No. 18-

IN THE

# Supreme Court of the United States

N.K., AN INFANT BY HIS MOTHER AND NATURAL GUARDIAN, TANJA BRUESTLE-KUMRA,

*Petitioner,*

*v.*

ABBOTT LABORATORIES,

*Respondent.*

**ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT**

## PETITION FOR A WRIT OF CERTIORARI

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## QUESTION PRESENTED

There now exists a new rule creating a significant split in how District Courts and Courts of Appeals are to interpret and apply Federal Rule of Evidence 702 and this Court's decision in Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579 (1993), when determining the admissibility of expert causation testimony. The Courts of Appeals that have addressed this issue agree that if an expert is qualified to testify, employs an accepted methodology, and a defendant points to an alternative cause of a plaintiff's injury, the expert's causation opinion should only be excluded when the expert does not provide an explanation as to why that alternative cause was ruled out.

In this case, Petitioner's experts were qualified to testify and employed the accepted methodology of differential diagnosis to rule out a genetic cause for Petitioner's birth defects. But in an unprecedented interpretation of Rule 702 and Daubert, at odds with other Circuit Courts of Appeals, the Second Circuit found these experts' opinions inadmissible in that defendant pointed to genetics as a cause, and, despite the experts providing an explanation as to why genetics was ruled out, the Court required additional genetic testing to eliminate the possibility of a genetic cause. No other Circuit Court has held this position. Such unilateral action by the Second Circuit creates uncertainty, confusion and lacks predictability.

The question before this Court is thus as follows:

For an expert's causation opinion to be admissible, do Federal Rule of Evidence 702 and Daubert require additional testing of a plaintiff to eliminate the possibility of an alternative cause pointed to by a defendant, where the expert completed a differential diagnosis and explained how that alternative cause was ruled out?

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**STATUTES AND OTHER AUTHORITIES**

Petitioner N.K., an infant by his mother and natural guardian, Tanja Bruestle-Kumra, hereby petitions for a writ of certiorari to review the final decision of the United States Court of Appeals for the Second Circuit entered in this action on June 20, 2018.

## OPINIONS BELOW

The Summary Order of the Court of Appeals was dated April 23, 2018, entered on June 20, 2018, and is annexed hereto as Appendix A. The decision of the Court denying reargument or an *en banc* rehearing of the opinion was issued on June 11, 2018, and is annexed hereto as Appendix B. The opinion of the District Court is annexed hereto as Appendix C.

## JURISDICTION

The final decision of the Court of Appeals was dated April 23, 2018, but entered on June 20, 2018. A petition for rehearing was timely filed in this matter, and denied by the Court of Appeals in a decision dated June 11, 2018, establishing a deadline for Petitioner to file a petition for a writ of certiorari to and including September 10, 2018. This Court's jurisdiction is invoked under 28 U.S.C. § 1254(1).

The District Court had subject matter jurisdiction of this action pursuant to 28 U.S.C. § 1332, as Petitioner is a citizen of a State different from the State where Defendant Abbott Laboratories ("Defendant") is incorporated and has its principal places of business, and the amount in controversy exceeds $75,000.00. The Second Circuit had appellate jurisdiction under the All Writs Act, 28 U.S.C. § 1651.

## STATUTORY PROVISIONS INVOLVED:

Federal Rules of Evidence Rule 702 ("Rule 702") Provides:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

(a) The expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;

(b) The testimony is based on sufficient facts or data;

(c) The testimony is the product of reliable principles and methods; and

(d) The expert has reliably applied the principles and methods to the facts of the case.

## STATEMENT OF THE CASE

This case raises a question of general importance in civil litigation: what is the proper interpretation of Federal Rule of Evidence 702 in connection to specific causation testimony based on differential diagnosis? The answer to this question is a matter of concern to countless actual and potential litigants, as such expert testimony is at the heart of innumerable actions. The resolution of this issue will ensure that federal courts allow juries to fulfill their proper role as evaluators of the weight of expert testimony, as this Court intended in Daubert, and prevent courts in the Second Circuit or elsewhere from usurping that role by imposing extrajudicial barriers to expert testimony.

Other Courts of Appeals to consider this issue have interpreted Rule 702 and Daubert in a method consistent with the basic tenet of Daubert that the remedy for an arguably less than perfectly compelling expert opinion is "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof," and that to exclude expert opinion based on a challenge to its weight is to be "overly pessimistic about the capabilities of the jury and of the adversary system in general." Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 596, 113 S. Ct. 2786, 2798, 125 L. Ed. 2d 469 (1993). When addressing differential diagnosis, these Courts of Appeals have determined that Rule 702 requires experts to have an explanation as to why they have ruled out a raised plausible alternative to their opinion as to specific causation, and only absent such an explanation is the opinion excluded from trial. Under the proper and majority interpretation of Daubert, the fact that an expert could have done more to exclude a proposed alternative cause with a greater degree of certainty is ammunition with which the weight of the expert's testimony may be attacked at trial, but not a basis for excluding the testimony.

In the decision below, the Second Circuit has split with the other Courts of Appeals, throwing the issue into confusion. Here, Petitioner's experts had valid medical and scientific reasons to reject a genetic cause to Petitioner's injuries when concluding Depakote was the specific cause. Nonetheless, the Second Circuit excluded their opinions because its panel opined that additional testing should have been conducted to allow Petitioner's experts to eliminate the possibility of a genetic cause. The level of certainty that the Second Circuit would require cuts against the liberal and reasonable intent of Daubert, and

would by necessity require courts to step into the role of a jury in assessing the weight of an expert's opinion. The Second Circuit's divergence from a proper interpretation of Daubert and Rule 702 should be corrected, and parties throughout the various Circuits provided consistent, proper and predictable rules by which to proffer expert opinions.

### A. Tanja Bruestle-Kumra's Use of Depakote

In August 1997, Petitioner's mother, Tanja Bruestle-Kumra ("Tanja") suffered a grand mal seizure and was hospitalized in London, England, where she was given Depakote to control seizures.[1] Upon release from the hospital, Tanja followed up with a neurologist in private practice in London, who continued prescribing her Depakote at 400 mg per day, and she continued thereafter to use the drug at various doctors' directions (A138-96).[2]

From 2003 to 2007, Tanja was treated by Dr. David J. Adams, a neurologist at Columbia Presbyterian Hospital in New York. He prescribed Depakote before and during her pregnancy, increasing the dosage during pregnancy to 2000 mg per day in November of 2004, and to 2500 mg

1. "Depakote" refers to Abbott's group of prescription drugs with the basic active ingredient valproic acid ("VPA"). Depakote is also sometimes referred to by the chemical names "valproic acid," "valproate," or "divalproex sodium." Depakote is an anti-epilepsy drug ("AED") that has been marketed by Abbott in the United States in some form since 1978.

2. Parenthetical references preceded by an "A" are to the Joint Appendix filed with the Second Circuit in connection to the appeal below.

per day in January of 2005. It was increased yet again to 3000 mg per day in February of 2005, and it remained at that level for the balance of Tanja's pregnancy with Petitioner (A139).

In conformity with the Depakote label, Dr. Adams advised Tanja to remain on Depakote during her pregnancy and assured her that other anti-convulsion medications carried equivalent risks of birth defects as Depakote (A142-A143).

### B. The 2004 Depakote Label

The Usage in Pregnancy section of the 2004 Depakote label stated that clinical research indicated that the association between use of Depakote during pregnancy and subsequent birth defects was "similar" with the use of other anti-epileptic drugs. (A156) This representation was false. In actuality, there were multiple reports in the scientific literature confirming that fetal exposure to valproate was associated with a higher incidence of birth defects when compared to other AEDs (A894-A899, A905). Equally untrue was the Depakote label's assertion that "the higher incidence of congenital anomalies in antiepileptic drug-treated women with seizure disorders cannot be regarded as a cause and effect relationship" and that "genetic factors or the epileptic condition itself, may be more important than drug therapy in contributing to congenital anomalies" (A894-A899, A905) (emphasis added). Defendant, in fact, knew that Depakote caused serious physical and cognitive birth defects, and that women who took Depakote to manage their seizure disorders faced a significantly higher risk of having children born with birth defects than women who took other AEDs (A894-A899, A905, A1818-A1827).

### C. Petitioner Born with Birth Defects Associated with Exposure to Depakote

Petitioner was born at term on March 18, 2005 at New York Presbyterian Hospital with numerous birth defects, including complete cleft palate, hypospadias, microcephaly, hypoplastic thumbs, hypotonia with muscle weakness, behavioral and intellectual deficits, and attention deficit disorder, all of which have been associated with in utero exposure to Depakote.

