, or elective, may justly be pronounced the very definition of tyranny."

The doctrine of separated powers is implemented by a number of constitutional provisions, some of which entrust certain jobs exclusively to certain branches, while others say that a given task is *not* to be performed by a given branch. For example, Article III's grant of "the judicial Power of the United States" to federal courts has been interpreted both as a grant of exclusive authority over certain areas, and as a limitation upon the judiciary, a declaration that certain tasks are not to be performed by courts.

Id. at 443 (Internal citations omitted.).

In addition to the separation-of-powers concerns, the Special Master's order creates, at the very least, an appearance of impropriety. Any independent observer would be justified in questioning the likelihood of a court denying a motion which the court itself ordered a respondent to make. The Special Master's decision is irreparably tainted by the separation-of-powers concerns raised herein. Judge Davis' Decision must be reversed on this basis alone.

C. <u>The Special Master's Violation of the Separation-of-Powers Doctrine</u> <u>Necessitates the Reversal of Judge Davis' Decision</u>

Judge Davis conceded that "the Special Master could have first inquired whether Respondent intended to raise a timeliness argument and then – having confirmed its intent – ordered briefing." Appx012. This would have indeed made all the difference between the initiating of the motion being constitutional as opposed to unconstitutional. The fact that the motion was not initiated in accordance with the Constitution was brushed aside by Judge Davis.

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This Court should reverse Judge Davis' Decision irrespective of whether the same motion to dismiss would have been granted anyway had it been filed by the Secretary under its own volition without the Special Master's improper order to do so. *Seila Law LLC* at 2196 ("We have held that a litigant challenging governmental action as void on the basis of the separation of powers is not required to prove that the Government's course of conduct would have been different in a 'counterfactual world' in which the Government had acted with constitutional authority.").

This Court is bound by U.S. Supreme Court precedent to reverse and remand in this case. Judge Davis' Decision should be reversed, and our petition remanded, on the basis of this issue alone.

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V. Equitable Tolling is Warranted in this Matter

Even though, as previously argued, evidence or the lack thereof are matters outside the pleadings that should not have been considered by the court, in response to the court's illicit assessment that we did not provide enough evidence to oppose the Rule 12(b)(6) motion to dismiss, Appx016, Appx039, we provide this discussion of our evidence.

A. Extraordinary Circumstances

In her Decision, Judge Davis states that the court rejected our extraordinary circumstances arguments, and therefore dismissed our petition, "because – as a minor – the law required W.J.'s parents to file a claim on his behalf regardless of his mental capacity." Appx017. Yet, Judge Davis never quotes or cites the specific provision of the law to which she refers. That's because there is no law which required us to file any claim. Yet, Judge Davis relies on this imaginary non-existent law as the sole basis for rejecting our extraordinary circumstances arguments and affirming the dismissal of our petition.

Judge Davis does allude to "a legal representative's rights and responsibilities under the Vaccine Act." Appx018. However, the Vaccine Act never requires any parent or guardian to file any claim on behalf of their minor child. It simply permits them to do so. 42 U.S.C. § 300aa-11(b)(1)(A).

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Judge Davis goes on to state that our situation "did not amount to extraordinary circumstances under the legal principles elucidated in K.G. because Petitioners retained the right to sue on his behalf." Appx018. However, Judge Davis misconstrues the legal principles in K.G., in which this Court held that

[t]he fact that the Vaccine Act expressly allows a legal guardian to bring a claim on a claimant's behalf does not foreclose the availability of equitable tolling for claimants with mental illness. Parents and legal guardians can ordinarily bring claims on behalf of their wards. ... Thus, Congress's decision to allow guardians to bring claims is unremarkable – a mere codification of common practice. We therefore do not construe the provision of the Vaccine Act that allows legal guardians to bring claims on behalf of petitioners as a bar to equitable tolling. Accordingly, we find that the Special Master erred in adopting a per se rule and considering only whether K.G. had a legal guardian. He should have instead analyzed the facts to determine whether K.G.'s legal guardianship alleviated the extraordinary circumstance of her mental illness.

K.G. at 1381. Similarly, the Special Master and Judge Davis also adopted a per se rule considering only whether W.J. had a parent or legal guardian. Judge Davis' Decision offers no analysis of the facts regarding W.J.'s extraordinary circumstances other than to reiterate that W.J. had parents and that, therefore, he is

purportedly not entitled to equitable tolling on the basis of his mental incapacity. Appx017-018.

Judge Davis' Decision should be reversed, and our petition remanded, on the basis of this issue alone.

B. The Federal Fraudulent Concealment Doctrine

1. <u>The Fraudulent Concealment Doctrine Applies to Claims</u> <u>Under The Vaccine Act</u>

Regarding the Federal Fraudulent Concealment Doctrine, Judge Davis stated: "The Court has not located any caselaw applying this doctrine to a petition for compensation brought pursuant the Vaccine Act, nor do Petitioners cite cases on the matter of whether it applies in this context." Appx016. However, regarding the Federal Fraudulent Concealment Doctrine, the U.S. Supreme Court has held that "[t]his equitable doctrine is read into every federal statute of limitation." *Holmberg* at 397. We pointed this out to the court. We cited this holding in our Petition. Appx060. The Special Master cited it in her Decision. Appx041.

The Federal Fraudulent Concealment Doctrine applies to claims under the Vaccine Act.

2. <u>We Submitted Ample Evidence in Support of</u> Our Fraudulent <u>Concealment Claim</u>

Judge Davis points out that

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[f]or purposes of the Motion to Dismiss, the relevant question before the Special Master was not whether there is a link between vaccines and autism. The relevant question was whether Petitioners alleged facts demonstrating they were misled by Respondents such that equitable tolling is appropriate because Respondent engaged in fraud.

Appx019. This is correct. It is neither our burden, nor our intention, to scientifically prove that there is a connection between any vaccine and autism. Our burden and intention is to demonstrate (1) that the U.S. Court of Federal Claims and the Court of Appeals for the Federal Circuit have both found that several petitioners merited compensation by establishing a link between the MMR vaccine and their autistic symptoms according to the requirements of the Vaccine Act,³ (2) that, therefore, a cause of action for similarly situated petitioners does indeed exist under the Vaccine Act, and (3) that the Government has made misleading statements to the general public which has resulted in the successful masking of the existence of this cause of action from most. *Hobson* at 34-35 (In order to be guilty of fraudulent concealment, a defendant/respondent "must engage in some misleading, deceptive or otherwise contrived action or scheme...that is designed to mask the existence of a cause of action.").

³ See Banks, Paluck, and Poling.

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We demonstrate all three of these points herein.

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The Special Master stated that "the petitioners did not file any evidence to suggest that the government was fraudulently concealing the connection between vaccines and autism." Appx039. This is patently untrue. We provided strong evidence. We presented argument in support of this claim at length along with evidence exhibits and legal citations. Appx101-112.

We submitted evidence of a judicially-determined link between vaccines and autism, which was subsequently suppressed and concealed by the Government, by showing that the Secretary lost a vaccine injury compensation case on the merits, which was decided a month after the Omnibus Autism Proceedings began, in which the petitioners indeed proved a causal link between the MMR vaccine and autism. Appx105-106, Appx138.

The administration of the MMR vaccine to Bailey Banks resulted in him getting Pervasive Developmental Disorder Not Otherwise Specified or PDD-NOS. Appx139. The court referred to the *Banks* case, as involving "[n]on-autistic developmental delay," Appx138, which is untrue because, at the time of the *Banks* decision, "PDD-NOS was one of several previously separate subtypes of autism that were [eventually] folded into the single diagnosis of autism spectrum disorder (ASD)." Appx166.

(58 of 397)

Today, the Secretary concedes that "[Autism Spectrum Disorder] includes what the American Psychiatric Association used to call autistic disorder, Asperger syndrome, and pervasive developmental disorder not otherwise specified." Appx171. Any cause of action which may have been triggered for others by *Banks* was masked by the Government, in large part, due to the Banks child's injury of Pervasive Developmental Disorder Not Otherwise Specified (PDD-NOS) being falsely labeled by the court as "[n]on-autistic developmental delay." Appx138.

We submitted another example of a judicially-determined link between vaccines and autism, which was subsequently suppressed and concealed by the Government, in the now much-publicized Hannah Poling case. *Poling* was one of the over five thousand cases, involving a child classified as autistic, that was not selected as a "test case" for the Omnibus Autism Proceedings. Appx129. The Hannah Poling case was secretly settled by Respondent in November of 2007. Appx137. This was some five months after the Omnibus Autism Proceedings hearings commenced. Appx132. The Poling case was then initially sealed.

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The *Poling* Attorney's Fees and Costs Decision, dated January 28, 2011, states, in relevant part:

Respondent conceded that petitioners are entitled to compensation based on a determination that she suffered an injury identified on the Vaccine Injury Table, specifically, a presumptive MMR vaccine (

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related injury of an encephalopathy. Hannah's encephalopathy eventually manifested as a chronic encephalopathy with features of autism spectrum disorder and a complex partial seizure disorder as a sequela.

Based on the persuasive factors supporting petitioner's vaccine claim and respondent's election not to challenge petitioner's claim, the undersigned issued a decision finding that petitioner is entitled to compensation under the Vaccine Program on July 21, 2010, and awarding damages.

Appx169. The court made a clear connection between "a presumptive MMR vaccine-related injury of an encephalopathy" and "a chronic encephalopathy with features of autism spectrum disorder." Id. Yet, the Secretary continues to publicly maintain that the *Poling* case does not establish any connection between the MMR vaccine and autism. Appx129-130.

In fact, in Orwellian Doublespeak fashion, the Secretary has been quoted in the press as saying that vaccines didn't *cause* Hannah Poling's autism, but *resulted* in it. Appx129. Any cause of action which may have been triggered for others by *Poling* was masked by the Government, in large part, due to its misleading refusal to use the word *cause*, in favor of the word *resulted*. Thus, enabling the Secretary, through its parsing of words, to repetitively claim that Poling did not demonstrate that her vaccines caused her autism-like symptoms. C

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(60 of 397)

We submitted yet another example of a judicially-determined link between vaccines and autism by showing that the Paluck family ultimately won their vaccine injury compensation case because one of their expert witnesses "presented a plausible medical theory explaining how vaccination could aggravate an underlying mitochondrial disorder." *Paluck* at 1377. The Paluck child won a favorable judgment based on his parents' amply supported allegation that he was someone "suffering from both a mitochondrial disorder and autism who experienced developmental regression following vaccination." Id. at 1379. The Paluck child was found, by the U.S. Court of Federal Claims, to have been harmed by the MMR vaccine and two other vaccines. Id. Paluck won his case on the merits. The Secretary appealed the determination of the Court of Federal Claims to this Court. This Court affirmed the lower court's finding that Paluck's autism-like symptoms had indeed been caused by the MMR vaccine.

Rather than honestly making the public more aware that the U.S. Court of Federal Claims has awarded compensation to petitioners who established a causal link between the MMR vaccine and autism, or autism-like symptoms, according to the standards of the Vaccine Act, in at least the three cases we cite, the Government repeatedly points instead to the six carefully selected cases of the Omnibus Autism Proceedings, which determined that there is no causal connection C

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(61 of 397)

between any vaccine and autism. This is misleading. This kind of dissuasion through misleading information is precisely what the Federal Fraudulent Concealment Doctrine contemplates. The Government's public position on this issue has convinced the overwhelming majority of the public that children with autism or autism-like symptoms have no cause of action under the Vaccine Act. But, the petitioners in *Banks, Poling*, and *Paluck*, and those familiar with those cases, know better.

We believe that the results of *Banks*, *Poling*, and *Paluck* alone warrant a statement to the general public on par with those being made pursuant to the recently enacted Camp Lejeune Justice Act of 2022 that, under the Vaccine Act, if they have a child who has been diagnosed with autism, they too may be eligible for compensation for injuries sustained after receiving an MMR vaccination. Instead, the Government ignores those decisions in favor of the carefully selected three or six cases involved in the Omnibus Autism Proceedings.

It is the Secretary's responsibility, under the Vaccine Act to "undertake reasonable efforts to inform the public of the availability of the [Vaccine Injury Compensation] Program." 42 U.S.C. § 300aa-10(c). When it comes to autistic children, however, the Secretary puts its efforts into telling them that the Program

is not available to them even though some have won compensation for their autism-related injuries from vaccines.

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In her Decision, the Special Master actually perpetuated the notion that the Omnibus Autism Proceedings have conclusively proven that there is no connection between vaccines and autism by stating that "[i]n the OAP three special masters conducted separate proceedings in test cases involving the two theories of autism causation" and that "[a]ll found petitioners had not provided preponderant evidence of causation." Appx040.

It is unclear why the Omnibus Autism Proceedings test cases carry so much weight but *Banks*, *Poling*, and *Paluck* apparently do not.

Our factual allegations regarding our Federal Fraudulent Concealment Doctrine claim are irrefutable. Appx058-060, Appx101-112. If taken as true, these allegations clearly support a claim "upon which relief can be granted." Rule 12(b)(6), RCFC. Judge Davis' finding that we didn't provide enough evidence to even defeat a Rule 12(b)(6) motion is arbitrary, capricious, an abuse of discretion, and not in accordance with the law.

3. <u>Intent to Defraud Is Not a Necessary Element of a</u> Cause of Action for Federal Fraudulent Concealment

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In her discussion of our fraudulent concealment claim, Judge Davis stated that "[f]raud also typically requires a showing of intent on behalf of the defrauder to make a false or misleading statement." Appx019.⁴ Judge Davis implies that we produced no evidence in support of a claim of fraudulent intent on the part of the Government. However, regarding the Federal Fraudulent Concealment Doctrine, the U.S. Supreme Court has held that a cause of action for fraudulent concealment can be brought "though there be no special circumstances or efforts on the part of the party committing the fraud to conceal it from the knowledge of the other party." *Holmberg* at 397. (Internal citations omitted). The *Holmberg* Court did not

⁴ Referring to ¶ 103 of our Petition, Judge Davis said that "the Petitioner disavowed any allegation that Respondent engaged in intentional fraud." Appx020. What we actually stated was: "Petitioners do not explicitly claim that these denials of any connection between vaccines and autism by the federal government ... are intentionally fraudulent." What we meant is that we do not necessarily impute fraudulent intent on any specific individuals in the Government's employ. We readily acknowledge that there are many honest, hard-working people serving the public interest in the HHS, the Justice Department, and all of the other government agencies. But we also do not rule out that the collective behavior of the Government, in the aggregate, can or has indeed had the effect of misleading the public about any connection between vaccines and autism or autism-like symptoms. We suggest that it is both impossible and unrealistic to impute fraudulent intent on an entire structure such as the Government. We also suggest that it is unreasonable to be expected to prove such intent from a structure like the Government in a court of law.

mention intent as a necessary element of a fraudulent concealment claim. Judge Davis' finding on this issue is not in accordance with the law.

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4. <u>The Federal Fraudulent Concealment Doctrine Tolls a Statute of</u> <u>Limitations Until the Fraud Is Discovered by the Plaintiff/Petitioner</u>

The Special Master stated that we are arguing "for the application of a discovery rule, suggesting that the Act's statute of limitations should not have begun to running until 2019," and that "[t]he Federal Circuit has held that there is no explicit or implied discovery rule under the Vaccine Act." Appx027. However, the U.S. Supreme Court has held, regarding the Federal Fraudulent Concealment Doctrine

that where a plaintiff has been injured by fraud and remains ignorant of it without any fault or want of diligence or care on his part, the bar of the statute does not begin to run until the fraud is discovered. ... This equitable doctrine is read into every federal statute of limitation.

Holmberg at 397. The lack of a discovery rule in the Vaccine Act notwithstanding, according to the Federal Fraudulent Concealment Doctrine the statute of limitations in our case should be tolled until the day we discovered that we had been misled into believing that we had no cause of action regarding any vaccine injury. We argue in our Petition that the statute of limitations in our case should be tolled until March 19, 2019. Appx061.

5. <u>Fraudulent Concealment Occurs When a Defendant/Respondent</u> <u>Makes Misleading Statements Which Mask the Existence of</u> <u>a Cause of Action Against It</u>

The Special Master stated that "petitioners failed to show how respondent's alleged concealment prevented them from filing a petition on behalf of W.J." Appx039. The Special Master seems to confuse the *dissuasion* from filing a claim, that comes from misleading statements from a potential respondent/defendant which are designed to mask the very existence of a cause of action, with the *physical inability* to file a claim. *Hobson* at 34-35 (In order to be guilty of fraudulent concealment, a defendant/respondent "must engage in some misleading, deceptive or otherwise contrived action or scheme...that is designed to mask the existence of a cause of action.").

