No. 18-327

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

BRIEF IN OPPOSITION

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QUESTIONS PRESENTED

This case challenges a decision by the U.S. District Court for the Eastern District of New York ("EDNY") to exclude the specific causation[1] opinions of Petitioner's expert witnesses under Federal Rule of Evidence 702, *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993), and progeny. The EDNY did so on two separate and independently sufficient grounds: (a) the experts were unqualified to render the opinions they were offering, and (b) their opinions lacked a sufficient scientific or medical basis. The Second Circuit affirmed on *both* grounds in an unreported opinion.

Petitioner does not seek review of the determination that his experts were unqualified. He seeks review only of the affirmance of the EDNY's discretionary determination that the expert opinions lacked an adequate scientific or medical basis. As to that issue, Petitioner misrepresents the material facts, including whether his expert had ruled out other causes, in order to manufacture an artificial conflict among the Circuits. Accordingly, this case presents the following questions:

(a) Does a district court abuse its discretion under Rule 702 and *Daubert* where it followed settled legal principles in exercising its gate-keeping function to assess the admissibility of expert opinions?

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1. "Specific causation" refers to the requirement that plaintiffs must prove that the defendant caused their injuries. *See Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 268 (2d Cir. 2002).

(b) Is this a proper case for review where (i) no conflict exists among the Circuits, and (ii) Petitioner does not challenge a separate and independently sufficient basis for the judgment below?

CORPORATE DISCLOSURE STATEMENT

Respondent Abbott Laboratories ("Abbott") is an independent, publicly held company (NYSE: ABT) that has no parent corporations. No publicly held company owns 10% or more of Abbott Laboratories' stock.

TABLE OF CONTENTS

Page

QUESTIONS PRESENTED i

CORPORATE DISCLOSURE STATEMENT iii

TABLE OF CONTENTS..... iv

TABLE OF CITED AUTHORITIES vi

CITATIONS TO RELEVANT OPINIONS AND ORDERS.....1

JURISDICTION.....1

STATUTORY PROVISIONS INVOLVED.....1

STATEMENT OF THE CASE 2

I. Petitioner Misstates the Second Circuit's Holding and the Facts of the Case 2

II. Factual Background 5

A. Dr. Lewis 5

B. The Opinions of Dr. Stodgell 7

ARGUMENT.....8

I. No Split Of Circuit Authority Exists 8

Table of Contents

Page

II. The Petition Seeks An Advisory Opinion. 10

CONCLUSION 11

TABLE OF CITED AUTHORITIES

Page

Cases

Ambrosini v. Labarraque,
101 F.3d 129 (D.C. Cir. 1996). 10

Conway v. California Adult Auth.,
396 U.S. 107 (1969). 11

Daubert v. Merrell Dow Pharms., Inc.,
509 U.S. 579 (1993). . . . . *passim*

Fla. Ass'n of Rehab. Facilities, Inc. v.
State of Fla. Dep't of Health & Rehab. Servs.,
225 F.3d 1208 (11th Cir. 2000) 10-11

Guinn v. AstraZeneca Pharm. LP,
602 F.3d 1245 (11th Cir. 2010). 9

Kannankeril v. Terminix Int'l, Inc.
128 F.3d 802 (3d Cir. 1997) 9

Kudabeck v. Kroger Co.,
338 F.3d 856 (8th Cir. 2003) 9

N.K., an Infant by his Mother and Natural
Guardian, Tanja Bruestle-Kumra v.
Abbott Labs.,
731 F. App'x 24 (2d Cir. April 23, 2018) 1

Cited Authorities

Page

N.K., an Infant by his Mother and Natural Guardian, Tanja Bruestle-Kumra v. Abbott Labs.,
No. 17-1777 (2d Cir. June 11, 2018) 1

N.K., an Infant by his Mother and Natural Guardian, Tanja Bruestle-Kumra v. Abbott Labs.,
No. 14-CV-4875, 2017 WL 2241507
(E.D.N.Y. May 22, 2017) 1

United States v. Chikvashvili,
859 F.3d 285 (4th Cir. 2017). 9

Other Authorities

Federal Rule of Evidence 702 . . . . . *passim*

CITATIONS TO RELEVANT OPINIONS AND ORDERS

The relevant lower-court orders are:

(1) *N.K., an Infant by his Mother and Natural Guardian, Tanja Bruestle-Kumra v. Abbott Labs.*, No. 14-CV-4875, 2017 WL 2241507 (E.D.N.Y. May 22, 2017) (Order and Op.) (App. to Pet. Cert. 10a-31a);

(2) *N.K., an Infant by his Mother and Natural Guardian, Tanja Bruestle-Kumra v. Abbott Labs.*, 731 F. App'x 24 (2d Cir. April 23, 2018) (Summ. Order) (App. 1a-9a); and

(3) *N.K., an Infant by his Mother and Natural Guardian, Tanja Bruestle-Kumra v. Abbott Labs.*, No. 17-1777 (2d Cir. June 11, 2018) (Den. Reh'g or, in the Alternative, Reh'g *En Banc*) (App. 32a-33a).