### D. Genetic Defects Ruled Out as Cause of Petitioner's Birth Defects

On March 21, 2005, while Petitioner was in the NICU, he was evaluated by the hospital's genetics department. At the consult, the geneticists arrived at a differential diagnosis: the cause of Petitioner's congenital anomalies was either Fetal Valproate Syndrome or the result of genetic factors (A1334-A1337). The genetics department determined that the potential genetic factors that Petitioner needed to be tested for were deletion syndromes and syndromes with midline defects. Accordingly, genetic testing was ordered to determine whether Petitioner suffered from any of those genetic conditions (Id.). Specifically, Petitioner was tested for (1) Opitz, FG Syndrome; (2) Pierre/Robin Sequence; and (3) Pallister-Hall Syndrome (Id.).

On March 30, 2005, after examining Petitioner and seeing his constellation of congenital abnormalities, Dr. Rachel Lewis, Petitioner's Harvard trained treating pediatrician, consulted Smith's Congenital Human Malformations, an authoritative medical textbook on the subject of birth defects and their causes, and saw that the

"best fit" for Petitioner's specific constellation of physical conditions was valproate embryopathy (A1379 at 145-146). In a telephone conversation on May 17, 2005, following an office visit in the genetics clinic, Dr. Yeboa, the geneticist, informed Dr. Lewis he was also testing Petitioner for Fanconi, DiGiorge, and other microdeletion/breakage syndromes (A1395-A1398).

In a letter dated August 4, 2005, Dr. Lewis received the results of the genetic testing (A1399). The results were negative, which indicated to Dr. Lewis that none of Petitioner's birth defects were attributable to genetic factors (Id.). Once she received the test results, Dr. Lewis ruled out a genetic component to Petitioner's defects and maintained her working diagnosis of valproate embryopathy (A1379 at 147).

On July 1, 2013, because of "café au lait" spots on Petitioner's skin, Petitioner's dermatologist, Dr. Kimberly Morel, suggested that genetic testing be performed to rule out a genetic condition called NF1 (A1400-A1402). Since individuals with NF1 syndrome present with a specific type of ocular nodule, Dr. Lewis referred Petitioner to an ophthalmologist to determine whether he had the nodule (A1371 at 113-14). The eye exam revealed that Petitioner did not have the nodule (A1403). As Petitioner did not meet the clinical criteria for NF1, Dr. Lewis had a sound basis to rule out NF1 without requiring further genetic testing (A1371 at 113-14).

### E. Pediatrician Rachel Lewis Expert Opinion

In the report of Petitioner's treating pediatrician, Rachel Lewis, M.D., she stated that in the course of her treatment of Petitioner, she performed a differential

diagnosis regarding the etiology of Petitioner's birth defects, concluding that the two differentials were in utero exposure to Depakote, (which is also known as Fetal Valproate Syndrome ("FVS") or valproate embryopathy) or genetic factors (A1338-A1342). Dr. Lewis stated that upon receiving the results of the battery of genetic tests performed on Petitioner, all of which were negative for a genetic cause, she ruled out genetics as the cause of Petitioner's defects and determined that the cause was prenatal valproate exposure (A1379 at 147).

### F. Teratologist Christopher Stodgell Expert Opinion

Petitioner also exchanged the report of a teratologist[3], Christopher Stodgell, Ph.D. (A893-A927). Dr. Stodgell reviewed the relevant medical records of Petitioner's mother to determine the dose and duration of Petitioner's in utero exposure to Depakote, a medical history assembled by Petitioner's treating pediatrician, Rachel Lewis, M.D., describing the presentation of Petitioner's birth defects, and records of prenatal and postnatal genetic testing performed on Petitioner which confirmed a normal karyotype which was negative for genetic or chromosomal abnormalities (A893).

As part of Dr. Stodgell's analysis, he conducted a comprehensive review of literature in the scientific community to determine whether there was a causal association between Petitioner's birth defects and in utero exposure to Depakote. Dr. Stodgell reviewed and cited to 118 separate articles and case studies in support of

3. An expert in human physical malformations.

his opinion that Petitioner's birth defects were causally related to in utero exposure to Depakote (A906-A916). He compared: (1) Petitioner's prenatal exposure to Depakote, including duration and dose to that reported in the scientific literature; and (2) Petitioner's birth defects to the constellation of birth defects that have been reported in the scientific literature to be causally associated with prenatal exposure to Depakote (A894-A905).

Dr. Stodgell offered two categories of opinions: First, Dr. Stodgell offered a "general causation" opinion that Petitioner's birth defects were consistent with in utero exposure to Depakote. Second, Dr. Stodgell offered a "specific causation" opinion, opining that Depakote was the cause of Petitioner's birth defects (Id.).

### G. Defendant's Daubert and Summary Judgment Motions

At the conclusion of discovery, Defendant moved under Rule 702 and Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 588-89 (1993) to exclude the specific causation opinion contained in Dr. Lewis's report – that is, that Depakote caused Petitioner's injuries (A1180-A1181). Defendant claimed that Dr. Lewis failed to conduct a proper differential diagnosis to rule out genetics as a potential cause for Petitioner's birth defects (A1182-A1203). Defendant also moved under Daubert to exclude Dr. Stodgell's specific causation opinions (A640-A641).

Before the District Court ruled on these motions, Defendant moved for summary judgment (A1421-A1422). In that motion, Defendant argued, inter alia, that if the

specific causation opinions of Drs. Lewis and Stodgell were excluded, Petitioner would be unable to prove his case (A1423-A1448).

### H. The District Court's Opinion & Order

On May 22, 2017, the District Court issued its Opinion & Order granting Defendant's Daubert motions to strike the specific causation testimony of Drs. Lewis and Stodgell. The District Court ruled, inter alia, that Dr. Lewis' differential diagnosis was inadequate due to Dr. Lewis not electing to pursue additional genetic testing to rule out potential genetic causes of Petitioner's condition. (App. 23a—26a.)[4] Dr. Stodgell's opinion was likewise excluded from trial, due in part to his reliance on Dr. Lewis's differential diagnosis. (App. 26a-27a.) Having eliminated Petitioner's ability to prove specific causation, the District Court granted summary judgment to Defendant. (App. 30a-31a.)

### I. The Second Circuit's Order

Petitioner appealed the District Court's Opinion and Order. In an order dated April 23, 2018, the Second Circuit upheld the District Court's rulings. Specifically, the Second Circuit found that the District Court had "adequate reason to find" that "a reliable differential diagnosis required the performance of additional genetic tests to eliminate the possibility" that Petitioner's birth defects were caused by genetic abnormalities (App. 7a-9a.).

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4. Parenthetical references preceded by an "App." are to the Appendix submitted herewith.

### J. The Second Circuit's Denial of Petitioner's Petition for Rehearing

Petitioner timely filed a petition for a panel rehearing, or, in the alternative, for a rehearing *en banc* of the Second Circuit's Summary Order. In an Order dated June 11, 2018, the Second Circuit denied Petitioner's petition.

## REASONS FOR GRANTING THE PETITION

## POINT I

## THE COURT SHOULD GRANT CERTIORARI TO RESOLVE CONFLICTING INTERPRETATIONS OF DAUBERT AND RULE 702 REGARDING THE ADMISSIBILITY OF EXPERT TESTIMONY

### A. Multiple United States Courts of Appeals Correctly Interpret Daubert and Rule 702 to Require Exclusion of Expert Testimony Only Where an Expert Fails to Provide an Explanation for Elimination of a Raised Potential Alternative Cause

In Ambrosini v. Labarraque, 101 F.3d 129, 140 (D.C. Cir. 1996), the D.C. Circuit was presented with a question strikingly similar to that which faced the Second Circuit in this matter. The D.C. Circuit was required to review a summary judgment decision which had found unreliable the testimony of a doctor proffered as a specific causation witness. The doctor had developed an expert opinion based on a differential diagnosis that the drug Depo-Provera, manufactured by one of the defendants, had caused the plaintiff's birth defects. (Id. at 131.) The D.C. Circuit over-turned the lower court's decision, and determined

that as the doctor had developed reasons to rule out the defendant's proposed alternative cause, namely, genetic defects, the doctor was not required to have conducted additional genetic testing to strengthen his case for eliminating this cause as a possibility:

> Dr. Goldman explained that he considered the other possible causes for Teresa's condition, including chromosomal abnormalities, genetic defects, and viruses, and by reviewing Teresa's and her mother's medical records, he ruled them out.
>
> Upjohn's efforts to discredit Dr. Goldman's methodology by pointing to the limits of the research he undertook into possible genetic or chromosomal causes of Teresa's birth defects - namely, that he had neither done a critical family history nor ordered a more state-of-the-art chromosomal study - goes to the weight rather than the admissibility of his testimony.

Id. (emphasis added).

In this matter, Dr. Lewis employed the accepted methodology of deferential diagnosis and similarly explained her basis for ruling out a genetic cause for Petitioner's injuries, including genetic testing that was negative, her examination of Petitioner, and reference to an authoritative medical text book on the causes of birth defects. Defendant's attempt to discredit Dr. Lewis's methodology by pointing out that she could have conducted additional genetic testing is precisely the argument that the D.C. Circuit rejected as going to weight rather than

admissibility in Ambrosini.[5] As noted by the Ninth Circuit, it is an abuse of discretion to exclude experts' testimony because "they could not completely rule out" a proposed alternative cause. Wendell v. GlaxoSmithKline LLC, 858 F.3d 1227, 1237 (9th Cir. 2017), cert. denied sub nom. Teva Pharm. USA, Inc. v. Wendell, 138 S. Ct. 1283, 200 L. Ed. 2d 470 (2018).