We never claimed we were "prevented" from filing a vaccine court petition as if we were not permitted to file one or were physically restrained from doing so. We claim we were dissuaded from filing a petition. The Government repeatedly told the people that we didn't have a cause of action because it had been conclusively proven that a connection between vaccines and autism does not exist. For a time, we took the Government at its word. That was a mistake.

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6. <u>Neither the Special Master nor Judge Davis Drew All Inferences</u> <u>from Our Fraudulent Concealment Evidence in Our Favor</u>

In contravention to the previously discussed *Twombly/Iqbal* plausibility standard, Judge Davis points out that, in deciding motions to dismiss under Rule 12(b)(6), the special master "need only assess whether the petitioner could meet the Act's requirements and prevail, *drawing all inferences from the available evidence* in petitioner's favor." Appx008 (Emphasis added). However, neither the Special Master nor Judge Davis drew any part of our fraudulent concealment evidence in our favor at all. Despite all of our ample evidence, Judge Davis decided that we did not even have enough evidence to state a claim upon which relief can be granted. This is clearly erroneous.

Judge Davis wrote:

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Accepting the pleaded facts as true, the Special Master observed that during the period in which Petitioners contended they were misled by Respondent, over 5,100 petitions alleging that vaccines caused autism were filed under the Vaccine Act in the OAP. ECF No. 29 at 19. In other words, their argument was significantly undercut by the fact that Respondent's position to the contrary did not dissuade or prevent thousands of other claimants with similar claims from filing suit.

Appx019. In a nation wherein some 2.3% of all children are born with autism,⁵ the 5,100 petitions referred to by Judge Davis represents a very small percentage of the autistic children population. Assuming a population of some 1.5 million children

⁵ https://www.nimh.nih.gov/health/statistics/autism-spectrum-disorder-asd

(67 of 397)

with autism in the United States,⁶ the 5,100 petitions represent 0.34% of that population. This means that the Government successfully dissuaded up to 99.66% of parents with autistic children from bringing claims under the Vaccine Act.

Judge Davis stated:

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For purposes of the Motion to Dismiss, the relevant question before the Special Master was not whether there is a link between vaccines and autism. The relevant question was whether Petitioners alleged facts demonstrating they were misled by Respondents such that equitable tolling is appropriate because Respondent engaged in fraud.

Appx019. No, the relevant question is whether our Petition contains factual allegations that "plausibly *suggest* an entitlement to relief" if taken as true. *Iqbal* at 1951 (Emphasis added). We do not need to demonstrate anything more than this at the Rule 12(b)(6) stage.

Judge Davis goes on to note that in order to prevail on a fraudulent concealment claim, we need to show that we were misled "without any fault or want of diligence" on our part. Id. (Internal citation omitted). This is akin to telling us that we should have known better than to take the Government at its word. Judge Davis does not point out any specific fault or want of diligence on our part.

⁶ https://www.nbcnews.com/health/kids-health/how-many-kids-have-autism-u-s-government-measures-3-n940126

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Links to the decisions of the selected cases of the Omnibus Autism Proceedings are still featured prominently on the U.S. Court of Federal Claims website.⁷ The obvious purpose of this webpage is to convey to anyone with an autistic child, who is thinking about filing a vaccine injury petition, that it has been conclusively proven by the Omnibus Autism Proceedings that there is no link between vaccines and autism and, therefore, there is no cause of action on their part. Notably absent (or concealed) from the court's webpage is any mention of the cases cited herein wherein compensation was awarded to petitioners who successfully proved a link between the MMR vaccine and their injuries which manifested as autism or autism-like symptoms.⁸

We provided ample examples of misleading statements and omissions on the Government's part regarding the cases in which compensation was indeed awarded for autism or autism-like symptoms caused by the MMR vaccine.

VI. Judge Davis' Decision Violates W.J.'s Rights Under the Fourteenth Amendment and Section 504 of the Rehabilitation Act of 1973

In our Petition, we claimed that if the court were to deny equitable tolling to W.J. after having granted equitable tolling to K.G. – this would amount to illegal

⁷ http://www.uscfc.uscourts.gov/autism-decisions-and-background-information ⁸ Ibid.

(69 of 397)

disability discrimination against W.J. Appx061-062. The rationale for this claim is that K.G. suffered from a temporary drug and alcohol induced bout of mental incapacity, *K.G.* at 1377, while W.J. suffers from permanent congenital mental incapacity. Our Petition claims that this discrimination violates W.J.'s equal protection rights under the Fourteenth Amendment. Appx061-062. We included W.J.'s rights under Section 504 of the Rehabilitation Act in this claim in our opposition to the motion to dismiss in addition to his Fourteenth Amendment rights. Appx115-116.

We now claim that Judge Davis' Decision unjustly discriminates against W.J. based on his disability in arbitrary and capricious fashion. She stated:

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Petitioners claim that denying equitable tolling in this case would be discriminatory against W.J. on the basis of his disability because courts have not denied such relief to other individuals who suffered from drug- and alcohol-based mental incapacity (for example, in K.G.).

Appx020. Judge Davis justifies the disparate treatment by falling back on the imaginary law in which we had the "responsibility to seek compensation on [W.J.'s] behalf," and that the discrimination laws do not apply in our case because we "did not demonstrate [we] were members of a protected class of persons." Id. It is unclear why we need to be "a protected class of persons" in order to vindicate the rights of our son, W.J., who is clearly protected by anti-discrimination laws

based on his disability. Judge Davis erroneously found that we do not have standing to bring a discrimination claim on behalf of W.J.

K.G. had temporary mental incapacity due, in large part, to her drug and alcohol abuse. *K.G.* at 1377. W.J., on the other hand, suffers from permanent mental incapacity because of a disability that he has through no fault of his own. The United States Supreme Court has held that when there is unjustified disparate treatment under the law between neuro-normal individuals with temporary mental issues and individuals with permanent mental incapacitation, a Fourteenth Amendment equal protection violation exists. *Cleburne v. Cleburne Living Center, Inc.*, 473 U.S. 432 (1985). In an opinion in which he concurred in part and dissented in part with the *Cleburne* decision, Justice Thurgood Marshall wrote the following:

For the retarded, just as for Negroes and women, much has changed in recent years, but much remains the same; outdated statutes are still on the books, and irrational fears or ignorance, traceable to the prolonged social and cultural isolation of the retarded, continue to stymie recognition of the dignity and individuality of retarded people. Heightened judicial scrutiny of action appearing to impose unnecessary barriers to the retarded is required in light of increasing recognition that such barriers are inconsistent with evolving principles of equality embedded in the Fourteenth Amendment.

Cleburne at 467.

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(71 of 397)

To afford equitable tolling, and therefore the benefits of the National Vaccine Injury Compensation Program, to K.G. but not to W.J., would also amount to unlawful disability discrimination under Section 504 of the Rehabilitation Act of 1973 which prohibits, solely by reason of W.J.'s disability, his exclusion from the participation in, or the denial of the benefits from, the National Vaccine Injury Compensation Program.

STANDARD OF REVIEW

Rule 12(b)(6) dismissals are reviewable under the U.S. Supreme Court's *Twombly/Iqbal* plausibility standard. *K-Tech Telecommunications* at 1282-1283 ("The plausibility standard set forth in *Twombly* is met when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.") (Internal citation omitted). All that is required to defeat a Rule 12(b)(6) motion is that the complaint contain factual allegations that "plausibly suggest an entitlement to relief." *Iqbal* at 1951. *Bill of Lading Transmission* at 1331-1332 ("This plausibility standard is met when the reasonable inference that the defendant is liable for the misconduct allows the court to draw the reasonable inference that the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. Although the standard asks for more than a sheer possibility that a defendant has acted unlawfully, it is not akin to a probability requirement. Of course, a well-pleaded

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complaint may proceed even if it strikes a savvy judge that actual proof of those facts is improbable, and that a recovery is very remote and unlikely.").

In this Court's review of Judge Davis' Rule 12(b)(6) dismissal, all allegations contained in our Petition must be "taken as true," *Advanced Cardiovascular Systems, Inc. v. Scimed Life Systems, Inc.*, 988 F.2d 1157, 1160 (Fed. Cir. 1993). *Iqbal* at 1949 ("[F]or the purposes of a motion to dismiss we must take all of the factual allegations in the complaint as true.") (Internal citation omitted).

Advanced Cardiovascular Systems at 1160-1161 ("A dismissal under Rule 12(b)(6), to be sustained, must be correct as a matter of law when the allegations of the complaint are taken as true. Disputed issues are construed favorably to the complainant, and all reasonable inferences are drawn in favor of the complainant. Thus, to the extent that factual questions are raised and are material to the result, dismissal is improper unless there is no reasonable view of the facts which could support the claim.") (Internal citations omitted).

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Redding v. District of Columbia, 828 F.Supp.2d 272, 278 (D.D.C. 2011) ("A defendant may raise a statute of limitations affirmative defense via a Rule 12(b)(6) motion when the facts that give rise to the defense are clear from the face of the complaint. Because statute of limitations issues often depend on contested

(73 of 397)

questions of fact, dismissal is appropriate only if the complaint on its face is conclusively time-barred.") (Internal citations omitted).

In Vaccine Act cases in which the Court of Federal Claims upholds the determination of the special master, this Court reviews de novo the court's determination as to whether or not the special master's decision was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law. *Knudsen v. HHS*, 35 F.3d 543, 546 (Fed. Cir. 1994).

This Court owes no deference to the Special Master or Judge Davis on questions of law. *Althen v. HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). This Court reviews questions of law de novo and reviews factual findings for clear error. Id.

This Court has jurisdiction over matters first raised on appeal if "the issue raised relate[s] to the validity of a statute or regulation, or an interpretation thereof, *and* that it have been relied on by the [] court in its decision." *Smith* at 1333.

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CONCLUSION AND RELIEF SOUGHT

For any or all of the reasons cited herein, we respectfully ask this Honorable Court to reverse Judge Davis' Decision and order that this matter be remanded to the U.S. Court of Federal Claims for further proceedings under correct instructions
and grant such other and further relief as this Court may deem just, equitable, and proper.

Dated: Staten Island, New York October 24, 2022

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<u>/ s / R.J.</u> R.J.

Family Representative – Vaccine Rule 14(a)(2) P.O. Box 100073, Staten Island NY 10310 Cell: (929) 352-4433 [call or text] Email: LitigantRJ@yahoo.com



Pursuant to the court's Memorandum Opinion And Order, filed June 21, 2022, affirming the special master's decision filed February 16, 2022,

IT IS ORDERED AND ADJUDGED this date, pursuant to Appendix B, Vaccine Rule 30, that petitioners' petition is dismissed.

Lisa L. Reyes Clerk of Court

By: Anthony Curry

Deputy Clerk

<u>NOTE</u>: As to petition for review, 60 days from this date, see Appendix B, Rule 32. Petition for review and filing fee of \$500.00 should be mailed to the following address: Clerk, U.S. Court of Appeals for the Federal Circuit, 717 Madison Place, NW, Washington, D.C. 20439.

IN THE UNITED STATES COURT OF FEDERAL CLAIMS

NOT FOR PUBLICATION

W.J., by his parents and legal guardians, R.J. and A.J.,))	
Petitioners,)	No. 21-1342V
v .))	Filed: June 21, 2022
SECRETARY OF HEALTH AND HUMAN SERVICES,)))	Reissued: July 7, 2022 ¹
Respondent.)))	

MEMORANDUM OPINION AND ORDER

Petitioners R.J. and A.J. seek review of a decision dismissing their request for vaccine injury compensation on behalf of their child, W.J. Petitioners filed their petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10 *et seq.* (the "Vaccine Act"), alleging W.J. suffered chronic encephalopathy (a Table injury) and immunodeficiency issues, including immune-related blood disorders, eczema, and allergies, as a result of receiving the measles, mumps, and rubella ("MMR") vaccine in February 2005. Petitioners claim the vaccine either directly caused the asserted injuries or significantly aggravated W.J.'s pre-existing cerebral and immunological damage. The Special Master dismissed the claims as untimely under the Vaccine Act's statute of limitations.

For the reasons discussed below, the Special Master's decision to grant Respondent's

¹ The Court issued this opinion under seal on June 21, 2022, and directed the parties to file any proposed redactions by July 6, 2022. On July 5, 2022, Petitioners requested the Court redact the case caption, as approved by the Special Master, but did not propose further redactions. *See* ECF No. 42. As such, the Court reissues the opinion publicly in full, with revisions to the case caption and first sentence of the text to protect the identity of Petitioners.

Motion to Dismiss was not arbitrary and capricious, an abuse of discretion, or otherwise not in accordance with law. Accordingly, the Court **DENIES** Petitioners' Motion for Review.

I. BACKGROUND

A. Factual History

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Petitioners alleged that W.J. was born a healthy, full-term infant on February 4, 2004, without significant neonatal problems. Pet. Ex. 1 at 1, ECF No. 1-2. He received routine vaccinations throughout his childhood, including influenza, hepatitis B, diphtheria-tetanus-acellular pertussis, Haemophilus influenzae type B, pediatric pneumococcal, polio, and MMR. Pet. Ex. 2 at 1, ECF No. 1-2. His MMR vaccines were administered on February 24, 2005, and March 15, 2008, without record of adverse reactions. *Id*.

On March 7, 2006, at the age of two, doctors diagnosed W.J. with a speech delay. Pet. Ex. 6 at 13, ECF No. 1-2. W.J.'s blood tests showed high platelet levels and low lymphocyte levels. Pet. Ex. 9 at 1, ECF No. 1-2. Subsequent audiologic evaluation in June 2006 revealed adequate hearing. *Id.* The following year, on January 5, 2007, doctors diagnosed W.J. with autism and pervasive developmental delay. Pet. Ex. 39 at 17, ECF No. 20-1. Pediatric neurologists determined that W.J.'s developmental delays and language disorder required intensive therapeutic programs. Pet. Ex. 13 at 1, ECF No. 1-2.

Over the next 15 years, W.J. presented to doctors for various physical and psychological ailments. From June 22 to 25, 2007, he was hospitalized with a fever and swollen glands consistent with a bacterial infection. Pet. Ex. 12 at 11, ECF No. 1-2. On February 20, 2012, he was assessed by doctors for "unstable atopic dermatitis" and tested for lead poisoning. Pet. Ex. 7 at 7, ECF No. 1-2. On February 19, 2014, he returned for treatment of severe eczema and rhinitis, conditions that the treating physician noted had gone untreated over the objections of W.J.'s healthcare

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providers. *Id.* at 10. W.J.'s behavioral problems, including irritability, mood swings, and poor sleep, prompted doctors to perform a comprehensive psychiatric evaluation on July 19, 2018. Pet. Ex. 71 at 59, ECF No. 1-2. Following this evaluation, doctors attempted to manage W.J.'s behaviors over the next three years with antipsychotic medications. *Id.* at 3. In February 2019, genetic testing revealed that W.J. has an MTHFR homozygous A1298C mutation and duplication of the Xq28 chromosome of uncertain clinical significance. Pet. Ex. 11 at 4, 6, 8, ECF No. 1-2; Pet. Ex. 14 at 1, ECF No. 1-2.

Based on a review of the medical records, the Special Master found that at no point did doctors diagnose W.J. with encephalopathy or immunodeficiency disorder. *See* Decision Den. Comp. at 8, ECF No. 29.

B. Procedural History

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On May 7, 2021, Petitioners filed a claim for vaccine injury compensation on behalf of W.J. See Pet., ECF No. 1. According to Petitioners, the MMR vaccine was inappropriately administered to W.J. in contravention of the vaccine's warnings because of W.J.'s Xq28 chromosomal duplication. *Id.* ¶ 17. As a result, Petitioners contend that W.J. has chronic encephalopathy and immunodeficiency issues caused either directly by the vaccine or by its significant aggravation of the pre-existing damage related to his chromosomal abnormality. *Id.* ¶ 19. They further contend these injuries led to several bouts of immune-related blood disorders and an infection resembling mumps that resulted in hospitalization. *See id.* ¶ 21–64.

On June 3, 2021, the Special Master held an initial status conference, during which she raised the issue of the statute of limitations. *See* Order dated June 3, 2021, at 1, ECF No. 14. Before addressing the merits of the claims, she directed Respondent to file a Rule 4(c) Report and Motion to Dismiss. *Id.* at 4–5. In accordance with this direction, Respondent moved to dismiss,

contending Petitioners filed their claims beyond the 36-month statute of limitations and that no basis for equitable tolling applied. *See* Resp't's Mot. to Dismiss, ECF No. 16. Respondent asserted that W.J.'s injuries, if they did exist, began to manifest by March 2006 when he was diagnosed with a speech delay. *See* Resp't's Rule 4(c) Report at 8, ECF No. 15. Accordingly, Respondent argued that the Vaccine Act required Petitioners to file a claim by no later than March 2009. *Id*.