JURISDICTION

Abbott concurs with Petitioner's statement of jurisdiction.

STATUTORY PROVISIONS INVOLVED

Abbott concurs that Federal Rule of Evidence 702 is the relevant provision.

STATEMENT OF THE CASE

I. Petitioner Misstates the Second Circuit's Holding and the Facts of the Case.

Petitioner's principal contention, that the Second Circuit created a split of authority when it affirmed the exclusion of two unqualified specific causation experts because they did not employ an adequate methodology to reliably rule out genetics as the cause of his injuries, is wrong. This assertion rests upon significant and material misrepresentations of both the Second Circuit's opinion and the facts of the case:

(1) Petitioner's claim that the Second Circuit required him to "eliminate" the possibility of a genetic cause misquotes the Second Circuit's ruling. (Pet. 3, 10). Without disclosing his editorial rewrite, he *adds* the following italicized clause to the Second Circuit's holding: "[A] reliable differential diagnosis required the performance of additional genetic tests [*to eliminate this possibility*]." (Pet. 10) (bracketed emphasis added). *Compare with* App. 8a (not containing bracketed clause). This misquotation fuels his entire argument: he bases the alleged split of authority upon the false proposition that the Second Circuit raised the bar for plaintiffs by requiring them to eliminate all other causes.

This mistake is not inadvertent. Later, Petitioner misrepresents the Second Circuit's decision in similar fashion: he eliminates the Second Circuit's ruling that additional testing was necessary for the expert to *reliably* eliminate alternate causes and further omits the qualifier that this was but one "part" of the EDNY's multiple grounds for its decision. His brief reads:

> 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).

(Pet. 16) (emphasis in original). The correct quotation is:

> 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.

(App. 7a) (emphasis added). By omitting the word "reliably," Petitioner misleadingly rewrites the sentence from an accurate articulation of settled Rule 702/*Daubert* principles to one that, *arguendo*, deviates from them. The Second Circuit did not require Petitioner's experts to eliminate all possibility of genetic defects. Instead, it merely required them to have sufficient grounds for a genetic cause to be reasonably or reliably ruled out. This approach is entirely consistent with *Daubert* and its progeny. Similarly, by omitting the qualifier "in part," Petitioner obscured the EDNY and Second Circuit's multiple grounds for excluding the experts.

(2) On the first page of his Petition, Petitioner erroneously states that "Petitioner's experts were qualified to testify" (Pet. i.) when, in actuality, the EDNY determined that both experts were *unqualified* to render specific causation opinions about his injuries. (App. 17a-19a). The Second Circuit affirmed: "Plaintiff next argues that the District Court abused its discretion when

it determined that Dr. Lewis . . . and Dr. Stodgell . . . were not qualified to testify as Rule 702 expert witnesses. We disagree." (App. 6a). As Petitioner does not seek certiorari to review this separate and independent ground for the EDNY's grant of summary judgment in favor of Abbott, this alternate basis for the decision is final and binding, rendering the Petition moot. His assertion that his experts were qualified grossly misstates the record.

(3) Petitioner's repeated assertions stating or implying that one of his experts, Dr. Lewis, "ruled out" a genetic cause for his injuries (Pet. 7; *see also id.* at 3, 8, 12, and 16, all referencing ruling out, or rejecting genetics as a cause) are untrue. The EDNY recounted multiple examples to demonstrate that Dr. Lewis did not "rule out" genetics, but perhaps the clearest is her own deposition testimony:

> Q: Are you able to rule out a genetic underlying cause of N.K.'s cognitive and physical disabilities?
>
> A: If we must provide "yes" or "no" answer, I guess I have to say "no."

(J.A. 1380 at 152:5-14) (objections omitted).[1] Dr. Lewis also testified that she "[hasn't] reached the conclusion that genetic testing, more detailed, more recent types of test [sic] would come back normal." (J.A. 1380 at 149:6-9).

The fundamental problem with Dr. Lewis' specific causation opinion is that, by her own admission, she did not, and indeed could not, rule out genetics as a cause.