The D.C. Circuit's approach is consistent with that of the various other circuits to have addressed this issue. In Heller v. Shaw, 167 F.3d 146, 156 (3d Cir. 1999), the Third Circuit, considering the reliability of a differential diagnosis, held the following:

> [O]nly where a defendant points to a plausible alternative cause and the doctor offers no explanation for why he or she has concluded that was not the sole cause, that doctor's methodology is unreliable.
>
> * * *
>
> [A] physician need not conduct every possible test to rule out all possible causes of a patient's illness.

5. Nor is Ambrosini a one-off decision from the D.C. Circuit. The D.C. Circuit has made it clear as recently as 2018 that "the fact that other potential causes for Plaintiff's illness cannot be definitely ruled out does not preclude Plaintiff's experts from testifying about what they conclude is the most likely of the remaining possible causes. West v. Bayer HealthCare Pharm. Inc., 293 F. Supp. 3d 82, 94 (D.D.C. 2018) (emphasis added); *see Bell v. Gonzales*, No. CIV.A. 03-163 (JDB), 2005 WL 3555490, at *17 (D.D.C. Dec. 23, 2005) ("failure to eliminate several possible causes 'goes to the weight rather than the admissibility of [the] testimony.'") (quotations omitted).

The Third Circuit noted that a defendant's alternative causes, having been addressed by plaintiff's expert, "affect the weight that the jury should give the expert's testimony and not the admissibility of that testimony." *Id*. at 157.

The Third Circuit's reasoning in the Heller decision has been adopted by the Courts of Appeals for both the Fourth Circuit and the Eighth Circuit. The Fourth Circuit, relying on Heller, confirmed "alternative causes suggested by a defendant 'affect the weight that the jury should give the expert's testimony and not the admissibility of that testimony,' unless the expert can offer 'no explanation for why she has concluded that an alternative cause was not the sole cause.'" United States v. Chikvashvili, 859 F.3d 285, 295 (4th Cir. 2017), (quoting Westberry v. Gislaved Gummi AB, 178 F.3d 257, 265 (4th Cir. 1999) (quoting Heller, 167 F.3d at 156-67)). In Kudabeck v. Kroger Co., 338 F.3d 856, 862 (8th Cir. 2003), the Eighth Circuit, quoting Heller, likewise confirmed that "only where a defendant points to a plausible alternative cause and the doctor offers no explanation for why he or she has concluded that was not the sole cause, the doctor's methodology is unreliable."

The Eleventh Circuit and Sixth Circuit have also interpreted Daubert in a manner consistent with this approach. See Guinn v. AstraZeneca Pharm. LP, 602 F.3d 1245, 1253 (11th Cir. 2010) (finding an expert need only "provide a reasonable explanation as to why 'he or she has concluded that [any alternative cause suggested by the defense] was not the sole cause'" of plaintiff's injury) (quoting Best v. Lowe's Home Ctrs., Inc., 563 F.3d 171, 179 (6th Cir.2009) (quoting In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 758 n. 27 (3d Cir.1994)).

Outside the Second Circuit, Courts of Appeals have been careful to limit their role and that of the District Courts to merely ascertaining that there is a reliable methodology behind an expert's testimony. This approach is in line with principles that even the Second Circuit acknowledged prior to the decision at issue: that "Daubert reinforces the idea that there should be a presumption of admissibility of evidence," and that Daubert has "advanced a bias in favor of admitting evidence short of that ... indisputably proven to be reliable," given the power of the adversary system to test "shaky but admissible" evidence. Borawick v. Shay, 68 F.3d 597, 610 (2d Cir. 1995). The other Courts of Appeals properly do not insert themselves into the process of evaluating the weight of an expert witness's opinion via differential diagnosis, or of deciding whether the expert has reached the correct result. So long as the expert has an explanation for excluding an alternative possible cause as part of a differential diagnosis, under Daubert and Rule 702, the expert's causation opinion should be admissible.

### B. The Second Circuit Has Developed an Improper, New Daubert Test, Excluding Petitioner's Experts for Not Conducting Additional Testing in an Attempt to Eliminate a Possible Alternative Cause

There can be no question that Dr. Lewis met the requirements of the other Courts of Appeals discussed above. Dr. Lewis narrowed the etiology of Petitioner's congenital anomalies to valproate exposure on the one hand and genetic abnormality on the other.[6] When the

6. Dr. Lewis included Depakote as a possible cause of Petitioner's birth defects after examining Petitioner, reviewing

results of the genetic testing came back negative, Dr. Lewis was able to rule out genetics as the cause, and conclude in utero Depakote exposure was to blame for Petitioner's conditions. She conducted a standard differential diagnosis, a method that has been long established as the reliable basis for an expert's specific causation opinion. E.g., Glaser v. Thompson Med. Co., 32 F.3d 969, 978 (6th Cir. 1994) (differential diagnosis is "a standard diagnostic tool used by medical professionals to diagnose the most likely cause or causes of illness, injury and disease"); Westberry v. Gislaved Gummi AB, 178 F.3d 257, 262 (4th Cir. 1999) (a differential diagnosis alone provides valid foundation for causation opinion, even when no epidemiological studies, peer-reviewed published studies, animal studies, or laboratory data are offered in support of the opinion); Glastetter v. Novartis Pharms. Corp., 252 F.3d 986 (8th Cir. 2001) (finding differential diagnosis presumptively admissible).

By upholding the exclusion of Dr. Lewis' and Dr. Stodgell's specific causation opinions, the Second Circuit has established a new Daubert standard which conflicts with other Circuit Courts and usurps the role of the jury. There is no dispute that Drs. Lewis and Stodgell provided explanations as to why a genetic cause had been rejected. Nonetheless, the Second Circuit decided that additional genetic testing was required, so that Dr. Lewis could "eliminate the possibility that N.K.'s injuries were caused by genetic defects." (App. 7a.) Such a conclusion is in direct conflict with the other Courts of Appeals.

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records of his fetal exposure to valproate (specifically, through Tanja's use of Depakote) and consulting an authoritative medical text – Smith's Congenital Human Malformations – that indicated that the constellation of Petitioner's abnormalities was consistent with valproate embryopathy.

The Second Circuit was required to ensure the District Court acted properly as gatekeeper to "make certain that an expert … employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 152 (1999). The Second Circuit cites no authority suggesting that Dr. Lewis failed to do so in her differential diagnosis in electing to follow her own medical judgment and not submit Petitioner to burdensome additional testing for unspecified, speculative conditions. In fact, one of Defendant's own experts confirmed that for children who have a clinical presentation similar to Petitioner "no specific genetic diagnosis can be made using currently available genetic tests" (A1021-A1022).

The Second Circuit affirmed the District Court's decision to exclude Dr. Lewis for not conducting additional genetic testing "recommended or suggested" by other doctors. But these recommendations or suggestions are irrelevant to the admissibility of Dr. Lewis' opinion given that she performed a differential diagnosis and had an explanation for ruling out a genetic cause.

Petitioner does not dispute that Dr. Lewis' decision regarding what genetic tests to subject Petitioner to could go to the weight of her testimony. The statements of other doctors adverse to Dr. Lewis concerning the desirability of additional genetic testing may make for fine fodder for cross-examination. But in requiring this additional testing as a prerequisite for permitting Dr. Lewis to testify, the Second Circuit has carved out a new rule that creates a significant split in how the Courts of Appeals and District Courts are to interpret and apply Rule 702 and Daubert when determining the admissibility of expert causation testimony. As explained by other Courts of Appeals,

Dr. Lewis need not have conducted additional testing to eliminate the possibility of genetic causes of Petitioner's injuries---she need only to have utilized a reliable methodology, e.g., a differential diagnosis, and to have had an explanation as to why she concluded Petitioner's injuries did not have a genetic cause.

### C. Reversal of Exclusion of Dr. Lewis Requires Reversal of Exclusion of Dr. Stodgell and Reversal of the Grant of Summary Judgment to Defendant

As the Second Circuit based its decision to uphold the exclusion of Dr. Stodgell's testimony on his supposed reliance of the medical records and testing performed by Dr. Lewis[7], reversal of the Second Circuit's decision in connection to Dr. Lewis likewise calls for reversal of the finding that Dr. Stodgell's testimony was properly excluded. Similarly, as the District Court's grant of Summary Judgment was based on the exclusion of Petitioner's specific causation expert witnesses, Drs.