The Special Master granted Respondent's Motion to Dismiss for failure to file a timely action under the Vaccine Act. ECF No. 29 at 2. Although the Special Master discussed the merits of Petitioners' claims throughout the decision, she dismissed the claims solely on the basis of the statute of limitations. *Id.* at 21. The Special Master explained that even if Petitioners were able to establish a viable Table Claim, cause-in-fact injury, or significant aggravation injury, their petition was filed beyond the Vaccine Act's 36-month filing period, which begins to run upon "the first symptom or manifestation of onset or of the significant aggravation of such injury." *Id.* at 8–9 (citing 42 U.S.C. § 300aa-16(a)(2)). Because Petitioners based their Table Claim on the MMR vaccine administered on February 24, 2005, and a Table Claim must manifest within 15 days of vaccination, the Special Master found they were required to file that claim no later than March 11, 2008. *Id.* at 12. Likewise, if W.J.'s speech delay—the alleged first manifestation of his chronic encephalopathy—was diagnosed on March 7, 2006, Petitioners were required to file the claim for a cause-in-fact injury by March 7, 2009.² *Id.* at 13. Similarly, the Special Master found that Petitioners were required to file a cause-in-fact injury claim related to any immunodeficiency issues by March 9, 2009, at the earliest, or April 8, 2017, at the latest. *Id.* at 14–15 (calculating

² The Special Master also noted that if W.J.'s autism diagnosis on January 5, 2007, was a first symptom or manifestation of the alleged chronic encephalopathy, the filing period expired on January 5, 2010. ECF No. 29 at 13.

36-month filing period based on abnormal blood tests on March 9, 2006, and April 13, 2007; unstable atopic dermatitis diagnosis on February 20, 2012; hospitalization on June 22–24, 2007; and high mumps count on April 8, 2014). She applied the same standard to the significant aggravation claim, finding it time-barred for the same reasons. *Id.* at 15.

The Special Master also rejected Petitioners' equitable tolling arguments. *Id.* at 16, 17–18. Although W.J. was an infant when he received the MMR vaccine, she held Petitioners, as his parents, retained the ability to file a claim on his behalf. *Id.* at 16. The Special Master therefore concluded that W.J.'s mental incapacity was not an extraordinary circumstance warranting equitable tolling. *Id.* She also determined that the doctrine of fraudulent concealment did not apply because Petitioners failed to plead facts demonstrating Respondent's alleged fraudulent conduct prevented them from timely pursuing compensation. *Id.* at 17–18.

On March 14, 2022, Petitioners filed a Motion for Review of the Special Master's decision. See Pet'rs' Mot. for Review, ECF No. 36; Pet'rs' Mem. of Obj., ECF No. 36-1. Petitioners challenge several aspects of the decision, including that the Special Master raised the statute of limitations issue sua sponte during the initial status conference and applied a purportedly incorrect legal standard to the motion. ECF No. 36-1 at 6. On April 14, 2022, Respondent responded to Petitioner's motion. See Resp't's Resp. to Pet'rs' Mot. for Review, ECF No. 39. It argues that the Special Master acted within her discretion by addressing timeliness as a potential threshold bar to recovery and properly applied both the standard of review and the case law governing equitable tolling. *Id.* at 12, 14.

II. LEGAL STANDARDS

A. Review of a Special Master's Decision

This Court has jurisdiction to review a special master's decision upon the timely request

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of either party. 42 U.S.C. § 300aa-12(e)(2). Under the Vaccine Act, a court deciding a motion for review may:

(A) uphold the findings of fact and conclusions of law of the special master's decision, (B) set aside any findings of fact and conclusions of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or (C) remand the petition to the special master for further action in accordance with the court's direction.

ld. §§ 300aa-12(e)(2)(A)–(C). The Court employs "a highly deferential standard" when reviewing a special master's decision. *Hines v. Sec'y of Health & Hum. Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991); *Munn v. Sec'y of Health & Hum. Servs.*, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992) (holding that findings of fact receive "great deference" under an "arbitrary and capricious" standard, legal conclusions are reviewed under the "not in accordance with law" standard, and discretionary rulings are reviewed for "abuse of discretion"). If the special master has "considered the relevant evidence of record, drawn plausible inferences[,] and articulated a rational basis for the decision," reversible error will be "extremely difficult" to demonstrate. *Lampe v. Sec'y of Health & Hum. Servs.*, 219 F.3d 1357, 1360 (Fed. Cir. 2000); *see Hayman v. United States*, No. 02-725V, 2005 WL 6124101, at *2 (Fed. Cl. May 9, 2005).

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On a motion for review, it is not the Court's role "to reweigh the factual evidence." *Doe* 93 v. Sec'y of Health & Hum. Servs., 98 Fed. Cl. 553, 565 (2011) (citing Lampe, 219 F.3d at 1360). Rather, "the probative value of the evidence [and] the credibility of the witnesses ... are all matters within the purview" of the special master as fact finder. *Id.* The Court should not substitute its judgment for that of the special master even though it may have reached a different conclusion. *Johnson v. Sec'y of Health & Hum. Servs.*, 33 Fed. Cl. 712, 720 (1995). This deference notwithstanding, when the matter for review is whether the special master's decision was in accordance with law---*i.e.*, when a question of law is at issue---the court reviews the decision de

novo. Althen v. Sec'y of Health & Hum. Servs., 418 F.3d 1274, 1277-78 (Fed. Cir. 2005).

B. Motion to Dismiss Standard

A motion to dismiss for failure to state a claim upon which relief may be granted "is appropriate when the facts asserted by the claimant do not entitle him to a legal remedy." *Lindsay* v. United States, 295 F.3d 1252, 1257 (Fed. Cir. 2002). It is well established that a complaint "must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)); Cary v. United States, 552 F.3d 1373, 1376 (Fed. Cir. 2009). A "plausible" complaint "does not need detailed factual allegations," but rather only enough "to raise a right of relief' beyond mere speculation. Twombly, 550 U.S. at 555. When reviewing a motion to dismiss for failure to state a claim, the Court may consider all allegations in the complaint and may also consider "matters incorporated by reference or integral to the claim, items subject to judicial notice, [and] matters of public record." A & D Auto Sales, Inc. v. United States, 748 F.3d 1142, 1147 (Fed. Cir. 2014) (citation omitted); see Terry v. United States, 103 Fed. Cl. 645, 652 (2012). "[A]ll well-pled factual allegations" should be assumed by the court as true and "all reasonable inferences [should be made] in favor of the nonmovant." United Pac. Ins. Co. v. United States, 464 F.3d 1325, 1327-28 (Fed. Cir. 2006). But "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements" are insufficient to prevent dismissal. Iqhal, 556 U.S. at 678.

In assessing motions to dismiss in the Vaccine Program, special masters have concluded that they "need only assess whether the petitioner could meet the Act's requirements and prevail, drawing all inferences from the available evidence in petitioner's favor." *Herren v. Sec'y of Health*

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& Hum. Servs., No. 13-1000V, 2014 WL 3889070, at *2 (Fed. Cl. Spec. Mstr. July 18, 2014); see also Warfle v. Sec'y of Health & Hum. Servs., No. 05-1399V, 2007 WL 760508, at *2 (Fed. Cl. Spec. Mstr. Feb. 22, 2007).

III. DISCUSSION

Petitioners raise nine objections to the Special Master's decision dismissing Petitioners' claims as untimely under the statute of limitations. These objections fall roughly into three categories. First, Petitioners contend the Special Master violated separation-of-powers principles by sua sponte ordering Respondent to file a motion to dismiss at the initial status conference. ECF No. 36-1 at 6. Second, they allege the Special Master erred in rejecting their equitable tolling arguments because she allegedly applied the wrong legal standard for reviewing a motion to dismiss. *Id.* at 10–11. Petitioners base this argument on the Special Master's alleged disbelief and rejection of their pleaded facts, which they argue demonstrate extraordinary circumstances and fraudulent concealment that warrants the tolling of the statute of limitations. *Id.* Finally, Petitioners contend the Special Master's decision went beyond the scope of Respondents' dismissal request and improperly ruled on the merits of Petitioners' claims. *Id.* at 8.

Having considered the arguments and record, the Court rejects Petitioners' objections and finds the Special Master acted rationally, within her discretion, and in accordance with law in finding Petitioners' claims time-barred by the statute of limitations. The issue of timeliness was apparent from the face of the Petition, and the Special Master did not force Respondent to adopt a particular legal strategy or position. Further, the Special Master applied the correct legal standard for a motion to dismiss by rejecting legal conclusions and determining that the pleaded facts, even accepted as true, did not justify equitable tolling. Moreover, regardless of whether the Special Master's decision included merits-type rulings, the sole basis of the decision was properly limited

to the statute of limitations question. Accordingly, the Special Master's decision is upheld.

A. The Special Master Did Not Violate Separation of Powers.

Petitioners first object to the Special Master raising the statute of limitations sua sponte during the initial status conference. *Id.* at 6. They contend that by directing the parties to brief the issue of timeliness, the Special Master violated the separation of powers or, at the least, created the appearance of impropriety by ordering Respondent to take a particular legal position and preemptively endorsing that position. *Id.* at 8. Respondent responds that there is nothing improper about a judge or special master raising a threshold, dispositive issue before reaching the merits of a party's claim. ECF No. 39 at 8.

The relevant exchange at the initial status conference is brief enough to reproduce in full.

On June 3, 2021, the Special Master addressed the parties as follows:

THE COURT: Okay. So I know you probably are aware of this based on the petition, there is a statute of limitations issue that we will need to address since that's a threshold issue, that is, if the statute of limitations has expired, then the case will be dismissed because it can no longer be brought. And I think that is something we probably need to deal with sooner rather than later so that we don't use a lot of your time, energy, and money and the Court's time and energy litigating a case where the statute of limitations has expired.

And by talking about this I'm not diminishing in any way the experiences and the difficulty that your family has had. I just don't want to lead you to have any unrealistic expectations about how the case may proceed.

So I think the best course of action . . . is probably for [Respondent] to file a Rule 4 report with any motion to dismiss or other legal filing with regard to the statute of limitations. And then I can ask [Petitioner] to file any reply or response which he may wish to do so, and then I can rule on that issue. [Respondent], what are your thoughts about that plan?

[RESPONDENT'S COUNSEL]: Yes, Special Master, that sounds like an appropriate plan.

THE COURT: [Petitioner], does that plan -- is that plan acceptable with you?

[PETITIONER]: That sounds fair. Yes.

Tr. at 4:6–5:9, ECF No. 19. Following the initial status conference, the parties submitted full briefing, which the Special Master subsequently reviewed. ECF No. 29 at 2. In her decision, the Special Master noted that she "ordered" Respondent to file a Rule 4(c) Report and Motion to Dismiss on the issue of the statute of limitations. *Id.*

Petitioners characterize the exchange at the status conference as a significant violation of judicial propriety because it showed the Special Master's desire to dismiss the case. ECF No. 36-1 at 8. They argue that her decision "is irreparably tainted by ... separation-of-powers concerns" because of the so-called general principle that "she who orders the motion to be filed must not adjudge that motion's merit." Id. However, based on the relevant portion of the transcript, there is no evidence that the Special Master acted improperly by ordering briefing on the statute of limitations. The issue of timeliness was originally raised by Petitioners-not the Special Masterin the equitable tolling section of the Petition. See ECF No. 1 9 80-121. The Special Master did not abuse her discretion or act contrary to law by recognizing that a patent statute of limitations question could be outcome determinative and deciding that it would be prudent to address the issue at as early a stage as possible. Cf. Kreizenbeck v. Sec'y of Health & Hum. Servs., 945 F.3d 1362, 1366 (Fed. Cir. 2018) (endorsing use of summary judgment motion "at an early stage of the proceedings" where a party believes "that no material facts are in dispute and they will prevail as a matter of law"). By addressing the threshold timeliness issue before the merits, the Special Master efficiently used judicial resources to save the parties time, energy, and money litigating untimely claims, which is consistent with the goals of the Vaccine Act and applicable rules. See 42 U.S.C. § 300aa-12(d)(2)(A); see R. 3(b)(2), Rules of the U.S. Court of Federal Claims, app. B ("Vaccine Rules").

Nor does the transcript reflect that the Special Master ordered Respondent to take a particular position on the statute of limitations or otherwise display bias in favor of dismissal on that basis. The Special Master raised the issue at the status conference by explaining it was likely "the best course of action" for Respondent to file "any motion to dismiss or other legal filing with regard to the statute of limitations." ECF No. 19 at 4:22–25. Although the Special Master could have first inquired whether Respondent intended to raise a timeliness argument and then—having confirmed its intent-ordered briefing, that she reasonably anticipated Respondent's position does not rise to the level of an abuse of discretion. See Cottingham on Behalf of K.C. v. Sec'y of Health & Hum. Servs., 971 F.3d 1337, 1345 (Fed. Cir. 2020) ("An abuse of discretion occurs if the decision is clearly unreasonable, arbitrary, or fanciful; is based on an erroneous conclusion of law; rests on clearly erroneous fact findings; or involves a record that contains no evidence on which the [special master] could base [her] decision."). And the Special Master's "best course of action" statement most naturally indicates her determination that it was procedurally efficient to resolve the statute of limitations question first, as opposed to suggesting a particular legal argument would improve Respondent's chance of obtaining dismissal. Notwithstanding the briefing order, the substance and scope of the legal arguments Respondent eventually made was entirely up to it, including whether the statute of limitations barred the claims, equitable tolling was warranted, or some other issue should be addressed before or contemporaneous with the issue of timeliness. Moreover, the Special Master solicited any objections from Petitioners (they posed none), id. at 5:9, and afforded Petitioners ample opportunity to be heard in opposition to the motion. See Kreizenbeck, 945 F.3d at 1366 (holding that, in reviewing the method of adjudicating a petitioner's claim, the material inquiry is whether the special master "afford[ed] each party a full and fair opportunity to present its case and create a record sufficient to allow review of [her] decision").

The Special Master then considered the literature and evidence provided by Petitioners and based her decision squarely on the pleaded facts and relevant law. ECF No. 29 at 2.

As such, the Court finds that the Special Master did not abuse her discretion in directing the parties to brief the statute of limitations issue following the initial status conference. The Special Master's decision should not be overturned on this ground.

B. The Special Master Did Not Misapply the Legal Standard In Ruling on Petitioners' Equitable Tolling Arguments.

Petitioners next object to the Special Master's rejection of their equitable tolling arguments. ECF No. 36-1 at 14–19. They contend the Special Master erred by failing to accept the pleaded facts as true for purposes of ruling on the motion to dismiss. *Id.* at 5. According to Petitioners, had the Special Master properly construed all reasonable inferences in their favor, she would have determined that the statute of limitations should be tolled because of extraordinary circumstances and the doctrine of fraudulent concealment. *Id.* at 7. Respondent responds that although special masters may not disregard well-pleaded facts when ruling on a motion to dismiss, the rules do not require they accept legal conclusions as true purely because they are couched as factual assertions. ECF No. 39 at 15. Respondent argues that the role of the special master is to draw reasonable inferences from the provided evidence and to determine if a viable claim exists by applying the law to such evidence and inferences. *Id.*

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Although the Vaccine Act and the Vaccine Rules contemplate case-dispositive motions, they do not expressly include a mechanism for a motion to dismiss. See 42 U.S.C. §§ 300aa-12(d)(2)(C)-(D); Vaccine R. 8(d) (providing that "[t]he special master may decide a case on the basis of a written motion[,]... [which] may include a motion for summary judgment," but not specifically mentioning a motion to dismiss). However, Vaccine Rule 1 provides that for any matter not specifically addressed by the Vaccine Rules, the special master "may regulate

(88 of 397)

applicable practice, consistent with these rules and with the purpose of the Vaccine Act, to decide the case promptly and efficiently." *See* Vaccine R. 1(b). Vaccine Rule 1 also provides that the Rules of the United States Court of Federal Claims ("RCFC") may apply to the extent they are consistent with the Vaccine Rules. Vaccine R. 1(c). Accordingly, there is a well-established practice of special masters' entertaining motions to dismiss under RCFC 12(b)(6), which provides for dismissal based on "failure to state a claim upon which relief can be granted." *See, e.g., Herren*, 2014 WL 3889070, at *1; *Bass v. Sec 'y of Health & Hum. Servs.*, No. 12-135V, 2012 WL 3031505, at *5 (Fed. Cl. Spec. Mstr. June 22, 2012). This includes in cases where Respondent raised a statute of limitations argument. *See, e.g., Clubh v. Sec 'y of Health & Hum. Servs.*, 136 Fed. Cl. 255, 263 (2018); *J.H. v. Sec 'y of Health & Hum. Servs.*, 123 Fed. Cl. 206, 215 (2015).