7. Although the issue was not addressed by the Second Circuit's order in this matter, as set forth in detail in the record and Petitioner's briefing before the Second Circuit, Dr. Stodgell also based his opinion on sources independent from Dr. Lewis's differential diagnosis. These included sources such as the undisputed facts with regard to the precise dosage and duration of Petitioner's exposure to valproate, the types of birth defects suffered by Petitioner, relevant scientific literature, and Defendant's admissions regarding the association of exposure to valproate with the types of birth defects suffered by Petitioner. Dr. Stodgell employed scientifically reliable and generally accepted methodology in the field of teratology, making use of his twenty years of experience in that field. This methodology has been found reliable in this specific field by federal courts in the past. See Dyson v. Winfield, M.D., 113 F.Supp.2d 44, 50, at n.5 (D.D.C. 2001).

Lewis and Stodgell, if their exclusion is not upheld, the grant of summary judgment, likewise should be reversed.

## CONCLUSION

For the reasons set forth above, this Petition for a Writ of Certiorari should be granted.

Respectfully submitted,

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Dated: Mineola, New York
September 7, 2018

# APPENDIX

**APPENDIX A — ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT, FILED JUNE 20, 2018**

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

17-1777-cv

N.K., AN INFANT BY HIS MOTHER AND NATURAL GUARDIAN, TANJA BRUESTLE-KUMRA,

*Plaintiffs-Appellants,*

v.

ABBOTT LABORATORIES,

*Defendant-Appellee.*

April 23, 2018, Decided

Rulings by summary order do not have precedential effect. Citation to a summary order filed on or after January 1, 2007, is permitted and is governed by Federal Rule of Appellate Procedure 32.1 and this Court's Local Rule 32.1.1. When citing a summary order in a document filed with this Court, a party must cite either the Federal Appendix or an electronic database (with the notation "summary order"). A party citing a summary order must serve a copy of it on any party not represented by counsel.

*Appendix A*

At a stated term of the United States Court of Appeals for the Second Circuit, held at the Thurgood Marshall United States Courthouse, 40 Foley Square, in the City of New York, on the 23rd day of April, two thousand eighteen.

PRESENT: JOSÉ A. CABRANES, RAYMOND J. LOHIER, JR., *Circuit Judges*, RICHARD M. BERMAN, *District Judge*.[*]

Appeal from a judgment of the United States District Court for the Eastern District of New York (Ramon E. Reyes, Jr., *Magistrate Judge*). [†]

**SUMMARY ORDER**

**UPON DUE CONSIDERATION WHEREOF, IT IS HEREBY ORDERED, ADJUDGED, AND DECREED** that the September 1, 2017 judgment of the District Court be and hereby is **AFFIRMED**.

Plaintiffs-appellants Tanja Bruestle-Kumra and her infant child N.K. (jointly, "Plaintiffs") appeal from a September 1, 2017 judgment of the District Court granting defendant-appellee Abbott Laboratories' ("Abbott Labs") motion to strike the specific causation testimony of two

[*] Judge Richard M. Berman, of the United States District Court for the Southern District of New York, sitting by designation.

[†] The parties consented to the referral of the case to a United States magistrate judge to conduct all proceedings and order the entry of a final judgment in accordance with 28 U.S.C. § 636(c) and Federal Rule of Civil Procedure 73.

of Plaintiffs' witnesses, and granting summary judgment in favor of Abbott Labs. On appeal, Plaintiffs argue that the District Court erred when it (1) applied the Federal Rule of Evidence 702 standard to the testimony of N.K.'s treating physician; (2) excluded the testimony of Plaintiffs' two expert witnesses on specific causation; (3) granted summary judgment in favor of Abbott Labs; and (4) denied Plaintiffs' motion to amend their pleadings. Upon review, we affirm the District Court's judgment.

We assume the parties' familiarity with the underlying facts, the procedural history of the case, and the issues on appeal.

## STANDARD OF REVIEW

This Court "review[s] the district court's decision to admit or exclude expert testimony under a highly deferential abuse of discretion standard." *Zuchowicz v. United States*, 140 F.3d 381, 386 (2d Cir. 1998). A district court's Rule 702 ruling "will be reversed only for manifest error." *United States v. Tin Yat Chin*, 371 F.3d 31, 40 (2d Cir. 2004). "That standard applies as much to the trial court's decisions about how to determine reliability as to its ultimate conclusion." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152, 119 S. Ct. 1167, 143 L. Ed. 2d 238 (1999).

This Court reviews *de novo* a district court's award of summary judgment, "construe[ing] the evidence in the light most favorable to the [losing party]" and "drawing all reasonable inferences and resolving all ambiguities in [its] favor." *Darnell v. Pineiro*, 849 F.3d 17, 22 (2d Cir.

2017) (internal quotation marks omitted). We "will affirm only when 'there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.'" *In re 650 Fifth Ave. & Related Props.*, 830 F.3d 66, 86 (2d Cir. 2016) (quoting Fed. R. Civ. P. 56(a)).

"We ordinarily review a district court's denial of a motion to amend the pleadings for abuse of discretion." *AEP Energy Servs. Gas Holding Co. v. Bank of Am., N.A.*, 626 F.3d 699, 725 (2d Cir. 2010).

## DISCUSSION

### I.

Plaintiffs first argue that the District Court erred when it applied Rule 702 to determine whether Dr. Lewis, N.K.'s treating physician, was qualified to offer testimony on causation. Specifically, Plaintiffs contend that the District Court should have considered Dr. Lewis as a *factual* witness—as opposed to an *expert* witness—because she developed her opinions in the course of treating N.K. And fact witnesses, Plaintiffs note, are not subject to Rule 702 scrutiny.

Plaintiffs' attempt to circumvent Rule 702 by proffering Dr. Lewis as a non-expert factual witness is self-defeating. Under New York law,[1] "expert medical

1. *See* 29 Charles Alan Wright & Victor James Gold, Federal Practice & Procedure: Evidence § 6263 (2d ed.) ("[S]tate law controls where it makes a precondition to recovery the proffer of expert testimony to prove an element of the

opinion evidence . . . is required, when the subject-matter to be inquired about is presumed not to be within common knowledge and experience." *Meiselman v. Crown Heights Hosp.*, 285 N.Y. 389, 34 N.E.2d 367, 370 (N.Y. 1941); *see also Fiore v. Galang*, 64 N.Y.2d 999, 478 N.E.2d 188, 189, 489 N.Y.S.2d 47 (N.Y. 1985). Plaintiffs wisely do not suggest that identifying the etiology of N.K.'s constellation of congenital anomalies is within common knowledge and experience. Expert medical opinion evidence is thus required to establish causation. *See Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 268 (2d Cir. 2002) ("[T]o establish causation, [Plaintiffs] must offer admissible *expert testimony* regarding both general causation . . . and specific causation." (emphasis added)).

The Federal Rules of Evidence provide that only Rule 702 expert witnesses may provide expert medical opinions. *See* Fed. R. Evid. 701(c) ("If a witness is not testifying as an expert, testimony in the form of an opinion is limited to one that is . . . not based on scientific, technical, or other specialized knowledge within the scope of Rule 702."). Accordingly, if Plaintiffs proffered Dr. Lewis as a non-expert factual witness, she could not provide the expert testimony required to establish causation.

In short, the District Court correctly determined that Dr. Lewis had to be admitted as a Rule 702 expert witness to provide expert testimony on specific causation.

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substantive-law claim, such as standard of care or causation."); *see also Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 268 (2d Cir. 2002).

**II.**

Plaintiffs next argue that the District Court abused its discretion when it determined that Dr. Lewis, N.K.'s treating physician, and Dr. Stodgell, a teratologist and toxicologist, were not qualified to testify as Rule 702 expert witnesses. We disagree.

When parties seek to introduce expert testimony under Rule 702, the district court must play a "gatekeeping role," *Amorgianos*, 303 F.3d at 265, "ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand," *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 597, 113 S. Ct. 2786, 125 L. Ed. 2d 469 (1993). As gatekeeper, the district court has significant discretion to consider numerous factors, including "[1] the theory's testability, [2] the extent to which it has been subjected to peer review and publication, [3] the extent to which a technique is subject to standards controlling the technique's operation, [4] the known or potential rate of error, and [5] the degree of acceptance within the relevant scientific community." *United States v. Romano*, 794 F.3d 317, 330 (2d Cir. 2015) (internal quotation marks omitted). We recognize that a district court's application of these factors "will necessarily vary from case to case." *Amorgianos*, 303 F.3d at 266.

The District Court here determined that, to lay a reliable foundation for their specific causation testimony, Plaintiffs' witnesses had to perform an adequate "differential diagnosis." That is, the witnesses had to "assess the patient's symptoms, create a list of possible

causes, and then seek to eliminate possible causes to identify the most likely cause." Special App'x at 14 (internal quotation marks and alterations omitted). The District Court found particularly wanting the method that the witnesses employed to eliminate the possibility that genetic defects caused N.K.'s injuries.