Section 300aa-16 of the Vaccine Act provides a limitations period for claims arising from vaccines administered after October 1, 1988. It reads:

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[I]f a vaccine-related injury occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program 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[.]

42 U.S.C. § 300aa-16(a)(2). The Federal Circuit has held that the Vaccine Act's limitations period begins to run from the onset of the "first event objectively recognizable as a sign of a vaccine injury by the medical profession at large," *Carson v. Sec'y of Health & Hum. Servs.*, 727 F.3d 1365, 1368 (Fed. Cir. 2013) (quoting *Markovich v. Sec'y of Health & Hum. Servs.*, 477 F.3d 1353, 1360 (Fed. Cir. 2007)), even if the symptom did not result in a diagnosis at the time or was not appreciated until after a doctor definitively diagnosed the injury, *id.* at 1369–70. Special Masters have regularly dismissed cases filed outside the limitations period, even if by only a single day. *See, e.g., Spohn v. Sec'y of Health & Hum. Servs.*, No. 95-0460V, 1996 WL 532610 (Fed. Cl. Spec. Mstr. Sept. 5, 1996) (dismissing case filed one day beyond the limitations period), *aff'd*, 132 F.3d 52 (Fed. Cir. 1997); *Cakir v. Sec'y of Health & Hum. Servs.*, No. 15-1474V, 2018 WL 4499835, at *4 (Fed. Cl. Spec. Mstr. July 12, 2018) (dismissing case filed two months beyond the limitations period).

The Federal Circuit has held that the doctrine of equitable tolling can apply to Vaccine Act claims in limited circumstances. See Cloer v. Sec'y of Health & Hum. Servs., 654 F.3d 1322, 1340–41 (Fed. Cir. 2011). To establish that equitable tolling is appropriate, claimants must prove: (1) they pursued their rights diligently; and (2) an extraordinary circumstance prevented them from timely filing their claim. K.G. v. Sec'y of Health & Hum. Servs., 951 F.3d 1374, 1379 (Fed. Cir. 2020) (citing Menominee Indian Tribe v. United States, 577 U.S. 250, 255 (2016)); see Baldwin Cnty. Welcome Ctr. v. Brown, 466 U.S. 147, 151 (1984) ("One who fails to act diligently cannot invoke equitable principles to excuse that lack of diligence."). Extraordinary circumstances exist when the "failure to file was the direct result of a mental illness or disability that rendered [the claimant] incapable of rational thought, incapable of deliberate decision making, incapable of handling [his or her] own affairs, or unable to function in society." K.G., 951 F.3d at 1381. But "[a] medical diagnosis alone or vague assertions of mental problems are insufficient" to establish extraordinary circumstances. Id. at 1381-82. To determine whether a mentally incapacitated claimant has demonstrated reasonable diligence, the Court must consider "all relevant facts and circumstances," including whether he or she had a legal guardian and the significance of that relationship. Id. at 1382 (holding that a court should evaluate the significance of a legal guardian based on a number of factors, including "the nature and sophistication of the guardian (parent, lawyer, family member, or third-party), the timing of the institution of the guardianship (before or after the vaccination, for example), ... the extent to which the claimant's mental incapacity interferes with her relationship and communication with her guardian, [and] the quality and nature

of the guardian's relationship with the claimant").

The doctrine of fraudulent concealment may also toll a statute of limitations where, "assuming due diligence on the part of the plaintiff . . . the misconduct in question 'has been concealed, or is of such character as to conceal itself." *Simmons Oil Corp. v. Tesoro Petroleum Corp.*, 86 F.3d 1138, 1142 (Fed. Cir. 1996) (citing *Bailey v. Glover*, 88 U.S. 342, 349–50 (1874)). However, "a mere failure to come forward with facts that would provide the plaintiff with a basis for suit does not constitute fraudulent concealment." *Id.* The Court has not located any caselaw applying this doctrine to a petition for compensation brought pursuant the Vaccine Act, nor do Petitioners cite cases on the matter of whether it applies in this context.

Petitioners argue that the Special Master misapplied the legal standard on a motion to dismiss by disregarding several of their factual assertions "simply because she didn't believe them." ECF No. 36-1 at 10. As an example, they note their allegation that W.J. has been unable to communicate for much of his life and is cerebrally incapacitated, which prevented them from fully assessing his injury from the MMR vaccine in time to file a claim. *Id.* at 14–15. They also reference at length the facts surrounding the Omnibus Autism Proceeding ("OAP") as evidence that Respondent concealed the link between the MMR vaccine and autism, which they assert discouraged them from filing a claim. *Id.* at 15–18. The Special Master ultimately rejected their arguments on equitable tolling, finding that "W.J.'s 'mental incapacity' does not serve as 'an extraordinary circumstance,'" ECF No. 29 at 16, and that the fraudulent concealment claim failed due to lack of evidence, *id.* at 18. Petitioners point to the Special Master's statement that she formed "inferences *from the available evidence*" as an example of her alleged legal error because, according to Petitioners, "[e]vidence should not be a factor" when determining whether a party states a viable claim for relief at the pleadings stage. ECF No. 36-1 at 11.

The record reflects that the Special Master acted in accordance with law in dismissing Petitioners' equitable tolling arguments. The basis for Petitioners' disagreement on this issue apparently stems from a misunderstanding of the role of a special master in ruling on a motion to dismiss. When determining if a petition states a viable claim for relief, special masters are not bound to accept legal conclusions as true. Only well-pleaded facts are presumed to be true. See Hill v. Sec'y of Health & Hum. Servs., No. 19-384V, 2020 WL 7231990, at *2 (Fed. Cl. Spec. Mstr. Nov. 13, 2020) (citing Papasan v. Allain, 478 U.S. 265, 286 (1986)); United Pac. Ins., 464 F.3d at 1327–28. A petition need only state a plausible claim for relief to survive a motion to dismiss, and special masters are tasked with applying the law to the pleaded facts to determine whether a case should move forward. *Iqbal*, 556 U.S. at 678. Although Petitioners may have alleged that extraordinary circumstances existed because of W.J.'s inability to communicate and that Respondent concealed information by contesting the link between vaccines and autism, the Special Master concluded that the sum of these alleged facts did not as a matter of law warrant equitable tolling. In reaching her decision, she assessed "all inferences from the available evidence" but, as Petitioners fail to note, she did so "in petitioner's favor." ECF No. 29 at 15 (emphasis added).

First, in considering whether the statute of limitations should be tolled because of extraordinary circumstances, the Special Master rejected Petitioners' arguments because—as a minor—the law required W.J.'s parents to file a claim on his behalf regardless of his mental capacity. The Special Master distinguished the circumstances of the instant case from those presented in K.G. In K.G., the Federal Circuit held that equitable tolling may apply in a case involving a vaccine injury suffered by an adult claimant who subsequently became incapacitated due to alcoholism, hospitalization, and amnesia. K.G., 951 F.3d at 1379. The Special Master

explained that, although K.G. "confirmed an equitable tolling right for incapacitated individuals, nothing in the decision negated a legal representative's rights and responsibilities under the Vaccine Act." ECF No. 29 at 16 (citing K.G., 951 F.3d at 1379). Put another way, the Special Master accepted Petitioners' facts as true—that W.J. had a mental incapacity—but still concluded that these facts did not amount to extraordinary circumstances under the legal principles elucidated in K.G. because Petitioners retained the right to sue on his behalf. See id. This is not an erroneous application of the standard of review for a motion to dismiss pursuant to RCFC 12(b)(6).

Petitioners argue that an injured party's relationship to their legal guardian is only one factor to be considered under the extraordinary circumstances analysis. ECF No. 36-1 at 15 (citing K.G., 951 F.3d at 1382). According to Petitioners, even if they were required to sue on W.J.'s behalf, they were unable to because his mental capacity and inability to communicate interfered with their ability to assess the basis of the claim. Id. Petitioners correctly state the law but, as Respondent noted in its Rule 4(c) Report, the Special Master must "analyze[] the facts to determine whether [the] legal guardianship alleviated the extraordinary circumstance" of the petitioner's mental incapacity. ECF No. 15 at 9 (quoting K.G., 951 F.3d at 1381). In this case, even though Petitioners attempt to thread their argument through W.J.'s speech delay, the Special Master considered all facts in the record and found that this did not amount to extraordinary circumstances. See K.G., 951 F.3d at 1382 ("[T]he reasonable diligence inquiry must also be based on a consideration of all relevant facts and circumstances." (emphasis added)). The Special Master found that, as in any vaccine case involving a child, "[t]he Vaccine Act expressly permits a legal representative to file a petition for compensation on behalf of a minor," and W.J.'s injuries objectively manifested prior to the expiration of the statute of limitations. ECF No. 29 at 16. Given the "great deference" afforded to the Special Master in applying the law to the facts of the

case, the Court does not find that her ruling on extraordinary circumstances (or the lack thereof) was arbitrary and capricious. *Munn*, 970 F.2d at 870.

Second, in considering whether the statute of limitations should be tolled under the doctrine of fraudulent concealment, the Special Master rejected Petitioners' arguments because the facts (accepted as true) did not demonstrate how the alleged fraud prevented them from seeking compensation. Petitioners argued that Respondent "fostered and promoted the scientific finding" that there is no link between the MMR vaccine and autism. ECF No. 1 ¶ 100. Petitioners assert that they included "hard evidence of a link between vaccines and autism" in the form of recent cases involving families who obtained compensation for their child's autism on the basis of a vaccine injury. ECF No. 36-1 at 12. But the framing of this narrow issue is important. For purposes of the Motion to Dismiss, the relevant question before the Special Master was not whether there is a link between vaccines and autism. The relevant question was whether Petitioners alleged facts demonstrating they were misled by Respondents such that equitable tolling is appropriate because Respondent engaged in fraud. *See Holmberg v. Armbrecht*, 327 U.S. 392, 396–97 (1946) (noting that fraudulent concealment requires the claimant be misled "without any fault or want of diligence").

Accepting the pleaded facts as true, the Special Master observed that during the period in which Petitioners contended they were misled by Respondent, over 5,100 petitions alleging that vaccines caused autism were filed under the Vaccine Act in the OAP. ECF No. 29 at 19. In other words, their argument was significantly undercut by the fact that Respondent's position to the contrary did not dissuade or prevent thousands of other claimants with similar claims from filing suit. Fraud also typically requires a showing of intent on behalf of the defrauder to make a false or misleading statement. *See XpertUniverse Inc. v. Cisco Sys., Inc.*, 597 F. App'x 630, 635 (Fed.

Cir. 2015). The fact that a special master awarded compensation, or Respondent agreed to settle, a vaccine-related injury claim involving autism does not raise such an inference. Indeed, the Petitioner disavowed any allegation that Respondent engaged in intentional fraud. ECF No. 1 ¶ 103. Based on these facts, as well as evidence that the first symptom or onset of W.J.'s injury occurred at the earliest in 2006 (again, accepting Petitioners' allegations as true), the Special Master properly concluded that Petitioners had sufficient time both before and after the OAP to seek compensation.³ *Id.*

Lastly, the Court need only briefly address Petitioners' arguments regarding the Fourteenth Amendment.⁴ Petitioners claim that denying equitable tolling in this case would be discriminatory against W.J. on the basis of his disability because courts have not denied such relief to other individuals who suffered from drug- and alcohol-based mental incapacity (for example, in *K.G.*).⁵ ECF No. 1 ¶ 114. The Special Master disagreed, holding that Petitioners—who as W.J.'s parents had the right and responsibility to seek compensation on his behalf—did not demonstrate they were members of a protected class of persons. ECF No. 29 at 20. Moreover, the Special Master correctly noted that the Vaccine Act's limitations period does not establish any classifications

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³ In their response to the Motion to Dismiss, Petitioners argued that they did not discover Respondent's fraud until they received W.J.'s genetic testing results in March 2019 and were put on notice of the potential claim. Pet'rs' Mem. of Law in Opp'n to Resp't's Mot. to Dismiss at 17, ECF No. 22. The Special Master correctly characterized this argument as raising the discovery rule. ECF No. 29 at 17. She also correctly rejected it. The Federal Circuit made clear in *Cloer* that a claim under the Vaccine Act accrues when the first symptom or manifestation of onset occurs, not when the petitioner learned of the alleged cause of his or her injury. 654 F.3d at 1338.

⁴ Although Petitioners listed an objection based on this ground, they did not include any substantive argument in their Motion for Review.

⁵ It should be noted that the Federal Circuit did not hold that equitable tolling in fact applied in K.G.'s case. Rather, the Court remanded the case to the special master "to consider all of the relevant facts in the first instance, with the purposes of the Vaccine Act in mind," "under the standard set out in this opinion." K.G., 951 F.3d at 1382.

(suspect or otherwise) but rather treats all vaccine-injury claimants equally. *Id.* (citing *Cloer v. Sec'y of Health & Hum. Servs.*, 85 Fed. Cl. 141, 151–52 (2008), *rev'd on other grounds*, 603 F.3d 1341. Whether a claimant has established that equitable tolling applies is likewise not dependent on any particular classification of claimants. *See K.G.*, 951 F.3d at 1382. That the Special Master found the facts and circumstances of this case not to warrant equitable tolling and to be distinguishable from *K.G.* does not amount to an equal protection violation. Petitioners' argument on review is squarely a disagreement with the Special Master's application of the established case law. The Special Master did not "disbelieve" pleaded facts on this point; she merely rejected Petitioners' interpretation of the law. *Id.*

In sum, the Court finds that the Special Master correctly applied the legal standard for a motion to dismiss under RCFC 12(b)(6) in denying equitable tolling of Petitioners' claims. Thus, there is no cause for reversal on this ground.

C. Any Merits-Type Rulings Do Not Provide a Basis to Set Aside the Decision.

Petitioners' final objection relates to the scope of the Special Master's decision. They claim the Special Master went beyond the stated grounds of the Motion to Dismiss (*i.e.*, the statute of limitations question) by finding that Petitioners had not proven their factual allegations of injury. ECF No. 36-1 at 9–10. The Court agrees with Respondent that to the extent the Special Master made rulings on the merits of Petitioners' underlying claims, those rulings did not serve as a basis for her dismissal decision. *See* ECF No. 39 at 14. Rather, the decision repeatedly held that—even if Petitioners were able to establish their claims—the Petition was time-barred and that no equitable tolling applied. *See* ECF No. 29 at 12–13, 14, 15, 16, 18. And it in no uncertain terms concluded that the case must be "dismissed for failure to timely file the petition within the statute of limitations." *Id.* at 21. Accordingly, as the rulings were not necessary to the Special Master's

statute-of-limitations analysis and did not affect the stated basis for dismissal, Petitioners have not shown that any legal error resulted.⁶

IV. CONCLUSION

For the reasons set forth above, Petitioners have not shown that the Special Master's decision dismissing their claims on the basis of the statute of limitations was arbitrary and capricious, an abuse of discretion, or otherwise not in accordance with law. Accordingly, the Special Master's decision is affirmed, and Petitioners' Motion for Review (ECF No. 36) is **DENIED**. Under Vaccine Rule 30(a), the Clerk is directed to enter judgment accordingly.

SO ORDERED.

Dated: June 21, 2022

/s/Kathryn C. Davis KATHRYN C. DAVIS Judge

⁶ As such, the Court need not address whether the substance of these rulings were arbitrary and capricious because such a determination would not save Petitioners' otherwise untimely claims.

In the United States Court of Federal Claims OFFICE OF SPECIAL MASTERS

Filed: February 16, 2022

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June, on behalf of their minor child	*		
W.J.,	*	UNPUBLISHED	
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Petitioners,	*	No. 21-1342V	
	*		
v .	*	Special Master Nora Beth Dorsey	
	*		
SECRETARY OF HEALTH	*	Dismissal Decision; Measles, Mumps,	
AND HUMAN SERVICES,	*	and Rubella ("MMR") Vaccine;	
	*	Encephalopathy; Statute of Limitations;	
Respondent.	*	Equitable Tolling.	
-	*		
* * * * * * * * * * * * *			

<u>Reaching and Apply Junear</u>, pro se, Staten Island, NY, for petitioners. <u>Sarah B. Rifkin</u>, U.S. Department of Justice, Washington, DC, for respondent.

DECISION¹

I. INTRODUCTION

On May 7, 2021, Restant and April Justice ("petitioners") filed a petition, on behalf of their minor child, W.J., pursuant to the National Vaccine Injury Compensation Program ("Vaccine Act" or "the Program"), <u>42 U.S.C. § 300aa-10 et seq.</u> (2012).² Petitioners generally allege that their minor child, W.J., suffered from a chronic encephalopathy Table claim and/or a cause-in-

² The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, <u>100 Stat. 3755</u>, codified as amended, <u>42 U.S.C. §§ 300aa-10</u> to -34 (2012). All citations in this Decision to individual sections of the Vaccine Act are to <u>42 U.S.C. § 300aa</u>.

¹ Because this Decision contains a reasoned explanation for the action in this case, the undersigned is required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. <u>44 U.S.C. § 3501</u> note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Decision will be available to anyone with access to the Internet.** In accordance with <u>Vaccine Rule 18(b)</u>, petitioners have 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material from public access.

fact or significant aggravation of pre-existing cerebral and immunological damage, including immune-related blood disorders, severe eczema, and many other allergies as a result of a measles, mumps, and rubella ("MMR") vaccination administered on February 24, 2005. Petition at 1 (ECF No. 1).

Respondent filed a Motion to Dismiss in conjunction with his Rule 4(c) Report on August 2, 2021, stating, "[t]he petition in this case was [] filed beyond the relevant statutory limitations period, and petitioners have not provided a basis for the extraordinary remedy of equitable tolling," and therefore the petition should be dismissed. Respondent's Rule 4(c) Report ("Resp. Rept."), filed Aug. 2, 2021, at 12 (ECF No. 15); Resp. Motion to Dismiss ("Resp. Mot."), filed Aug. 2, 2021 (ECF No. 16). The undersigned agrees. Petitioners have failed to provide evidence to show why their case should not be dismissed.

Based on the reasons set forth below, the undersigned **GRANTS** respondent's motion to dismiss and **DISMISSES** petitioners' case for failure to file a timely action pursuant to Section 16(a)(2) of the Vaccine Act.

II. PROCEDURAL HISTORY

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Petitioners filed their claim on May 7, 2021, on behalf of their minor child, W.J. Petition at 1. Petitioners alleged W.J. suffered from chronic encephalopathy and immunological issues as a result of an MMR vaccination administered on February 24, 2005. <u>Id.</u> Petitioners filed a compact disc of medical records along with the petition. Petitioners' Exhibits ("Pet. Exs.") 1-29.

On May 13, 2021, the case was assigned to the undersigned. Notice of Reassignment dated May 13, 2021 (ECF No. 9). An initial status conference was held on June 3, 2021, and the undersigned raised the threshold question of the statute of limitations. Order dated June 3, 2021, at 1 (ECF No. 14). The undersigned ordered respondent to file a Rule 4(c) Report and Motion to Dismiss, and to set a briefing schedule for petitioners to file a response. Id.

Respondent filed a Motion to Dismiss and Rule 4(c) Report on August 2, 2021. Resp. Rept.; Resp. Mot. In September and October 2021, petitioners filed medical records, medical literature, and a response to respondent's motion to dismiss. Pet. Exs. 30-72; Pet. Response to Resp. Mot. ("Pet. Response"), filed Sept. 30, 2021 (ECF No. 22). Respondent filed a reply to petitioners' response on October 28, 2021. Resp. Reply, filed Oct. 28, 2021 (ECF No. 27).

This matter is now ripe for adjudication.

III. PARTIES' CONTENTIONS

A. Petitioners' Contentions

Petitioners first allege that the MMR vaccine was inappropriately administered to W.J. in contravention of the vaccine's warnings due to W.J.'s Xq28 chromosomal duplication. Petition at 3. Petitioners contend "[m]any chromosomal aberrations cause immunodeficiencies" and the MMR vaccine was contraindicated for individuals with "[p]rimary and acquired

immunodeficiency states." <u>Id.</u> The MMR vaccine insert also cautions against vaccination "to persons with a history of cerebral injury." <u>Id.</u> Petitioners state the MMR vaccine "significantly aggravated [W.J.'s] pre-existing immunodeficiency, stemming from his Xq28 duplication." <u>Id.</u> Additionally, petitioners allege that W.J.'s "chronic encephalopathy and immunodeficiency issues were either directly caused by the administration of the MMR vaccine, or that the MMR vaccine significantly aggravated pre-existing cerebral and immunological damage caused by [W.J.'s] chromosomal aberration." <u>Id.</u> at 3-4, 11.

Second, petitioners allege W.J. suffered from thrombocytosis,³ lymphocytopenia,⁴ lymphocytosis,⁵ monocytosis,⁶ granulocytopenia,⁷ severe eczema, and "many other allergies" that his "physicians offered no cause or diagnosis for." Petition at 4-8. They state "[o]ver the course of some seven years that followed the administration of [W.J.'s] MMR vaccine, [W.J.'s] immune system struggled with no less than four immuno-related blood disorders . . . and a several years long battle with severe eczema, and many other allergies." Id. at 8. Petitioners state that because W.J.'s physicians found no cause for his conditions, "in the absence of any evidence to the contrary, [] the many immuno-related adverse events were caused by the MMR vaccine administration to [W.J.] on February 24, 2005." Id. at 20.

Third, petitioners allege W.J. had an extremely high mumps antibody count on April 18, 2014, which "may be indicative of an unusual and chronic allergic reaction to the MMR vaccine." Petition at 8.

Petitioners also allege that W.J. was admitted to the emergency room on June 22, 2007, for a swollen jaw and face, and a high fever. Petition at 8. His blood test showed a high white blood cell count and high lymphocyte, monocyte, and granulocyte counts. <u>Id.</u> at 9. Petitioners

⁴ Lymphocytopenia is the "reduction in the number of lymphocytes in the blood." <u>Lymphocytopenia</u>, Dorland's Online Med. Dictionary, https://www.dorlandsonline.com/ dorland/definition?id=29030 (last visited Feb. 3, 2022).

⁵Lymphocytosis is the "excess of normal lymphocytes in the blood or in any effusion." <u>Lymphocytosis</u>, Dorland's Online Med. Dictionary, https://www.dorlandsonline.com/dorland/ definition?id=29034 (last visited Feb. 3, 2022).

⁶ Monocytosis is the "increase in the proportion of monocytes in the blood." <u>Monocytosis</u>, Dorland's Online Med. Dictionary, https://www.dorlandsonline.com/dorland/definition? id=31969 (last visited Feb. 3, 2022).

⁷ Granulocytopenia is the "reduction in the number of granular leukocytes in the blood." <u>Granulocytopenia</u>, Dorland's Online Med. Dictionary, https://www.dorlandsonline.com/dorland/ definition?id=20930 (last visited Feb. 3, 2022).

³ Thrombocytosis is "an increase in the number of circulating platelets; called also thrombocythemia." <u>Thrombocytosis</u>, Dorland's Online Med. Dictionary, https://www.dorlandsonline.com/dorland/definition?id=49877 (last visited Feb. 3, 2022).

state W.J.'s "symptoms during this hospitalization were very similar to mumps, which may point to some adverse chronic reaction to the MMR vaccine." Id.

Fifth, petitioners contend W.J. suffered from an encephalopathy Table injury after MMR vaccine administration. Petition at 10. "Prior to the administration of the MMR vaccine on February 24, 2005, [W.J.'s] medical records indicate no developmental delays or any other indication of mental incapacitation." Id. Petitioners allege that "[a]fter the administration of the MMR vaccine, [W.J.'s] developmental delays soon began to surface." Id. "The table injury timeframe for [W.J.'s] MMR injury is the fifteen days between February 24, 2005 and March 11, 2005." Id. at 11.

Sixth, petitioners allege equitable tolling of the statute of limitations is warranted. Petition at 12. Petitioners state W.J.'s encephalopathy is an "extraordinary circumstance" that tolls the statute of limitations in cases under the Vaccine Act and cite <u>K.G. v. Secretary of Health</u> <u>& Human Services</u>, <u>951 F.3d 1374</u> (Fed. Cir. 2020) for support. Petitioners contend the Federal Circuit in <u>K.G.</u> held "that equitable tolling under the Vaccine Act applied to an adult who was mentally incapacitated for some five years. . . . It stands to reason, then, that the same should apply to a minor with permanent brain damage." <u>Id.</u> at 13. Petitioners also state they exercised reasonable diligence in bringing this matter. <u>Id.</u> at 14. W.J. was diagnosed with autism and they "had no basis for questioning" his diagnosis. <u>Id.</u> at 15. However, petitioners state "that vaccines do sometimes cause or enhance autism-like symptoms." <u>Id.</u> at 16. Petitioners cite <u>Paluck v.</u> <u>Secretary of Health & Human Services</u>, <u>786 F.3d 1373, 1379</u> (Fed. Cir. 2015) where "K.P. won a favorable judgment based on his parents' amply supported allegation that he was a child 'suffering from both a mitochondrial disorder and autism who experienced developmental regression following vaccination." <u>Id.</u>

Petitioners discovered W.J.'s genetic aberration on March 19, 2019 and "soon came to the conclusion that because of the Xq28 duplication, [W.J.], in spite of his autism-like symptoms, either might not be autistic at all or that the Xq28 duplication is a cause of his autism." Id. at 17. They allege that they realized in light of the genetic mutation, the MMR vaccine should not have been administered, and that the MMR vaccine caused W.J.'s permanent injury. Id. at 18. W.J.'s parents assert that they exercised reasonable diligence and "the statute of limitations in this matter began to toll no earlier than March 19, 2019, when [W.J.'s] parents were first informed of his Xq28 duplication." Id.

Petitioners also allege "[t]o consider equitable tolling for K.G.'s drug and alcohol induced mental incapacity, but not for [W.J.'s] congenital genetically-caused mental incapacity, would be disability discrimination in violation of [W.J.'s] Fourteenth Amendment rights." Petition at 18. Petitioners cite Justice Marshall's concurring in part opinion in <u>City of Cleburne</u>, <u>Tex. v. Cleburne Living Ctr., 473 U.S. 432</u> (1985) for support.

Finally, petitioners allege that the <u>K.G.</u> standard—"that the proper analysis of equitable tolling based on mental incapacity in the Vaccine Act context must consider both extraordinary circumstances and diligence"—applies in this matter. Petition at 19.

B. Respondent's Contentions

Respondent contends petitioners filed their claim for compensation "after the expiration of the statutorily prescribed limitations period set forth in Section 16(a)(2) of the Vaccine Act." Resp. Reply at 1. Further, respondent asserts that "petitioners have not demonstrated the extraordinary circumstances necessary to equitably toll the Act's statute of limitations." <u>Id.</u>

Specifically, respondent states "[s]ymptoms of W.J.'s alleged injury began to manifest before March 2006, when W.J. was diagnosed with a speech delay. Therefore, to comply with Section 16(a)(2) of the Vaccine Act, petitioners needed to file a petition on W.J.'s behalf by March 2009." Resp. Reply at 2. Respondent states that petitioners argue for the application of the discovery rule, "suggesting that the Act's statute of limitations should not have begun running until March 2019, when they conceived of a possible connection between W.J.'s autism and the MMR vaccine. The Federal Circuit has held that there is no explicit or implied discovery rule under the Vaccine Act." Id. at 3. "Accordingly, [respondent contends that] the statutory filing period began to run in 2006, when W.J. experienced the first symptoms of his autism spectrum disorder—not in 2019, when petitioners devised a purported connection between W.J.'s symptoms and the MMR vaccine." Id.

Regarding equitable tolling, respondent states, "petitioners have not shown a diligent pursuit of W.J.'s rights or extraordinary circumstances." Resp. Reply at 4. "The Federal Circuit has expressly held that equitable tolling is not a substitute for the discovery rule and is not available simply because the application of the statute of limitations would otherwise deprive a petitioner of his claim." Id. "W.J.'s age and incapacity are not bases for equitable tolling." Id. Respondent claims <u>K.G.</u> does not support petitioners' position. First, "K.G. was an incapacitated adult." Id. at 5. "Her relationship with her appointed guardian became strained and was later terminated." Id. "Accordingly, during the relevant time period, K.G. had no one to act on her behalf and was incapable of filing a claim under the Vaccine Act; for this reason, the Court found that equitable tolling was appropriate in her case." Id. Respondent alleges, "[u]nlike K.G., W.J. was an infant at the time of his vaccination, and his parents (the petitioners) were entirely capable of filing a claim on his behalf." Id. Respondent also argues that "[t]aken to its logical conclusion, petitioners' equitable tolling argument would essentially mean that the threeyear statute of limitations is irrelevant in all cases involving young children who cannot file claims on their own behalf. This is not what the Vaccine Act contemplates." Id.

Lastly, the respondent asserts that petitioners have not provided a procedural basis for their assertions. "Procedurally, petitioners have not demonstrated a basis for equitable tolling, and their claim should be dismissed as untimely." Resp. Reply at 6. To the extent that petitioners are asserting an injury based on their child's condition of autism, the respondent points out that "[s]ubstantively, it is important to note that the theory of MMR vaccines causing autism has been thoroughly evaluated and repeatedly rejected by the courts." Id.

IV. FACTUAL SUMMARY⁸

⁸ The factual summary is abbreviated to provide relevant information. Additionally, complete medical records were not filed. The records that have been filed, however, are sufficient for the purposes of this Decision.

W.J. was born on February 8, 2004. Pet. Ex. 1 at 1. He was a healthy, full-term infant, with no significant neonatal problems apart from meconium which was suctioned at birth. Pet. Ex. 5 at 1; Pet. Ex. 13.

W.J. received several childhood vaccinations, including influenza ("flu") vaccines from Dr. Stephen Borchman. Pet. Ex. 2 at 1. W.J. received his first hepatitis B vaccine on February 8, 2004, his second hepatitis B vaccine on May 12, 2004, and his third hepatitis B vaccine on August 23, 2004. <u>Id.</u> He also received his diphtheria-tetanus-acellular pertussis ("DTaP") vaccinations in April, June, and August 2004, August 2005, and February 2009. <u>Id.</u> The Haemophilus influenzae type B ("hib") vaccines were given at the same time as DTaP in April, June, and August 2004. <u>Id.</u> W.J. received his pediatric pneumococcal ("PCV7") and polio ("IPV") vaccinations in 2004, 2005, and 2009. <u>Id.</u> MMR vaccinations were administered on February 24, 2005 and March 15, 2008. <u>Id.</u> Flu vaccines were given in 2007, 2008, and 2010. <u>Id.</u> No adverse reaction to any of the vaccines was noted in the medical records.

On March 7, 2006, Dr. Ann Marie Abbondante examined W.J. and diagnosed him with a "speech delay." Pet. Ex. 6 at 13. W.J. then underwent an audiology evaluation on June 26, 2006, which revealed adequate hearing. Pet. Ex. 8 at 1. Dr. Abbondante ordered a blood test performed on March 9, 2006 that showed high platelet levels (424, normal range is 140-400) and low lymphocyte levels (3,276, normal range is 4,400-10,500). Pet. Ex. 9 at 1. Dr. Abbondante did not diagnose W.J. with encephalopathy or any immunodeficiencies.

On January 5, 2007, W.J. was diagnosed with Autism and Pervasive Developmental Delay following a psychological evaluation at Words 'N Motion Pediatric Multi-Disciplinary Diagnostic Evaluation and Treatment Center by Psychologist D. Jeanne Romeo. Pet. Ex. 39 at 17.

W.J. presented to Dr. John Wells, pediatric neurologist, for a neurologic evaluation on January 24, 2007. Pet. Ex. 13 at 1. Dr. Wells stated W.J.'s developmental delays and language disorder required intensive therapeutic programs. <u>Id.</u> At that time, Dr. Wells considered ordering an MRI and genetic testing depending on W.J.'s progress. <u>Id.</u> Dr. Wells did not diagnosis W.J. with encephalopathy.