In 2005, when N.K. was twelve days old, Dr. Lewis determined that N.K.'s injuries were likely caused by either exposure to Depakote or genetic defects. In an attempt to rule out genetic defects, Dr. Lewis referred N.K. for genetic testing. While the initial tests for genetic abnormalities came back negative, the geneticist recommended that N.K. "be re-evaluated in Genetics in six months or earlier if his tests are positive." App'x at 1397. We do not know from the record whether Dr. Lewis followed the geneticist's 2005 recommendation to have N.K. re-evaluated. *Id.* at 1366, 94:4-96:6 (Dr. Lewis's deposition testimony in which she is unable to find record of re-evaluation). But we do know that since 2005 at least four other physicians recommended or suggested additional genetic testing, and no additional genetic tests were ever conducted. *See, e.g.*, *id.* at 1371 (Dr. Morel); *id.* at 1373 (Dr. Engel); *id.* at 1288 (Dr. Wells); *id.* at 1295 (Dr. Mandel).

Based in part on the absence of additional genetic testing, the District Court determined that Dr. Lewis could not reliably eliminate the possibility that N.K.'s injuries were caused by genetic defects. We agree with the District Court. The District Court had more than adequate reason to find, under the circumstances of this

case, that a reliable differential diagnosis required the performance of additional genetic tests.

Dr. Stodgell did not conduct an independent differential diagnosis on N.K., but relied upon the same medical records as Dr. Lewis. Accordingly, the District Court also had adequate reason to exclude Dr. Stodgell's testimony on specific causation.

In short, we conclude that the District Court did not abuse its discretion when it excluded the testimony of Drs. Lewis and Stodgell on specific causation.

**III**.

New York law requires expert witnesses to establish specific causation. *Meiselman*, 34 N.E.2d at 370; *see also Fiore*, 478 N.E.2d at 189. With the testimony of Drs. Lewis and Stodgell excluded, Plaintiffs could not proffer any expert witness testimony on specific causation. We therefore conclude that the District Court properly granted summary judgment in favor of Abbott Labs.

**IV**.

Finally, Plaintiffs appeal the District Court's denial of their motion to amend their pleadings. Plaintiffs filed their motion over two years after their initial complaint and after the close of discovery. We affirm the District Court's denial principally for the reasons set forth in its February 28, 2017 Memorandum and Order.

**CONCLUSION**

We have reviewed all of the arguments raised by Plaintiffs on appeal and find them to be without merit. For the foregoing reasons, we **AFFIRM** the September 1, 2017 judgment of the District Court.

FOR THE COURT:
/s/_____
Catherine O'Hagan Wolfe, Clerk

## APPENDIX B — OPINION OF THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NEW YORK, FILED MAY 22, 2017

UNITED STATES DISTRICT COURT FOR
THE EASTERN DISTRICT OF NEW YORK

No 14-CV-4875 (RER)

N.K. AN INFANT BY HIS MOTHER AND
NATURAL GUARDIAN, TANJA
BRUESTLE-KUMRA,

*Plaintiff,*

VERSUS

ABBOTT LABORATORIES,

*Defendant.*

May 22, 2017, Decided;
May 22, 2017, Filed

**OPINION & ORDER**

**RAMON E. REYES, JR., U.S.M.J**,

Tanja Bruestle-Kumra ("Bruestle-Kumra") and her infant child N.K. (collectively "Plaintiffs") commenced this action against Abbott Laboratories ("Abbott") in May of 2014, alleging that Abbott failed to adequately warn of the teratogenic effects of its drug, Depakote, which caused

N.K. to suffer from a constellation of severe birth defects. (Dkt. No. 1-2). Following removal to Federal Court and the close of discovery, Abbott moved for summary judgment pursuant to Fed. R. Civ. P. 56, on the grounds that: (1) Plaintiff had failed to offer admissible evidence regarding either specific causation or labeling deficiency; and (2) Plaintiffs' claim was precluded by federal law. (Dkt. No. 111). Intimately related to this motion are two of Abbott's pre-trial motions to exclude witness testimony on specific causation. (Dkt. Nos. 70, 84). Upon review of the proposed testimony and witness qualifications, I conclude that neither of the proffered witnesses may testify as to specific causation. Because Plaintiffs are incapable of offering any other admissible evidence on this required element of their claims, I find summary judgment appropriate and grant Abbott's motion.

## BACKGROUND

Abbott produces and distributes Depakote, an anti-epileptic drug whose active ingredient, valproic acid, is a known teratogen linked to increased incidents of certain birth defects if taken during pregnancy. (Dkt. No. 1-2 ("Complaint") ¶ 4; Dkt. No. 1-3 ("Answer") ¶ 4; Dkt. No. 113 (Abbott's Rule 56.1 Statement ("Df. R. 56.1")) ¶ 23; Dkt. No. 116 (Plantiffs' Rule 56.1 Reply ("Pl. R. 56.1")) ¶ 23 (agreeing that Depakote was teratogenic but disputing the level of risk)). Plaintiffs contend that the warning label provided for Depakote was inadequate. (Complaint ¶ 14).

In mid-1997 Bruestle-Kumra suffered two seizures, resulting in her hospitalization. (Df. R. 56.1 ¶ 2; Pl. R.

56.1 ¶ 2). As a result of her seizures, Bruestle-Kumra was prescribed Depakote. (Df. R. 56.1 ¶ 3; Pl. R. 56.1 ¶ 3). She became pregnant in 2004, (Df. R. 56.1 ¶ 19; Pl. R. 56.1 ¶ 19), and continued taking Depakote throughout her pregnancy. (Df. R. 56.1 ¶14; Pl. R. 56.1 ¶ 14).

Bruestle-Kumra›s son N.K. was born in March of 2005. (Df. R. 56.1 ¶ 19; Pl. R. 56.1 ¶ 19). N.K. suffers from a number of physical and developmental impairments including «cleft palate, hypospadias..., hypoplastic thumbs, micrognathia..., microcephaly, wide-set nipples, low-set ears, and facial dysmorphologies[,]» as well as a host of «cognitive developmental delays» and «autistic-like traits[.]»(Df. R. 56.1 ¶ 20; Pl. R. 56.1 ¶ 20). These wide-ranging and severe physical and mental injuries have caused great hardship for N.K. and his family and are the subject of this lawsuit. (Complaint). Plaintiffs allege that it was N.K.›s prenatal exposure to Depakote that caused his injuries, and they now seek just compensation. (Complaint).

## DISCUSSION

### I. Summary Judgment

#### 1. Legal Standard

Abbott has moved for summary judgment, advancing several arguments including that Plaintiffs are unable to present evidence in support of each element of their claims. (Dkt. No. 111 (Memorandum in Support of Defendants Motion for Summary Judgment ("Df. MSJ Br.") at 4)).

*Appendix B*

Under Rule 56, the party seeking summary judgment bears the burden of proving that "there is no genuine dispute as to any material fact" and that it is "entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); *see also Goenaga v. March of Dimes Birth Defects Found*, 51 F.3d 14, 18 (2d Cir. 1995). Where the nonmoving party "will bear the ultimate burden of proof at trial" the movant may satisfy its burden by "point[ing] to an absence of evidence to support an essential element of the nonmoving party's claim." *Goenaga*, 51 F.3d at 18; *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986). If the movant satisfies its burden, it then falls to the nonmoving party to identify a genuine dispute of material fact that calls the movant's right to judgment into question. *United States v. Rem*, 38 F.3d 634, 643 (2d Cir. 1994). Doing so requires actual evidence in the form of "depositions, documents...or other materials[.]" Fed. R. Civ. P. 56(c)(1)(A); see also *Celotex Corp.*, 477 U.S. at 324.

To prevail at trial, Plaintiffs must prove the element of causation by presenting "admissible expert testimony regarding both general causation, i.e., that [Depakote] exposure can cause the type of [injury suffered]; and specific causation, i.e., that [Depakote] exposure actually caused" N.K.'s injuries. *Amorgianos v. National R.R. Passenger Corp.*, 303 F.3d 256, 268 (2d Cir. 2002). Plaintiffs intend to meet their specific causation burden through the testimony of Dr. Rachel Lewis, M.D. ("Dr. Lewis") and Christopher Stodgell, Ph.D. ("Dr. Stodgell"). (Dkt. No. 114 (Memorandum in Opposition to Summary Judgment ("Pl. MSJ Br.")) at 3-4).

Abbott has filed multiple motions *in limine* seeking to exclude witness testimony pursuant to Fed. R. Evid. 702 and *Daubert v. Merrell Dow Pharms. Inc.*, 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993). Among them are Abbott's motions to strike the specific causation testimony of Drs. Lewis and Stodgell. (Dkt. Nos. 70, 84). Absent this testimony Plaintiffs will be unable to meet their burden as to an essential element of their claims, entitling Abbott to judgment as a matter of law.[1]

**2. Proposed Witnesses**

Dr. Lewis is a pediatrician licensed to practice in New York. (Dkt. No. 88-2 (Affidavit of Dr. Lewis ("Lewis Aff.")) ¶¶ 1-2). She received her Medical Degree from Harvard Medical School and completed her residency at Morgan Stanley Children's Hospital of New York-Columbia University in 2003. (Lewis Aff. ¶ 3-5). She has been N.K.'s treating pediatrician since he was twelve days old. (Dkt. No. 88-3 (Deposition Testimony of Dr. Lewis ("Lewis Depo.")) 69:8-9).