From June 22 to June 25, 2007, W.J. was hospitalized with a fever and swollen glands. Pet. Ex. 12 at 11. W.J. presented in the emergency room with swelling in the jaw and neck, runny nose, and a moderately-sore throat. <u>Id.</u> at 9. His white blood cell count was consistent with a bacterial infection, and he was admitted to the hospital with a diagnosis of cervical lymphadenitis.⁹ <u>Id.</u> at 11, 18. Three days later, he was discharged with antibiotics. <u>Id.</u> at 11. Bloodwork performed on July 3, 2007, showed W.J. had an elevated white blood count (11.9, normal range is 4.8-10.8), elevated platelet count (548), as well as high monocyte (0.6, normal

⁹ Cervical lymphadenitis is the "enlarged, inflamed, and tender cervical lymph nodes, seen in certain infectious diseases of children, such as acute infections of the throat." <u>Cervical Lymphadenitis</u>, Dorland's Online Med. Dictionary, https://www.dorlandsonline.com/dorland/ definition?id=87515 (last visited Feb. 3, 2022).

range is 0.11-0.59) and lymphocyte numbers (5.9, normal range is 1.2-3.4). Pet. Ex. 10 at 7. W.J. was not diagnosed with encephalopathy at any time during this hospitalization. Additionally, W.J. was not diagnosed with any immunodeficiencies.

W.J. attended yearly follow-up visits with Dr. Borchman from February 2009 to February 2014. Pet. Ex. 7 at 3-11. On February 21, 2011, W.J. presented to Dr. Borchman for a follow up of strep throat. Id. at 5. Dr. Borchman noted W.J.'s moderate to severe autism diagnosis. Id. W.J. also received his first hepatitis A vaccine. Id. No adverse reaction to the vaccine was noted. During these years, W.J. was not diagnosed with encephalopathy or immunodeficiencies.

On February 20, 2012, W.J. returned to Dr. Borchman for atopic dermatitis. Pet. Ex. 7 at 7. Dr. Borchman again noted W.J.'s moderate to severe autism, and a past history of lead poisoning. Id.; Pet. Ex. 10 at 9. Dr. Borchman assessed W.J. for "unstable atopic dermatitis" and ordered heavy metal testing to rule out lead poisoning, plus allergy testing. Pet. Ex. 7 at 7. Dr. Borchman explained to petitioners there was a lack of data associating autism spectrum disorders with diet. Id. W.J.'s blood work showed he had numerous abnormal reactions to a variety of allergens and had an elevated platelet count (496). Pet. Ex. 10 at 11.

On February 19, 2014, W.J. returned to Dr. Borchman for eczema and rhinitis. Pet. Ex. 7 at 10. W.J. had numerous environmental allergies, and Dr. Borchman documented that his parents "refuse[] any steroid nasal sprays" and medications. Id. Dr. Borchman also expressed his concern with W.J.'s mother's refusal to use prescription steroid creams or any medications to control W.J.'s allergies. Id. at 10-11. W.J.'s mother agreed to return to W.J.'s immunologist, Dr. Russo, and to restart allergy and eczema medications. She refused the diphtheria, pertussis, and tetanus ("DPT") vaccine. Id. at 11.

On April 4, 2014, W.J. underwent a variety of lab tests, including genetic screening, ordered by Dr. Maya Klein. Pet. Ex. 11 at 1-10. Testing showed a normal blood panel, normal platelet count, and normal levels of heavy metals. <u>Id.</u> at 1-3. W.J. exhibited high antibodies to the mumps virus (71.2, negative range <9.0), and the records noted that "[a] positive result generally indicates past exposure to Mumps virus or previous vaccination." <u>Id.</u> W.J. also had elevated antibodies to the Streptococcus B virus (210, negative range 0-170), herpes virus (17.66, negative range, <0.76), and pneumonia virus (118, indeterminate range 100-320), noting "[v]alues >100 may indicate a recent infection . . . and need to be confirmed." <u>Id.</u> at 4, 6, 8. Genetic testing revealed a MTHFR homozygous A1298C mutation.¹⁰ <u>Id.</u> at 4, 6, 8.

¹⁰ MTHFR is "a common, autosomal recessive, inborn error of folate metabolism caused by mutation in the MTHFR gene (locus: 1p36.3), which encodes the enzyme. The chief biochemical finding is homocystinuria with normal levels of plasma methionine." <u>Methylene Tetrahydrofolate Reductase (MTHFR) Deficiency</u>, Dorland's Online Med. Dictionary, https://www.dorlandsonline.com/dorland/definition?id=30976 (last visited Jan. 21, 2022). "Clinical manifestations, age of onset, and severity are highly variable; characteristics include signs of neurologic damage ranging from psychiatric symptoms to fatal developmental delay, microcephaly, ectopia lentis, and thrombosis." <u>Id.</u>

W.J. presented to Dr. Maria Del Pilar Trelles-Thorne for a psychiatric evaluation on July 9, 2018. Pet. Ex. 71 at 59. Dr. Trelles-Thorne performed a comprehensive evaluation to help petitioners manage W.J.'s irritability, mood swings, and poor sleep. <u>Id.</u> Dr. Trelles-Thorne prescribed Risperdal.¹¹ <u>Id.</u> at 60.

W.J. returned to Dr. Trelles-Thorne on January 30, 2019, for medication management of irritability and disruptive behaviors. Pet. Ex. 71 at 32. Dr. Trelles-Thorne ordered a number of medications for W.J. and noted his autism spectrum disorder diagnosis. <u>Id.</u> at 33-34.

On February 22, 2019, W.J. underwent genetic testing that revealed he had a duplication on the Xq28 chromosome of "uncertain clinical significance—likely benign." Pet. Ex. 14 at 1.

On February 11, 2021, Dr. Trelles-Thorne saw W.J. for psychopharmacology evaluation. Pet. Ex. 71 at 2. W.J. was noted to have autism spectrum disorder and unspecified bipolar disorder. <u>Id.</u> Dr. Trelles-Thorne changed W.J.'s dosage of lithium.¹² <u>Id.</u> at 3. The records do not indicate that Dr. Trelles-Throne ever diagnosed W.J. with encephalopathy or any immunodeficiency disorder.

Although the petitioners allege that the MMR vaccination administered to W.J. on February 24, 2005 caused encephalopathy as well as a number of immunodeficiencies, the medical records do not include a diagnosis of encephalopathy or immunodeficiency disorder. See Petition at 1.

V. LEGAL FRAMEWORK

A. Vaccine Act Statute of Limitations

Section 16(a)(2) of the Vaccine Act governs claims resulting from vaccines administered after October 1, 1988, and reads,

if a vaccine-related injury occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program 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

¹¹ Risperdal is a trademark name for risperidone, "a benzisoxazole derivative used as an antipsychotic agent." <u>Risperdal</u>, Dorland's Online Med. Dictionary, https://www.dorlandsonline.com/dorland/definition?id=43964 (last visited Jan. 20, 2022); <u>Risperidone</u>, Dorland's Online Med. Dictionary, https://www.dorlandsonline.com/dorland/ definition?id=43965 (last visited Jan. 20, 2022).

¹² Lithium carbonate, the carbonate salt of lithium, is "used as a mood stabilizer in treatment of acute manic and hypomanic states in bipolar disorder and in maintenance therapy to reduce the intensity and frequency of subsequent manic episodes." <u>Lithium Carbonate</u>, Dorland's Online Med. Dictionary, https://www.dorlandsonline.com/dorland/definition?id=87087 (last visited Jan. 21, 2022).

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§ 16(a)(2). Therefore, claims resulting from vaccines administered <u>after</u> October 1, 1988 must be filed within 36 months of the first symptom or manifestation of onset of the alleged vaccine-related injury. The statute of limitations begins to run from the onset of the first objectively cognizable symptom, whether or not that symptom is sufficient for diagnosis. <u>Carson v. Sec'y of Health & Hum. Servs.</u>, 727 F.3d 1365, 1369 (Fed. Cir. 2013). Special masters have appropriately dismissed cases that were filed outside the limitations period, even by a single day or two. <u>See</u>, e.g., Spohn v. Sec'y of Health & Hum. Servs., No. 95-0460V, 1996 WL 532610 (Fed. Cl. Spec. Mstr. Sept. 5, 1996) (dismissing case filed one day beyond the 36-month limitations period), <u>aff'd</u>, 132 F.3d 52 (Fed. Cir. 1997); <u>Cakir v. Sec'y of Health & Hum. Servs.</u>, No. 15-1474V, 2018 WL 4499835, at *4 (Fed. Cl. Spec. Mstr. July 12, 2018).

B. Motion to Dismiss

Although the Vaccine Act and the Vaccine Rules contemplate case dispositive motions, the dismissal procedures included within the Vaccine Rules do not specifically include a mechanism for a motion to dismiss. See §§ 12(d)(2)(C)-(D); Vaccine Rule 8(d); Vaccine Rule 21. However, Vaccine Rule 1 provides that for any matter not specifically addressed by the Vaccine Rules, the special master may regulate applicable practice consistent with the rules and the purpose of the Vaccine Act. Vaccine Rule 1(b). Vaccine Rule 1 also provides that the Rules of the Court of Federal Claims ("RCFC") may apply to the extent they are consistent with the Vaccine Rules. Vaccine Rule 1(c).

Accordingly, there is a well-established practice of special masters entertaining motions to dismiss in the context of <u>RCFC 12(b)(6)</u>, which allows the defense of "failure to state a claim upon which relief can be granted" to be presented via motion. <u>See, e.g., Herren v. Sec'y of Health & Hum. Servs.</u>, No. 13-1000V, <u>2014 WL 3889070</u> (Fed. Cl. Spec. Mstr. July 18, 2014); <u>Bass v. Sec'y of Health & Hum. Servs.</u>, No. 12-135V, <u>2012 WL 3031505</u> (Fed. Cl. Spec. Mstr. June 22, 2012); <u>Guilliams v. Sec'y of Health & Hum. Servs.</u>, No. 11-716V, <u>2012 WL 1145003</u> (Fed. Cl. Spec. Mstr. Mar. 14, 2012); <u>Warfle v. Sec'y of Health & Hum. Servs.</u>, No. 05-1399V, <u>2007 WL 760508</u> (Fed. Cl. Spec. Mstr. Feb. 22, 2007).

Under <u>RCFC 12(b)(6)</u>, a case should be dismissed "when the facts asserted by the claimant do not entitle him to a legal remedy." <u>Extreme Coatings, Inc. v. United States, 109 Fed.</u> <u>Cl. 450, 453</u> (2013) (quoting <u>Lindsay v. United States, 295 F.3d 1252, 1257</u> (Fed. Cir. 2002)). In considering a motion to dismiss under <u>RCFC 12(b)(6)</u>, allegations must be construed favorably to the pleader. <u>Id.</u> (citing <u>Scheuer v. Rhodes, 416 U.S. 232, 236</u> (1974)). However, the pleading must "contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face." <u>Golden v. United States, 137 Fed. Cl. 155, 169</u> (2018) (quoting <u>Ashcroft v. Iqbal, 556 U.S. 662, 678</u> (2009)); see also Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 570 (2007).

"To determine whether a complaint states a plausible claim for relief, the court must engage in a context-specific analysis and 'draw on its judicial experience and common sense." <u>Golden, 137 Fed. Cl. at 169</u> (quoting <u>lqbal</u>, <u>556 U.S. at 679</u>). However, "Rule 12(b)(6) does not countenance . . . dismissals based on a judge's disbelief of a complaint's factual allegations." <u>Neitzke v. Williams</u>, <u>490 U.S. 319, 327</u> (1989). Nonetheless, on a motion to dismiss, courts "are not bound to accept as true a legal conclusion couched as a factual allegation." <u>Papasan v.</u> <u>Allain, 478 U.S. 265, 286</u> (1986). In assessing motions to dismiss in the Vaccine Program, special masters have concluded that they "need only assess whether the petitioner could meet the Act's requirements and prevail, drawing all inferences from the available evidence in petitioner's favor." <u>Herren, 2014 WL 3889070</u>, at *2; see also Warfle, 2007 WL 760508, at *2.

C. Doctrine of Equitable Tolling

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The Federal Circuit has held that the doctrine of equitable tolling can apply to Vaccine Act claims in limited circumstances. <u>See Cloer v. Sec'y of Health & Hum. Servs.</u>, <u>654 F.3d</u> <u>1322, 1340-41</u> (Fed. Cir. 2011). The Federal Circuit determined equitable tolling on the basis of mental incompetence is available in Vaccine Act cases. <u>K.G.</u>, <u>951 F.3d at 1381</u>. However, lack of knowledge of an actionable claim is not a basis for equitable tolling. <u>Id.</u> at 1380 (citing <u>Cloer</u>, <u>654 F.3d at 1344-45</u>).

To establish that equitable tolling of a statute of limitations is appropriate, a claimant must prove (1) he pursued his rights diligently and (2) an extraordinary circumstance prevented him from timely filing the claim. K.G., 951 F.3d at 1379 (citing Menominee Indian Tribe v. United States, 136 S. Ct. 750, 755 (2016). In K.G., the Federal Circuit determined "the proper analysis of equitable tolling based on mental incapacity in the Vaccine Act context must consider both extraordinary circumstances and diligence." Id. at 1381. All relevant facts and circumstances must be considered when determining whether a claimant pursued his rights diligently. Id. at 1382. "It is possible, for instance, that a reasonable amount of diligence for an individual with memory loss or hallucinations would equate to no diligence for an able-minded individual." Id. Additionally, "[a] claimant need only establish diligence during the period of extraordinary circumstances to meet this test." Id. (citing Checo v. Shinseki, 748 F.3d 1373, 1380 (Fed. Cir. 2014)).

To show extraordinary circumstances, "a Vaccine Act claimant must show that [his] failure to file was the direct result of a mental illness or disability that rendered [him] incapable of rational thought, incapable of deliberate decision making, incapable of handling [his] own affairs, or unable to function in society." <u>K.G., 951 F.3d at 1381</u>. However, "[a] medical diagnosis alone or vague assertions of mental problems are insufficient" to establish extraordinary circumstances. <u>Id.</u> at 1381-82.

Under the provisions of the Vaccine Act, a petition seeking compensation on behalf of a minor may only be filed by the minor's "legal representative," 11(b)(1)(A), a term which the Act defines as "a parent or an individual who qualifies as a legal guardian under State law." 33(2).

D. Equal Protection Under the Fourteenth Amendment

The Equal Protection Clause of the Fourteenth Amendment to the Constitution, and through the Due Process Clause of the Fifth Amendment, implicitly forbids most discriminations

by the Federal Government against individuals. <u>Bolling v. Sharpe, 347 U.S. 497</u> (1954). A potential violation of equal protection arises whenever the Government treats one group differently than it treats another while it pursues some social goal. <u>Black v. Sec'y of Health & Hum. Servs.</u>, 33 Fed. Cl. 546, 554 (1995), aff'd sub nom. <u>Black v. Sec'y of Health & Hum.</u> <u>Servs.</u>, 93 F.3d 781 (Fed. Cir. 1996). Legislation, which classifies people into favored and nonfavored groups based upon race, is subject to "strict scrutiny." <u>Palmore v. Sidoti</u>, 466 U.S. 429 (1984); Loving v. Virginia, 388 U.S. 1 (1967); Anderson v. Martin, 375 U.S. 399 (1964).

However, under the Vaccine Program, the Vaccine Act's limitation period is rationally related to the dual legitimate legislative purposes undergirding the Vaccine Act: (1) the settling of claims quickly and easily, and (2) the protecting of manufacturers from uncertain liability making "production of vaccines economically unattractive, potentially discouraging vaccine manufacturers from remaining in the market." <u>Cloer v. Sec'y of Health & Hum. Servs., 85 Fed.</u> <u>Cl. 141, 151-52</u> (2008) (quoting <u>Brice v. Sec'y of Health & Hum. Servs., 240 F.3d 1367, 1368</u> (Fed. Cir. 2001)), <u>rev'd on other grounds, 603 F.3d 1341</u> (Fed. Cir. 2010), <u>aff'd on rehearing en banc, 654 F.3d 1322</u> (Fed. Cir. 2011).

VI. **DISCUSSION**

A. Applicable Statute of Limitations in the Vaccine Program

1. Alleged Injuries in the Petition

Petitioners allege that W.J. sustained injuries, including "chronic encephalopathy and immunodeficiency issues," resulting from adverse effects of the MMR vaccination received on February 24, 2005. Petition at 3. Petitioners allege that W.J.'s "chronic encephalopathy and immunodeficiency issues were either directly caused by the administration of the MMR vaccine, or that the MMR vaccine significantly aggravated pre-existing cerebral and immunological damage caused by [W.J.'s] chromosomal aberration." <u>Id.</u> at 4. Petitioners also alleged that W.J. suffered from thrombocytosis, lymphocytopenia, lymphocytosis, monocytosis, granulocytopenia, severe eczema, and "many other allergies" that his "physicians offered no cause or diagnosis for;" an extremely high mumps antibody count on April 18, 2014, which "may be indicative of an unusual and chronic allergic reaction to the MMR vaccine;" and an emergency room visit for a swollen jaw and face and high fever, and "symptoms during this hospitalization were very similar to mumps, which may point to some adverse chronic reaction to the MMR vaccine." Petition at 4-9. Finally, petitioners allege W.J. suffered a chronic encephalopathy Table Claim. Id. at 11.

a. Petitioners' Table Claim

The Vaccine Injury Table defines chronic encephalopathy as a condition that "occurs when a change in mental or neurologic status, first manifested during the applicable Table time period as an acute encephalopathy or encephalitis, persists for at least 6 months from the first symptom or manifestation of onset or of significant aggravation of an acute encephalopathy or encephalitis." <u>42 C.F.R. § 100.3(d)(1)(i)</u>. Acute encephalopathy, for children less than 18 months of age, that presents without a seizure "is indicated by a significantly decreased level of

consciousness that lasts at least 24 hours." <u>42 C.F.R. § 100.3(c)(2)(i)(A)(1)</u>. Typical symptoms of encephalopathy include, but do not in themselves demonstrate an acute encephalopathy or a significant change in either mental status or level of consciousness, "[s]leepiness, irritability (fussiness), high-pitched and unusual screaming, poor feeding, persistent inconsolable crying, bulging fontanelle, or symptoms of dementia." <u>42 C.F.R. § 100.3(c)(2)(i)(C)</u>. Exclusionary criteria for encephalopathy include, "[a]n underlying condition or systemic disease shown to be unrelated to the vaccine (such as malignancy, structural lesion, psychiatric illness, dementia, genetic disorder, prenatal or perinatal central nervous system (CNS) injury)." <u>42 C.F.R. § 100.3(c)(2)(ii)(A)</u>. The time period for first symptom or manifestation of onset or of significant aggravation of encephalopathy is between 5 and 15 days after MMR vaccine administration. <u>42 C.F.R. § 100.3(a)(III)(B)</u>.

Petitioners alleged, "[p]rior to the administration of the MMR vaccine on February 24, 2005, [W.J.'s] medical records indicate no developmental delays or any other indication of mental incapacitation." Petition at 10. "After the administration of the MMR vaccine, [W.J.'s] developmental delays soon began to surface." <u>Id.</u> Petitioners cited W.J.'s March 7, 2006 doctor's appointment where he was diagnosed with speech delay as evidence of his developmental delays.

Petitioners claim,

Given the before and after circumstantial evidence in the record, and based on the record as a whole, the Special Master should find that "the first symptom or manifestation of onset" of [W.J.'s] chronic encephalopathy, or the "significant aggravation" of a pre-existing encephalopathy, occurred within the fifteen-day time period described in the Vaccine Injury Table, "even though the occurrence of such symptom or manifestation within the time period was not recorded." <u>42</u> U.S.C. § 300aa-13(b)(2).

Petition at 11.

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"The symptoms associated with an acute encephalopathy are neither subtle nor insidious." <u>Blake v. Sec'y of Health & Hum. Servs.</u>, No. 03-31V, <u>2014 WL 2769979</u>, at *6 (Fed. Cl. Spec. Mstr. May 21, 2014) (quoting <u>Waddell v. Sec'y of Health & Hum. Servs.</u>, No. 10-316V, <u>2012 WL 4829291</u>, at *6 (Fed. Cl. Spec. Mstr. Sept. 19, 2012)). Acute and chronic encephalopathy is a serious injury that can necessitate hospitalization. <u>Miller v. Sec'y of Health & Hum. Servs.</u>, No. 02-235V, <u>2015 WL 5456093</u>, at *37 (Fed. Cl. Spec. Mstr. Aug. 18, 2015).

W.J. has never been diagnosed with acute or chronic encephalopathy, nor have any of his treating physicians suspected the condition or noted either conditions as a differential diagnosis in the medical records. Therefore, in assessing all inferences from the available evidence in petitioner's favor, the undersigned finds that W.J. did not suffer from encephalopathy and does not fulfill the criteria for an encephalopathy Table claim.

However, even if petitioners were able to establish W.J. suffered an encephalopathy Table injury, petitioners filed their claim beyond the statute of limitations. W.J. received the MMR vaccine on February 24, 2005. In order for the encephalopathy Table claim to apply, W.J.'s injury would have to have manifested between 5 and 15 days after MMR vaccine administration, or by March 11, 2005. Therefore, petitioners had 36 months from March 11, 2005 to file a Table claim in the Vaccine Program, or by March 11, 2008. Petitioners did not file their petition until May 7, 2021, and thus any Table claim is time-barred.

b. Cause-In-Fact Injuries

i. Chronic Encephalopathy

First, in regard to W.J.'s "chronic encephalopathy" claim, W.J. medical records do not include a diagnosis of or reference to encephalopathy or chronic encephalopathy by his treating physicians. W.J. was seen by multiple physicians to review his developmental progress, including Dr. Abbondante on March 7, 2006 who diagnosed him with speech delay, psychologist Romeo who diagnosed him with autism on January 5, 2007, and Dr. Wells who conducted a neurologic evaluation on January 24, 2007. None of W.J.'s treating physicians diagnosed or mentioned encephalopathy.

There is no evidence in W.J.'s medical records establishing that he was diagnosed with chronic encephalopathy. Thus, the undersigned finds that petitioners have failed to provide evidence with regard to the injury or condition of encephalopathy.

W.J. received the MMR vaccination at issue on February 24, 2005. W.J.'s medical records show W.J. was diagnosed "speech delay" on March 7, 2006, and with autism spectrum disorder on January 5, 2007. Pet. Ex. 6 at 13; Pet. Ex. 39 at 17. Even if petitioners were able to establish W.J. suffered a chronic encephalopathy injury, petitioners filed their claim beyond the statute of limitations. Assuming the date of diagnosis for either condition (speech delay or autism spectrum disorder) was the first symptom or manifestation of the alleged vaccine-related injury, petitioners would have been required to file their petition prior to March 7, 2009 or January 5, 2010. Petitioners did not file their petition until May 7, 2021, and thus their claim is time-barred.

ii. Immunodeficiency Issues

In regard to W.J.'s "immunodeficiency issues" claim, petitioners alleged that W.J.'s blood tests on March 9, 2006, June 23, 2007, July 3, 2007, April 13, 2007, February 12, 2012, and April 8, 2014 "demonstrate[d] that his immune system suffered from irregularities for several years after the administration of the MMR vaccine." Petition at 4. However, the blood tests do not constitute evidence of a diagnosis of an immunodeficiency disorder. And the medical records do not contain any evidence that W.J. was diagnosed with an immunodeficiency disorder.

First, petitioners allege W.J. struggled with thrombocytosis. Petition at 4. Petitioners state W.J.'s blood sample collected on March 9, 2006 showed a high platelet count at 424 (normal range 140-400). Id. They state lab results were "indicative of a blood disorder known as thrombocytosis." Id. Petitioners then point to a blood samples drawn on July 3, 2007 and February 20, 2012, which again showed a high platelet counts (548 and 469, respectively).
However, on April 4, 2014, W.J. had a normal platelet count. W.J.'s abnormal platelet counts occurred during periods when he was ill. Further, none of W.J.'s physicians diagnosed him with thrombocytosis.

Similarly, from blood samples collected on March 9, 2006, April 13, 2007, and July 3, 2007, petitioners state these lab results showed an "indication" of blood disorders known as "lymphocytopenia or lymphopenia," "lymphocytosis," "monocytosis," and "granulocytopenia, a form of immunosuppression." Petition at 5-7. Again, these blood tests were drawn when W.J. was ill with a viral or bacterial infection. Most importantly, W.J.'s treating physicians did not diagnose W.J. with an abnormal immune illness due to these lab results.

Petitioners also alleged that W.J. suffered from eczema and "many other allergies," and stated "[t]here is research pointing to eczema as an autoimmune disease." Petition at 8. Additionally, petitioners stated W.J.'s April 2014 lab results indicated he had high mumps antibodies that "may be indicative of an unusual and chronic allergic reaction to the MMR vaccine." Id. However, the lab results state that "[a] positive result generally indicates past exposure to Mumps virus or previous vaccination." Pet. Ex. 11 at 3.

Finally, petitioners stated W.J.'s hospitalization on June 22, 2007 showed a high white blood count as well as high lymphocyte, monocyte, and granulocyte counts. <u>Id.</u> at 8-9. Petitioners allege that W.J.'s "symptoms during this hospitalization were very similar to mumps, which may point to some adverse chronic reaction to the MMR vaccine." <u>Id.</u> at 9. However, the petitioners provide no evidence to suggest that W.J. had any adverse reaction to the MMR vaccine.

W.J. was never diagnosed with an immunodeficiency disorder and petitioners' own statements and beliefs are not evidence of a diagnosis of an immunodeficiency disease or disorder. W.J.'s physicians did not associate his illnesses with an immunodeficiency disorder or with the MMR vaccine, or any of W.J.'s vaccinations. During his hospitalization in June 2008, his physicians noted his white blood cell count was consistent with a bacterial infection and he was diagnosed of cervical lymphadenitis. However, W.J. was not diagnosed with an immunodeficiency disease or disorder. Overall, there is no evidence in W.J.'s medical records establishing that he was diagnosed with an immunodeficiency disorder.

Even if petitioners were able to establish W.J. suffered from an immunodeficiency disorder, petitioners filed their claim beyond the statute of limitations. The records show W.J. received a number of blood tests that showed, at various times, high platelet count (March 9, 2006), low absolute lymphocyte count (March 9, 2006), high lymphocyte count (April 13, 2007), high monocyte count (April 13, 2007), and low granulocyte count (April 13, 2007). Dr. Borchman diagnosed W.J. with unstable atopic dermatitis on February 20, 2012, and diagnosed eczema and rhinitis on February 19, 2014. Thus, petitioners' allegations that W.J.'s immune system struggled with "no less than four immuno-related blood disorders: granulocytopenia, lymphocytopenia, lymphocytosis, and monocytosis, and a several years long battle with severe eczema, and many other allergies" is untimely.

In order to have filed a timely petition for thrombocytosis and lymphocytopenia, petitioners would have needed to assert these alleged injuries before March 9, 2009, 36 months after the 2006 blood test. For the lymphocytosis, granulocytopenia, and monocytosis allegations, petitioners would have needed to assert these alleged injuries before April 13, 2010, 36 months after the 2007 blood test. For the eczema and "many other allergies" claims, petitioners would have needed to assert these alleged injuries before February 20, 2015, 36 months after Dr. Borchman's exam and allergy testing. Assessing all inferences from the available evidence in petitioners' claims are time-barred.

Additionally, even if W.J.'s hospitalization on June 22-24, 2007 and high mumps count on April 8, 2014, were caused by the MMR vaccination, petitioners were required to file their petition prior to June 24, 2010 and April 8, 2017, respectively. Petitioners did not file their petition until May 7, 2021. As filed, the onset of W.J.'s claim, in order to be timely under the Vaccine Act, would have had to occur on or after May 7, 2018. Thus, their claim is time-barred.

c. Significant Aggravation Injuries

Petitioners argue W.J.'s "chronic encephalopathy and immunodeficiency issues were either directly caused by the administration of the MMR vaccine, or the MMR vaccine caused 'significant aggravation' of pre-existing cerebral and immunological damage caused by [W.J.'s] Xq28 duplication, a chromosomal aberration." Petition at 2. As discussed above, petitioners failed to provide evidence that the MMR vaccine caused-in-fact W.J.'s alleged injuries.

As set forth earlier, there is no factual support in the contemporaneous medical records to support chronic encephalopathy or immunodeficiency disorder occurred after vaccination. Because there is no evidence, petitioners' significant aggravation claims fail as well.

Petitioners argue that the MMR vaccine caused significant aggravation of pre-existing cerebral and immunological damage caused by W.J.'s Xq28 duplication. However, petitioners have failed to provide any evidence to suggest vaccination or the Xq28 chromosomal duplication significantly or was any way associated with W.J.'s alleged injuries. Genetic testing on February 22, 2019, revealed the Xq28 chromosome duplication was "of uncertain clinical significance likely benign." Pet. Ex. 14 at 1. None of W.J.'s physicians have documented that W.J.'s vaccinations or his genetic testing was associated with his alleged injuries.

Further, as discussed above, even if petitioners were able to establish the MMR vaccine significantly aggravated W.J.'s pre-existing injuries, petitioners filed their claim beyond the statute of limitations.

2. Equitable Tolling

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The Vaccine Act required petitioners to file their claim on behalf of W.J. under the Vaccine Act within 36 months of the onset of the earliest symptom or manifestation of an injury. See Markovich v. Sec'y of Health & Hum. Servs., 447 F.3d 1353, 1357 (Fed. Cir. 2007) (holding

that "either a 'symptom' or a 'manifestation' of onset of a vaccine-related injury is the first event objectively recognizable as a sign of a vaccine injury by the medical profession at large").¹³

The petition was filed on May 7, 2021. In order for petitioners' vaccine claim to be timely, W.J. would have had to experience the initial onset of his vaccine-related injuries, as pled in the petition, on or after May 7, 2018. Any claims for injuries that manifested prior to May 7, 2018, are time-barred.

However, petitioners assert equitable tolling of the statute of limitations is warranted in this matter. For equitable tolling to apply, petitioners must prove two elements: (1) they pursued their rights diligently, and (2) an extraordinary circumstance prevented them from timely filing the claim. K.G., 951 F.3d at 1379. In K.G., the court allowed equitable tolling for the period of K.G.'s mental incapacity and held equitable tolling is available to mentally incapacitated individuals under the Vaccine Act. Id. In that case, petitioner, an adult, alleged the flu vaccine caused chronic inflammatory demyelinating polyneuropathy ("CIDP") in 2011. Id. at 1376. "During the same period, K.G. succumbed to alcoholism, spent months in the hospital, and developed amnesia. In Spring 2014, an Iowa state court declared K.G. incapable of caring for herself and, against K.G.'s will, appointed K.G.'s sister as her guardian." Id. K.G. regained her mental faculties by May 2016 and filed a claim in the Vaccine Program for her alleged vaccine injury in January 2018. Id.

Unlike K.G., W.J. was an infant at the time of his vaccination, and the petitioners, W.J.'s parents, were capable of filing a claim on his behalf. W.J.'s parents have not filed any evidence to suggest that they were incapacitated in any way during any time frame relevant to their petition. While the Court in <u>K.G.</u> confirmed an equitable tolling right for incapacitated individuals, nothing in the decision negated a legal representative's rights and responsibilities under the Vaccine Act. A legal representative is "a parent or an individual who qualifies as a legal guardian under State law." § 33(2). The Vaccine Act expressly permits a legal representative to file a petition for compensation on behalf of a minor. § 11(b)(1)(A). Therefore, petitioners had the right and responsibility to bring a timely claim on W.J.'s behalf. The decision in <u>K.G.</u> did not alter this provision.

W.J.'s "mental incapacity" does not serve as an "extraordinary circumstance." Petitioners, as W.J.'s legal representatives as his parents, had the ability to file a petition 36 months from the onset of the earliest symptom or manifestation of W.J.'s injury. The same is true for all petitions brought on behalf of all minors. Parents or other legal representatives must file the petition on behalf of a minor within the applicable statute of limitations.

¹³ For cases that have been dismissed for failure to file within the prescribed statute of limitations, see <u>Villalobos ex rel. A.D. v. Sec'y of Health & Hum. Servs.</u>, No. 20-96V, <u>2020 WL</u> <u>5797865</u> (Fed. Cl. Spec. Mstr. Sept. 2, 2020); <u>Palencia ex rel. C.A.P. v. Sec'y of Health & Hum.</u> <u>Servs.</u>, No. 20-180V, <u>2020 WL 5798504</u> (Fed. Cl. Spec. Mstr. Sept. 2, 2020); <u>Edoo v. Sec'y of</u> <u>Health & Hum. Servs.</u>, No. 13-302V, <u>2014 WL 1381341</u> (Fed. Cl. Spec. Mstr. Mar. 19, 2014); <u>Boettcher v. Sec'y of Health & Hum. Servs.</u>, No. 17-1402V, <u>2018 WL 2925043</u> (Fed. Cl. Spec. Mstr. May 2, 2018).

3. The Discovery Rule

Petitioners argue that it was not until genetic testing on March 19, 2019 which revealed that W.J. had a chromosomal aberration known as Xq28 duplication, that they believed that the MMR vaccine should not have been administered to him. Petition at 17-18. The petitioners assert "the statute of limitations in this matter began to toll no earlier than March 19, 2019, when [W.J.'s] parents were first informed of his Xq28 duplication." Id. at 18.