Dr. Lewis has never conducted research on Depakote or valproic acid. (Lewis Aff.) Nor has she researched the effects of in utero exposure to valproic acid ("valproate exposure"). (Lewis Aff.). Prior to N.K.'s first visit, her knowledge of Depakote was limited to refilling prescriptions for epileptic patients. (Lewis Depo. 23:12-

1. To the extent that the expert report of Timothy Anderson, M.S., M.B.A., could be read as addressing specific causation, his testimony is inadmissible as he is unqualified to proffer a medical diagnosis. (Dkt. No. 77).

23). Since that initial visit, she has conducted little to no additional research on Depakote, valproic acid, or valproate exposure. (*Id.* 11:4-7, 23:3-7).

According to Dr. Lewis' expert report pursuant to Rule 26(a)(2), "[N.K.'s] condition is a result of his prenatal valproate exposure." (Lewis Aff. at 5).

Dr. Stodgell is an associate professor at the University of Rochester School of Medicine and Dentistry in the Obstetrics & Gynecology department. (Dkt. No. 74-1 (Dr. Stodgell's Expert Report ("Stodgell Report")) at 1). He has a B.A. in biology, a M.S. and Ph.D. in pharmacology and toxicology, and has received post-doctoral training in genetics. (*Id*; Dkt. No. 74-2 August Deposition Testimony of Dr. Stodgell ("Stodgell Depo.) 55:14). However, he is not a medical doctor. (*Id.*)

Dr. Stodgell's research focuses on teratology and autism; he is a member of the Teratology Society and is chair of the Autism Research Program. (Stodgell Report at 1). He has conducted extensive testing on the effect of in utero exposure to valproic acid on animals. (*Id.*) However, Dr. Stodgell has never conducted human testing and has never diagnosed valproate exposure in a human patient. (Stodgell Depo. 42:23-43:2).

It is Dr. Stodgell's opinion that N.K.'s injuries were caused by in utero exposure to valproic acid. (Stodgell Report 9-13).

*Appendix B*

## II. Admissibility of Expert Testimony

### 1. Legal Standard

When a litigant seeks to introduce the opinion testimony of an expert witness, courts assume the active and important role of gatekeeper. *Daubert*, 509 U.S. at 589. In fulfilling this gatekeeper function, the Second Circuit requires courts to determine: "(1) whether the witness is qualified as an expert to testify as to a particular matter, (2) whether the opinion is based upon reliable data and methodology, (3) whether the expert's testimony on the particular matter is relevant...and (4)" whether the proposed testimony complies with Fed. R. Evid. 403. *Glowczenski v. Taser Intern., Inc.*, No. 04-cv-4052 (SJF) (WDW), 2012 U.S. Dist. LEXIS 39438, 2012 WL 976050, at *4 (E.D.N.Y. Mar. 22, 2012). If the expert cannot satisfy these requirements, their testimony must be excluded. *Nimely v. City of New York*, 414 F.3d 381, 396-97 (2d Cir. 2005). The party seeking to introduce expert testimony bears the burden of proving by a preponderance of the evidence that these requirements have been met. *United States v. Morgan*, 675 Fed. Appx. 53, 2017 U.S. App. LEXIS 712, 2017 WL 129902, at *1 (2d Cir. 2017).

### 2. Qualifications

Pursuant to Rule 702, "[a] witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion[.]" Fed. R. Evid. 702. The witness' qualifications do not need to be perfectly on point, and testimony is permitted where

the witness'"educational and experiential qualifications in a general field closely related to the subject matter in question." *Davids v. Novartis Pharmaceuticals Corp.*, 857 F.Supp.2d 267, 276 (E.D.N.Y. 2012).

However, "[a]n expert, although generally qualified, may not be competent to render opinions under the circumstances of a particular case which are outside the expert's area of expertise." *Bourassa v. Black & Decker (U.S.) Inc.*, No. 12-CV-1476 (FJS/CFH), 2015 U.S. Dist. LEXIS 103672, 2015 WL 4715250, at *3 (N.D.N.Y. Aug. 7, 2015). The court retains "the screening function traditionally played by trial judges[,]" *Nimely*, 414 F.3d at 395-9), and must determine whether "the expert [is] qualified to testify in the specific...or specialized area at issue." *Bourassa*, 2015 U.S. Dist. LEXIS 103672, 2015 WL 4715250, at *3.

*a*) *Dr. Lewis*

Dr. Lewis is not qualified to testify that Depakote caused N.K.'s injuries. While undoubtedly qualified as an expert in general pediatric medicine, Dr. Lewis has no experience qualifying her to testify on the subject of specific causation. She has no training in teratology. (Lewis Depo. 23:2-6). She has never prescribed Depakote, only refilling prescriptions when her patient's prescribing doctors were unavailable. (*Id* at 23:12-23). Indeed there is no indication that she has any expertise, training, or experience that would qualify her to testify that Depakote was the cause of N.K.'s injuries.

Deficiencies in knowledge or experience may be overcome through "a review of other studies and scientific literature[, which] can be enough to qualify experts to testify and to make that proposed testimony reliable." *In re Mirena IUD Products Liability Litig.*, 169 F.Supp.3d 396, 412 (S.D.N.Y. 2016). There is no indication that Dr. Lewis conducted such research. Her familiarity with current medical literature on valproic acid and Depakote is limited to its use "in treating epileptic children." (Lewis Deop. at 23:24-24:7; 11:4-7 ("Q. In addition to your medical records, was there anything else you relied on in forming your opinion? A. In forming them, no."). Dr. Lewis did not perform any research or make any additional investigation that might qualify her as an expert on valproate exposure. (*Id* at 25:3-7). Her attempts to understand the cause of N.K.'s injuries were limited to a single review of a single medical book, the day of his first visit. (*Id* at 146:2-9). This is insufficient to qualify her as an expert and as such she may not testify to specific causation.

*b) Dr. Stodgell*

Dr. Stodgell has a more substantial background in the effects of valproate exposure. He is undoubtedly qualified to testify as to general causation, but just "because a witness qualifies as an expert with respect to certain matters or areas of knowledge, it by no means follows that he or she is qualified to express expert opinions as to other fields." *Nimely*, 414 F.3d at 399 n.13.

In the context of medical opinions, courts have consistently drawn a distinction between the qualifications

of medical and non-medical doctors, noting that non-medical doctors who are qualified to diagnose a medical condition may be unable to reliably determine its cause. *Plourde v. Gladstone*, 69 Fed.Appx. 485, 487 (2d Cir. 2003) (Witness who was "a toxicologist and not a medical doctor" was not qualified to opine on specific causation in humans); *Coene v. 3M Co.*, 303 F.R.D. 32, 55 (W.D.N.Y. 2014) ("Although a toxicologist may be qualified to testify as to causation, a toxicologist is generally not qualified to offer a medical diagnosis."); *Munafo v. Metropolitan Transp. Auth.*, No. 98-CV-4572 (ERK)(RLM), 00-CV-0134 (ERK)(RLM), 2003 U.S. Dist. LEXIS 13495, 2003 WL 21799913, at *20 (E.D.N.Y. Jan. 22, 2003) (finding a phsychopharmocologist, who diagnosed and prescribed medication to treat conditions was not qualified to opine on the cause of said condition.").

As a teratologist and toxicologist, Dr. Stodgell may be qualified to testify that Depakote exposure can cause N.K.'s injuries. However, by his own testimony he has never evaluated children, has never been called upon to diagnose dysmorphic features or autism in a child, and is not a clinician. (Stodgell Depo. 42:23-44:14). His expertise is limited to the teratogenic effect of substances, such as valproic acid, in animals generally. (*Id*). This is insufficient to qualify him as an expert on the specific cause of N.K's injuries.

**3. Methodology**

Even if they possessed the necessary expertise, Drs. Lewis and Stodgell may not testify to specific causation

because their opinions are not based upon reliable data and methodology, as required under Rule 702. *Glowczenski*, 2012 U.S. Dist. LEXIS 39438, 2012 WL 976050, at *4. Courts are charged with "ensur[ing] that 'any and all scientific testimony or evidence admitted is not only relevant, but reliable.'" *Nimely*, 414 F.3d at 396 (quoting *Daubert*, 509 U.S. at 589). Rule 702 seeks to ensure reliability by requiring expert testimony to be "based on sufficient facts or data" and be "the product of reliable principles and methods" that "the expert has reliably applied[.]" Fed. R. Evid. 702.

Under the facts of this case, reliable methods require a differential diagnosis, in which doctors assess the patient's symptoms, create "a list of possible causes[,]" and then seek to eliminate possible causes "to identify the most likely cause[.]" *Ruggiero v. Warner-Lambert Co.*, 424 F.3d 249, 254 (2d Cir. 2005).

Courts have consistently found specific causation opinions reached without the aid of a differential diagnosis to be unreliable and requiring exclusion. *Israel v. Springs Industries, Inc.*, No. 98 CV 5106 (ENV)(RML), 2006 U.S. Dist. LEXIS 80863, 2006 WL 3196956, at *10 (E.D.N.Y. Nov. 3, 2006) (Causation testimony "will satisfy *Daubert's* prerequisites for reliability only if the expert conducted a meaningful differential diagnosis ruling out other possible contributing factors."); *see also Davids*, 857 F.Supp.2d at 278 ("[E]ven though an expert need not rule out every potential cause in order to satisfy *Daubert*, the expert's testimony must at least address obvious alternative causes and provide a reasonable explanation for dismissing

specific alternate factors identified by the defendant.") (internal quotations omitted); *Glowczenski*, 2012 U.S. Dist. LEXIS 39438, 2012 WL 976050, at *5 (listing additional factors courts consider, including "whether the expert has adequately accounted for obvious alternative explanations."); *Munafo*, 2003 U.S. Dist. LEXIS 13495, 2003 WL 21799913, at*18 ("To the extent that [expert] testimony touches upon matters of causation, it will satisfy *Daubert's* prerequisites for reliability only if the doctor conducted a meaningful 'differential diagnosis' ruling out other possible contributing factors.").

*a) Dr. Lewis*

Plaintiffs argue that Dr. Lewis "arrived at her conclusion by using a differential diagnosis" because she initially determined that N.K.'s condition was either genetic or the result of valproate exposure and then eliminated the potential genetic causes. (Dkt. No. 87 (Plaintiff's Memorandum in Opposition to Motion to Strike the Testimony of Dr. Lewis ("Pl. Lewis Opp")) at 17). Plaintiffs are only partially correct. Dr. Lewis' records and deposition testimony confirm that she viewed N.K.'s condition as either genetic or the result of prenatal valproate exposure. (Lewis Depo. 145:13-20). However, it is clear that Dr. Lewis failed to adequately investigate or eliminate potential genetic causes before arriving at her opinion.

By Dr. Lewis' own admission, both in her deposition and her medical records, N.K.'s condition might have been caused by prenatal valproate exposure or have resulted

from genetic factors. (Lewis Depo. 144:20-22, 145:13-20). Despite this, Dr. Lewis testified that immediately after N.K.'s first appointment she came to believe his injuries were caused prenatal valproate exposure. *Id* at 144:20-22). She reached this conclusion before eliminating any genetic causes, based only on a review of N.K.'s symptoms in a medical textbook — Smith's Congenital Human Malformations. *Id* at 146:2-9.

Not only did Dr. Lewis fail to eliminate alternative causes before reaching her initial conclusion, she lacked the knowledge to independently rule out genetic causes. She has no background in genetics and has never treated patients with the genetic disorders capable of causing N.K.'s constellation of injuries. (*Id* at 23:2-6, 62:6-10, 76:7-11). As such, her initial opinion was reached through improper methodology.

Subsequent to the formation of her opinion, additional but ultimately insufficient testing was conducted.

In 2005 N.K. was sent to Dr. Yebao, a geneticist, who ran tests for Pierre Robin, Smith-Lemli-Opitz ("Opitz"), DiGreorge, and Fanconi. (Dkt. No. 88-4 (Dr. Lewis' Notes on Phone Call With Dr. Yebao ("Yebao Call")); Stodgell Depo. 159:6-17). Following testing, Dr. Yebao informed Bruestle-Kumra and Dr. Lewis that N.K.'s results were normal, but he called for a "re-evaluation in Genetics in six months" to determine if any additional testing was warranted. (Dkt. No. 88-6; Dkt. No. 88-5 (Yebao Report) at 2). Dr. Lewis is not sure if this re-evaluation ever occurred. (Lewis Depo. 95:13-23). She did testify, however, that Dr.

Yebao did not believe N.K.'s condition was the result of valproate exposure. (*Id* at 99:2-9; Yebao Call).

Dr. Lewis disagreed with this conclusion. (Lewis Depo. 81:15-18). However, she lacks the expertise to challenge Dr. Yebao's assessment. With regard to Pierre Robin, she stated that the disorder was "not my area of expertise[.]" *Id* at 62:6-10. She has never treated a patient with Opitz or Fanconi. *Id* at 76:7-11. When asked if she was sure these causes had been ruled out, Dr. Lewis testified "DiGeorge, for sure. They did that specific FISH. And DiGeorge they did a specific test. Fanconi and Opitz, you would have to ask the geneticist....But I think it is implied by their testing." *Id* at 78:5-24.

In addition to Dr. Yebao's call for more testing, at least four other treating physicians have recommended further genetic testing to determine the cause of N.K.'s injuries.

In 2013 N.K. received a dermatological examination from Kimberly Morel, M.D. ("Dr. Morel"). (Dkt. No. 88-7 ("Morel Report") at 1). Dr. Morel recommended that N.K. be sent to Dr. Yebao to be tested for NF1. *Id* at 3. Dr. Lewis has no record of additional genetic testing following Dr. Morel's recommendation. (Lewis Depo. 113:23). She did not believe further testing was necessary as she disagreed with Dr. Morel's assessment that N.K. met the clinical criteria for NF1. (*Id* at 114:3-8).

In 2014 Dr. Murray Engel, M.D. ("Dr. Engel") provided Dr. Lewis with a report on N.K. in connection with reported staring spells. (Dkt. No. 86-4 ("Engel

Report") at 1-2). Like Dr. Morel, Dr. Engel recommended further genetic testing for "the possibility of NF1 or other genetic diagnosis in addition to [N.K.'s] in utero exposure to anti-epileptic medication." *Id* at 7. According to Dr. Engel, Bruestle-Kumra declined further testing because she believed N.K.'s condition was the result of Depakote exposure. (*Id* at 6). Despite a second opinion citing NF1 as a potential cause, no additional genetic tests were ever conducted. (Lewis Depo. 124:8-23).

In 2015, John T. Wells, M.D. ("Dr. Wells") conducted a neurological evaluation of N.K. related to his academic difficulties. (Dkt. No. 86-5 ("Wells Report") at 5). Dr. Wells was aware of the original genetic testing, but in felt N.K. should "have a follow up genetics evaluation." (*Id* at 6).

Later that year N.K. was evaluated by Arthur Mandel, M.D. ("Dr. Mandel") for attention problems. (Dkt. No. 86-6 ("Mandel Report") at 2). Like Dr. Wells, Dr. Mandel stated that "genetics ha[ve] advanced and it may be helpful to see genetics again in order to get more advanced testing." (*Id* at 6). No further tests were performed and Dr. Lewis did not consult with a geneticist regarding the possibility of new testing. (Lewis Depo. 134:15-17).

Five doctors, including Dr. Yebao, recommended additional genetic testing at some point in N.K.'s treatment. Dr. Lewis, however, has conducted no additional testing. Rather, she has neglected to explore alternative potential causes such as NF1.

Dr. Lewis has also ignored improvements in genetic testing over the past decade which might yield more

concrete results. As noted above, Dr. Yebao was unable to definitively determine causation and he, along with four other treating doctors, recommended renewed testing. However, when asked if improvements in genetic testing over the past decade might lead to more conclusive results, Dr. Lewis stated that "what they would add to a child I saw ten years ago who couldn't have had that test, I don't know. They are very specific genetic tests. I have never ordered them myself[.]" (*Id* at 48:17-25).

Still, Dr. Lewis "ha[s]n't reached the conclusion that genetic testing, more detailed, more recent...would come back normal." (*Id* at 149:6-9). Based on the lack of adequate results, she is unable to rule out genetic causes. (*Id* at 135:10-12) ("Q. Are you able to rule out a genetic underlying cause of NK's cognitive and physical disabilities?...A. If we must provide 'yes' or 'no answer, I guess I have to say no."). Despite her own admission that renewed testing might indicate genetic causes, she has made no effort to explore this possibility.

In addition to potential genetic factors, Dr. Mandel also referenced a possible structural brain lesion. (Mandel Report). Dr. Lewis could not testify as to any testing done to explore Dr. Mandel's concerns. (Lewis Depo. 132:21-133:7). She did reference an MRI conducted prior to Dr. Mandel's evaluation, but noted that it "might not be a perfect study" because of problems with the original test. (*Id* at 133:3-7). She was also unable to "make a conclusion" as to whether cerebral hemorrhaging was the cause of N.K.'s mental or emotional problems or whether it might be caused by valproate exposure. (*Id* at 160:7-12).

Dr. Lewis has not adequately explored or eliminated viable alternative causes. Because she failed to order tests necessary for an accurate diagnosis and did not apply reliable methods to assessing the limited information she did possess, Dr. Lewis' opinion is incapable of satisfying the requirements of Rule 702.