Essentially, petitioners argue for the application of a discovery rule, suggesting that the Act's statute of limitations should not have begun running until March 19, 2019. The Federal Circuit has held that there is no explicit or implied discovery rule under the Vaccine Act. <u>Cloer</u>, <u>654 F.3d at 1337</u>. The date of the occurrence of the first symptom or manifestation of onset "does not depend on when a petitioner knew or reasonably should have known anything adverse about [the] condition." <u>Id.</u> at 1339. Nor does it depend on when a petitioner knew or should have known of a connection between an injury and a vaccine. <u>Id.</u> at 1338 ("Congress made the deliberate choice to trigger the Vaccine Act statute of limitations from the date of occurrence of the first symptom or manifestation of the injury for which relief is sought, an event that does not depend on the knowledge of a petitioner as to the cause of an injury."); <u>see also Markovich</u>, <u>477</u> <u>F.3d at 1358</u> ("Congress intended the limitations period to commence to run prior to the time a petitioner has actual knowledge that the vaccine Act."). Accordingly, the statutory filing period was not tolled until March 19, 2019, when petitioners learned of W.J.'s test results.

4. Fraud

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Petitioners claim they were unable to file a claim on behalf of W.J. because the government fraudulently concealed the connection between vaccines and autism. Petition at 17. However, the petitioners did not file any evidence to suggest that the government was fraudulently concealing the connection between vaccines and autism. Furthermore, petitioners failed to show how respondent's alleged concealment prevented them from filing a petition on behalf of W.J. At the time W.J. was vaccinated and later diagnosed with autism the Vaccine Program was conducting an Omnibus Autism Proceeding ("OAP"), which included more than 5,100 petitions filed under the Vaccine Act alleging that vaccines caused autism. See Snyder v. Sec'y of Health & Hum. Servs., No. 01-162V, 2009 WL 332044, at *4 n.12 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), aff'd, 88 Fed. Cl. 706 (2009). Petitioners could have filed a petition during that timeframe, but did not do so.

Petitioners also cite <u>Paluck</u>, <u>786 F.3d 1373</u> to emphasize that "that vaccines do sometimes cause or enhance autism-like symptoms." Petition at 16. The Court in <u>Paluck</u> held that the parents of K.P. demonstrated "by preponderance of evidence that their son's existing mitochondrial disorder was significantly aggravated by his receipt of vaccines within medically acceptable time, and thus he was entitled to compensation under National Childhood Vaccine Injury Act." <u>786 F.3d at 1373</u>. K.P. demonstrated significant developmental delays when he was nine months old and underwent evaluations that showed he had gross motor delays. <u>Id.</u> at 1375. K.P. received an MMR vaccine and pneumococcal vaccines at his one-year well baby visit, and two days later had a high temperature. <u>Id.</u> at 1376. After a series of tests and a three

Appellant's Brief pg. 102

weeklong hospitalization, K.P. was subsequently diagnosed with an unspecified mitochondrial disorder "most likely present from the time of K.P.'s birth." <u>Id.</u> The petitioners in <u>Paluck</u> showed by preponderant evidence, the first sign of neurodegeneration was within 23 days of vaccines, and the findings of his pediatrician, neurologist, and speech therapist, as well as MRI exams, showed K.P.'s rapid, progressive neurodegeneration as predicted by his expert's medical theory. <u>Id.</u> at 1379.

Here, petitioners did not show W.J. has a mitochondrial disorder. W.J. was assessed with speech delay over a year after the MMR vaccine at issue was administered and was diagnosed with autism two years later. Petitioners failed to provide any evidence linking W.J.'s speech delay or autism diagnosis to the MMR vaccination, how the government contributed to obstructing petitioner's ability to file a petition on behalf of W.J., or how W.J.'s condition is similar to that of K.P.'s in <u>Paluck</u>. Additionally, the <u>Paluck</u> case did not involve the issues of the statute of limitations or equitable tolling.

Petitioners have the burden of establishing the timely filing of their claim, and they have failed to provide evidence that their petition was filed within "36 months after the date of occurrence of the first symptom or manifestation of onset ... of such injury" as required by the Vaccine Act. Because petitioners have alleged injury onset in 2006 (diagnosis of speech delay), and at the latest, 2012 (eczema and allergies), the undersigned, in assessing all inferences from the available evidence in petitioner's favor, finds it appropriate to dismiss the case for failure to establish that the petition was timely filed.

5. Petitioner's Autism Diagnosis

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In the OAP, three special masters conducted separate proceedings in test cases involving the two theories of autism causation. All found petitioners had not provided preponderant evidence of causation. See Hazlehurst v. Sec'y of Health & Hum. Servs., No. 03-654V, 2009 WL 332306 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), aff'd sub nom. Hazlehurst ex rel. Hazlehurst v. Sec'y of Health & Hum. Servs., 88 Fed. Cl. 473 (2009), aff'd sub nom. Hazlehurst v. Sec'y of Health & Hum. Servs., 604 F.3d 1343 (Fed. Cir. 2010); Cedillo v. Sec'y of Health & Hum. Servs., 604 F.3d 1343 (Fed. Cir. 2010); Cedillo v. Sec'y of Health & Hum. Servs., No. 98-916V, 2009 WL 331968 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), aff'd, 89 Fed. Cl. 158 (2009), aff'd, 617 F.3d 1328 (Fed. Cir. 2010); Mead ex rel. Mead v. Sec'y of Health & Hum. Servs., No. 03-215V, 2010 WL 892248 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); King ex rel. King v. Sec'y of Health & Hum. Servs., No. 03-584V, 2010 WL 892296 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); Dwyer ex rel. Dwyer v. Sec'y of Health & Hum. Servs., No. 03-1202V, 2010 WL 892250 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); Snyder, 2009 WL 332044.

Here, petitioners state, "[b]ased on his symptoms and behaviors, [W.J.] was diagnosed by his physician as having autism. . . . Indeed, [W.J.] does have several autism-like symptoms." Petition at 15. Petitioners assert respondent's denial "of any connection between vaccines and autism can be misleading because they serve to obscure any connection between vaccines and injuries resulting in autism-like symptoms, if not autism proper, in children." Id. at 16. "Since the cause of autism is unknown, the postulation that vaccines may sometimes cause autism-like symptoms, rather than autism proper in children, cannot be ruled out." Id.

Petitioners further state respondent's "categorical denials have the effect of misleading and discouraging parents with children who have autism-like symptoms from even thinking that the symptoms might have been caused by a vaccine." Petition at 16. Petitioners argue that "[r]espondent's assertions that hard science has ruled out any connection between vaccines and autism-like symptoms can amount to a 'fraudulent defense' to any claims suggesting otherwise, warranting equitable tolling in some cases. <u>Holmberg v. Armbrecht, 327 U.S. 392, 397</u> (1946)."¹⁴ Id.

Equity will not lend itself to such fraud and historically has relieved from it. It bars a defendant from setting up such a fraudulent defense, as it interposes against other forms of fraud. And so this Court long ago adopted as its own the old chancery rule that where a plaintiff has been injured by fraud and remains in ignorance of it without any fault or want of diligence or care on his part, the bar of the statute does not begin to run until the fraud is discovered, though there be no special circumstances or efforts on the part of the party committing the fraud to conceal it from the knowledge of the other party.

This equitable doctrine is read into every federal statute of limitation. <u>Holmberg</u> <u>v. Armbrecht</u>, <u>327 U.S. 392, 396-397</u> (1946) (Internal citations and quotation marks omitted).

Petition at 17.

Petitioners then assert that after genetic testing, a chromosomal aberration, Xq28 duplication, was discovered. Petition at 17. Petitioners believe the Xq28 duplication impaired [W.J.'s] immune system and caused his mental incapacities, and he "might not be autistic at all or that the Xq28 duplication is a cause of his autism." <u>Id.</u> Finally, petitioners state, "because of the Xq28 duplication, the MMR vaccine should not have been administered to [W.J.] at all, and that it probably significantly aggravated his congenital chromosomal aberration." <u>Id.</u> at 18.

Petitioners, however, do not provide any evidence to support their contentions that respondent's actions prevented them from filing a timely claim in the thirty-six months after W.J. first began to show signs of autistic spectrum disorder or how the fraudulent defense pertains to this case. Around the time of W.J.'s vaccination and autism diagnosis, more than 5,100 petitions were filed under the Vaccine Act alleging that vaccines caused autism. See Snyder, 2009 WL 332044 at *4 n.12.

There is no evidence here to suggest that fraud or concealment prevented petitioners from timely filing claims on behalf of W.J. for allegations of autism following vaccination. Thus, the undersigned does not agree that respondent's "categorical denials" had the "effect of misleading and discouraging parents with children who have autism-like symptoms" from filing petitions, or

¹⁴ Petitioners cite <u>Holmberg v. Armbrecht</u>, an equity case where shareholders and creditors of the Southern Minnesota Joint Stock Land Bank of Minneapolis sued the defendant for fraudulently concealing his shareholder interest, which delayed petitioners from bringing suit. <u>327 U.S. 392</u>, <u>393</u> (1946).

that this claim warrants "equitable tolling" based on any assertion of fraud. Petition at 16. Therefore, in assessing all inferences from the available evidence in petitioner's favor, petitioners have failed to show respondent's actions prevented them from filing a timely petition.

6. Petitioner's Fourteenth Amendment Claim

Petitioners contend, "[t]o consider equitable tolling for K.G.'s drug and alcohol induced mental incapacity, but not for [W.J.'s] congenital genetically-caused mental incapacity, would be disability discrimination in violation of [W.J.'s] Fourteenth Amendment rights." Petition at 18. Petitioners cite <u>City of Cleburne, 473 U.S. 432</u>, stating disparate treatment between neuro-normal and mentally incapacitated individuals violates the Fourteenth Amendment's Equal Protection clause. <u>Id.</u> "The equal protection clause of the Fourteenth Amendment dictates that [W.J.] receive the same consideration for equitable tolling that was offered to K.G." <u>Id.</u> at 19. But petitioners fail to comprehend that they, as parents and legal representatives of W.J., had the right and responsibility to timely file a petition. They have not asserted that they have any disability or mental incapacity. Thus, their argument based on the Fourteenth Amendment fails.

Further, under the Vaccine Program, the Vaccine Act's limitation period is rationally related to the dual legitimate legislative purposes undergirding the Vaccine Act: (1) the settling of claims quickly and easily, and (2) the protecting of manufacturers from uncertain liability making "production of vaccines economically unattractive, potentially discouraging vaccine manufacturers from remaining in the market." <u>See Cloer, 85 Fed. Cl. 141</u> (2008) (quoting <u>Brice, 240 F.3d at 1368</u>).

Highlighting in <u>Cloer</u> that the "neutral" nature of the 36-month statute of limitations "treats all petitioners equally," the Federal Circuit appears to have affirmed, without overt discussion, the Court of Federal Claims' use of rational basis review to conclude that the statutorily prescribed limitations period is rationally related to the "legitimate legislative purposes undergirding the Vaccine Act." <u>Cloer, 85 Fed. Cl. at 151-52</u> (quoting <u>Brice, 240 F.3d at 1368</u>). <u>See id.</u> ("[T]here can be no question that applying the Vaccine Act's limitation period is rationally related to the dual legitimate legislative purposes undergirding the Vaccine Act." (1) the settling of claims quickly and easily, and (2) the protecting of manufacturers from uncertain liability [that makes the] 'production of vaccines economically unattractive, [and] potentially discourag[es] vaccine manufacturers from remaining in the market."") (internal footnote omitted). The Court of Federal Claims further stated in <u>Cloer</u> that "Congress is not obligated to extend the coverage of the Vaccine Act. . . . to all person[s] suffering a vaccine-related injury." <u>Id.</u> at 150 (citing <u>Leuz v. Sec'y of Health & Hum. Servs.</u>, <u>63 Fed. Cl. 602, 608</u> (2005)).

The petitioners have not shown that they fall within a protected class of persons. The claims of all petitioners, regardless of the alleged injury, must be evaluated consistent with the terms of the Vaccine Act, provided the claimants have met the threshold requirement of filing the petition within the time limit prescribed by the statute. Here, petitioners have failed to file within the appropriate time frames set forth under the statute.

VII CONCLUSION

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Appellant's Brief pg. 105

It is clear from the medical records that W.J. has struggled with illness, and the undersigned has great sympathy for what he and his parents have endured due to his illness. The undersigned's decision, however, cannot be decided based upon sympathy, but rather on the evidence and law.

Accordingly, for all the reasons stated above, in assessing all inferences from the available evidence in petitioner's favor, the undersigned **GRANTS** respondent's motion to dismiss and this case is dismissed for failure to timely file the petition within the statute of limitations. In the absence of a timely filed motion for review pursuant to <u>Vaccine Rule 23</u>, the Clerk of Court **SHALL ENTER JUDGMENT** in accordance with this Decision.

IT IS SO ORDERED.

Ç,

s/Nora Beth Dorsey Nora Beth Dorsey

Special Master

FORM 19. Certificate of Compliance with Type-Volume Limitations

Form 19 July 2020

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATIONS

Case Number: 2022-2119

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	Name:	R.J.

IN THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

	-X	
W.J., by his parents and legal guardians, R.J. and A.J.,	: : :	
Petitioner-Appellant,		Case No. 2022-2119
v.	•	
SECRETARY OF HEALTH AND HUMAN SERVICES,	:	
Respondent-Appellee.	· : V	
	·^	

CERTIFICATE OF SERVICE

I, R.J., a Petitioner-Appellant in the above-captioned case, under penalty of perjury and in lieu of affidavit as permitted by 28 U.S.C. § 1746, hereby certify that on October 24, 2022, I served a copy of Brief of Appellant W.J., by His Parents and Legal Guardians R.J. and A.J., dated October 24, 2022, on Sarah B. Rifkin, Esq., U.S. Department of Justice, by electronic mail at sarah.rifkin@usdoj.gov with Appellee's prior consent in accordance with Federal Circuit Rule 25(e)(4).

I declare under penalty of perjury that the foregoing is true and correct.

Dated: Staten Island, New York October 24, 2022

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<u>s/ R.J.</u> R.J.

(120 of 397)



UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT 717 MADISON PLACE, N.W. WASHINGTON, D.C. 20439

Peter R. Marksteiner Clerk of Court Clerk's Office 202-275-8000

October 12, 2022

2022-2119 - W. J. v. HHS

NOTICE OF NON-COMPLIANCE

Your submitted document (Opening Brief) is not in compliance with the rules of this court. Within <u>fourteen</u> days from the date of this notice, please submit a corrected version of this document correcting the following:

- A cover must not indicate the document is "nonconfidential" or "public" unless the document is filed in two versions pursuant to Fed. Cir. R. 25.1(e)(1). Fed. Cir. R. 32(a).
- The caption provided on the document does not follow the official caption provided by the Clerk. Fed. Cir. R. 32(a) (documents submitted with a cover).

[Clerk's Note: The official caption is as follows:]

W. J., by his parents and legal guardians, R.J. and A.J., Petitioner-Appellant

v.

SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent-Appellee

The brief does not contain a statement of related cases. Fed. Cir. R. 28(a)(4); Fed. Cir. R. 47.5.

Any reference in a brief to the underlying record or to material authorized to be included in an appendix must be to the corresponding appendix page number(s) and follow the format prescribed by the court's <u>Electronic Filing</u> <u>Procedures</u> ("Appendix Formatting"). Fed. Cir. R. 28(f); Fed. Cir. R. 29(c). đ

The document uses a non-compliant signature format. All briefs, motions, and other papers must be signed. Fed. R. App. P. 32(d). An electronic signature must follow the format prescribed by Fed. Cir. R. 25(g)(1)-(2). Refer to the court's <u>Electronic Filing Procedures</u> ("Signature Format"); see also Fed. Cir. R. 32(g) for documents requiring multiple signatures.

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The brief does not contain all required addendum material. Fed. Cir. R. 28(a)(11).

If applicable, the deadline for the next or responsive submission is computed from the original submission date, not the submission date of the corrected version.

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A party's failure to timely file a corrected document curing all defects identified on this notice may result in the original document being stricken from the docket. An appellant's failure to cure a defective filing may also result in the dismissal of the appeal pursuant to Fed. R. App. P. 31(c).

FOR THE COURT

<u>/s/ Peter R. Marksteiner</u> Peter R. Marksteiner Clerk of Court By: E. Dumont, Deputy Clerk R. J. P.O. BOX 100073 STATEN ISLAND NY 10310

CLERK OF COURT U.S. COURT OF APPEALS FOR THE FEDERAL CIRCUIT 717 MADISON PLACE, NW (ROOM 401) WASHINGTON DC 20439