*b) Dr. Stodgell*

Dr. Stodgell did not conduct his own independent investigation. His opinion is based entirely on reviewing existing reports provided to him by Plaintiffs, such as that of Dr. Lewis. (Stodgell Depo. 40:4-12; Dkt. No. 74-9 (November Deposition Testimony of Dr. Stodgell ("Stodgell Depo. 2")) 41:17-19). Dr. Stodgell relied entirely on Plaintiffs' counsel to determine which records were relevant and which did not need to be provided or reviewed. (Stodgell Depo 2 41:22-42:3). It is also clear that he did not have access to all the relevant reports when he produced his expert report. (Stodegll Depo. 2 22:1-23:3) ("I saw those documents after I prepared my report" referring to multiple pediatric records and notes). As such, his report suffers from the same defects as Dr. Lewis'.

Further, a no time prior to forming his opinion did Dr. Stodgell view pictures or videos of N.K., personally examine N.K., or otherwise interview N.K. (*Id* at 36:4-14). Nor did Dr. Stodgell speak directly with any of N.K.'s treating doctors or relatives. (*Id* at 36:24-37:6). He also lacked key facts, like the results of N.K.'s MRI evaluation, which revealed hemorrhaging. (*Id* at 79:4-5). As a result, Dr. Stodgell does not possess adequate facts on which to base his causation opinion.

Nor did he apply proper methodology to the facts he did possess, failing to conduct a differential diagnosis. Dr. Stodgell's attempt to rule out potential alternative causes of N.K.'s condition is plagued by the same problems as Dr. Lewis'. He relied on Dr. Lewis' flawed report in ruling out genetic causes. (*Id* at 41:9-18) ("A. There was comment that genetic testing was done, chromosomal analysis and those were negative for known genetic defects or chromosomal abnormalities. So to me that was the major rule-out. Q. All right. Who was the geneticist...who ruled out genetic causes...A. This was a comment that was made in the medical record by the pediatrician[.]").While an expert witness may rely on the treating physician's reports and records, where the "treating physicians...have not been shown to satisfy the requirements of Rule 702" the expert's testimony is deemed similarly flawed. *Mallozzi v. EcoSMART Technologies, Inc.*, No. 11-CV-2884 (SJF) (ARL), 2013 U.S. Dist. LEXIS 77723, 2013 WL 2415677, at *13 n.8 (E.D.N.Y. May 31, 2013).

He did not consider other genetic causes because "[he] was under the assumption that genetic causes had been ruled out or were not being considered." (Stodgell Depo 163:3-7). Even if he had wanted to conduct a differential diagnosis, he could not have because he did not know which tests had been conducted and was unfamiliar with key genetics reports such as Dr. Yeboa's initial clinical notes or follow-up genetic summary. (*Id* at 42:18-19, 148:7-14, 158:7-159:8, 160:9-14).

Because he has relied on Dr. Lewis' flawed analysis and took no independent steps to conduct his own

differential diagnosis, Dr. Stodgell's testimony does not satisfy the requirements of Rule 702.

**III. Admissibility of Fact Witness Testimony**

Plaintiffs argue that "since Dr. Lewis' opinion as to the cause of N.K.'s injuries was formed during the course of her treatment of N.K., such opinion testimony is considered factual in nature, and therefore not subject to *Daubert* exclusion." (Pl. Lewis Opp. at 15). Plaintiffs cite multiple cases in support of this proposition. (*Id.* at 16-17). Plaintiffs' cases focus on the fact verses expert distinction for the purpose of compliance with Fed. R. Civ. P. 26's disclosure requirements and payment of fees, not with motions to exclude testimony under Rule 702 and *Daubert*. e.g. *Puglisi v. Town of Hempstead Sanitary Dist. No. 2*, No. 11-CV-0445 (PKC) (GRB), 2013 U.S. Dist. LEXIS 111972, 2013 (WL 4046263 at *1 (E.D.N.Y. Aug. 8, 2013) ("Treating physicians may be treated as fact witnesses not required to provide an expert report[.]"); *Turner v. Detla Air Lines, Inc.*, No. 06 CV 1010 (NGG)(CLP), 2008 U.S. Dist. LEXIS 5528, 2008 WL 222559, at *1 (E.D.N.Y Jan. 25, 2008) ("[I]f a treating physician is asked to render opinion testimony based on the physician's specialized skill and knowledge that falls within Federal Rule of Evidence 702, the treating physician may be entitled to an expert fee.").

However, "the testimony of a treating physician... is not without bounds," *Ali v. Connick*, No. 11-cv-5297 (NGG) (VMS), 2016 U.S. Dist. LEXIS 67466, 2016 WL 3002403, at *7 (E.D.N.Y. May 23, 2016), and "treating

physicians who are designated as non-retained experts... are not...permitted to render opinions outside the course of treatment and beyond the reasonable reading of the medical records." *Davids*, 857 F.Supp.2d at 280. Dr. Lewis testified that, during her treatment of N.K., she concluded that his condition was caused by valproate exposure. However, such a conclusion is not reflected in her medical records.

In her initial assessment, following N.K.'s first visit, Dr. Lewis wrote "? Valproate embryopathy" which she testified meant "possible valproic embryopathy[,]" but never expressly wrote that N.K.'s injuries were caused by Depakote or valproic acid. (Lewis Depo. 70:3-5, 161:7-24). She further testified that at that time she could not definitively determine that N.K.'s injuries were the result of valproate exposure. (*Id* at 70:12). In her subsequent reports she makes reference to valproate exposure, but consistently writes "unknown etiology." (*Id* at 99:2-100:6). The conclusion that N.K. was the victim of valproate exposure is simply not reflected in Dr. Lewis' medical records.

Even if such an opinion could be read into her records, classifying Dr. Lewis as a fact expert does not relieve this Court of its duty to ensure she utilized reliable methods in reaching her opinion. *Munafo*, 2003 U.S. Dist. LEXIS 13495, 2003 WL 21799913, at *18 (*Daubert's* "requirements are not diminished merely because the expert witness is a 'treating physician' rather than an expert retained solely for the purposes of litigation."); *see also In re Zypreza Products Liability Litig.*, 489 F.Sup.2d 230, 282 (E.D.N.Y.

2007) (noting that fact witnesses may also be experts, subject to the requirements of Rule 702).

Courts in this district have found that "when [a] treating physician seeks to render an opinion on causation, that opinion is subject to the same standards of scientific reliability that govern the expert opinions of physicians hired solely for the purposes of litigation." *Davids*, 857 F.Supp.2d at 280 (internal quotations omitted); *see also Mallozzi*, 2013 U.S. Dist. LEXIS 77723, 2013 WL 2415677, at *13 n.8 ("[T]he deficiencies in Dr. Levy's testimony cannot be overcome by his reliance upon causation opinions of plaintiff's treating physicians that have not been shown to satisfy the requirements of Rule 702."); *Deutsch v. Novartis Pharms. Corp.*, 768 F.Supp.2d 420, 472 (E.D.N.Y. 2011) (finding a treating physician's causation opinion to be limited by the reliability requirements of Rule 702).

For the reasons discussed above, Dr. Lewis' flawed methodology is unreliable. Therefore, she is unable to testify as to causation regardless of how Plaintiffs seek to characterize her.

## CONCLUSION

For the reasons set forth above, Defendant's motions to strike the causation testimony of Drs. Lewis and Stodgell are GRANTED. As a result, they will be unable to testify that Bruestle-Kumra's use of Depakote during pregnancy caused N.K.'s injuries. Plaintiff can offer no other admissible evidence of specific causation. Therefore, I find that they will be unable to meet their burden of

proof at trial and GRANT Abbott's motion for summary judgment.

SO ORDERED.

/s/ Ramon E. Reyes, Jr.
RAMON E. REYES, JR.
United States Magistrate Judge

Dated: May 22, 2017
Brooklyn, New York

## APPENDIX C — DENIAL OF REHEARING OF THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT, DATED JUNE 11, 2018

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

Docket No: 17-1777

At a stated term of the United States Court of Appeals for the Second Circuit, held at the Thurgood Marshall United States Courthouse, 40 Foley Square, in the City of New York, on the 11th day of June, two thousand eighteen.

N.K., an infant by his mother and natural guardian, Tanja Bruestle-Kumra,

*Plaintiff-Appellant,*

v.

ABBOTT LABORATORIES,

*Defendant-Appellee.*

**ORDER**

Appellant, Tanja Bruestle-Kumra and N.K., filed a petition for panel rehearing, or, in the alternative, for rehearing *en banc*. The panel that determined the appeal has considered the request for panel rehearing, and the active members of the Court have considered the request for rehearing *en banc*.

*Appendix C*

IT IS HEREBY ORDERED that the petition is denied.

FOR THE COURT:

s/_____
Catherine O'Hagan Wolfe, Clerk