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1. "J.A." refers to the Joint Appendix submitted in the Second Circuit.

Petitioner's repeated assertions that she did does not make it so. The statements are demonstrably false.

II. Factual Background.

In consultation with her physicians, Tanja Bruestle-Kumra took the medication Depakote when pregnant to control her seizure disorder. Her son, N.K., was born with a constellation of physical anomalies, a number of which were not consistent with the kinds of anomalies seen in children born to mothers taking Depakote. (J.A. 1363 at 83:18-23; J.A. 1365 at 89:4-91:2). Moreover, some are common in children with genetic disorders. (J.A. 1356 at 56:20-23).

A. Dr. Lewis.

Dr. Lewis, N.K.'s pediatrician, first saw N.K. when he was 12 days old. At that time, Dr. Lewis gave a "broad" differential diagnosis for N.K.'s physical anomalies of either valproate exposure (valproate is a generic name for Depakote) or a genetic syndrome. (J.A. 1379 at 145:13-25). She admitted that she had not yet ruled out genetics as a possible cause. (J.A. 1379 at 146:22-147:10).

Dr. Lewis testified that the hospital's genetics department would have been responsible for determining if the anomalies were genetic in origin. (J.A. 1354 at 47:23-48:7). Upon reviewing the initial genetic study results, the hospital geneticist wrote that "[t]he etiology of his features is not clear," ordered additional genetic testing, and requested to re-evaluate N.K. within six months. (J.A. 1365-1366 at 92:20-93:18; J.A. 1396-1397). Dr. Lewis had a follow-up conversation with the geneticist and was told

that the geneticist had concluded that "[n]o prognosis [is] possible at this time. Doesn't think valproate explains all symptoms." (J.A. 1361 at 75:14-20; J.A.1395).

Dr. Lewis candidly admitted that she did not know if the additional genetic testing ordered by the geneticist was sufficient to rule out the genetic disorders that the geneticist had identified as possible diagnoses. (J.A. 1362 at 77:6-80:6). She also did not know and had no records indicating whether Petitioner was sent for re-evaluation, as requested by the geneticist. (J.A. 1366 at 93:20-96:6).

Over the next twelve years, Dr. Lewis consistently documented the cause of N.K.'s anomalies as "unknown." (J.A. 1367 at 97:6-100:6; J.A. 1383 at 162:5-163:17). She explained this by testifying that "the geneticist never reached that conclusion himself . . . . So the etiology was not proven by the geneticist . . . to be valproate embryopathy. So that's why it says unknown etiology." (J.A. 1367 at 99:2-16).

As the EDNY recounted, in the years since the initial genetics consultation, at least four of his treating physicians have recommended that N.K. undergo additional genetic testing to determine the cause of his anomalies. These include a pediatric dermatologist at Columbia University in 2013 (J.A. 1370 at 111:21-25; J.A. 1400-1402), a neurologist at Weill Cornell Medicine in 2014 (J.A. 1372 at 119:5-123:22; J.A. 846-850), a neurologist from NYU Medical Neurology Associates in 2015 (J.A. 1374 at 125:11-126:23; J.A. 1284-1289), and a neurologist at Columbia University also in 2015 (J.A. 1374 at 127:21-134:25; J.A. 1291-1297). Despite these repeated recommendations, N.K. was never sent for additional testing. (J.A. 1376 at 134:3-17).

The EDNY found that Dr. Lewis' methodology was inadequate under *Daubert* because (a) the genetic testing that was conducted was inconclusive; (b) the geneticist told Dr. Lewis that he did not believe that N.K.'s condition was the result of Depakote exposure; and (c) Dr. Lewis effectively conceded that she lacked the expertise to challenge the geneticist's opinion in this regard. (App. 22a-23a). The EDNY thus found that Dr. Lewis' causation opinions failed to meet the demands of Rule 702:

> 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.

(App. 26a).

B. The Opinions of Dr. Stodgell.

Dr. Stodgell is Petitioner's other specific causation expert. He is a teratologist by training, not a physician. As pertinent here, Dr. Stodgell specializes in the use of animal models to study the effects of *in utero* exposure to valproic acid and to reproduce the symptoms of autism in these animals. (J.A. 893). Because he is not a physician, Dr. Stodgell conceded that he made no diagnoses on his own and instead relied on the diagnoses contained in the medical records and reports. (J.A. 937 at 39:22-40:12). In other words, he relied on the opinions of Dr. Lewis for his conclusion that genetics had been ruled out as a potential cause of injury. Because his opinion was derivative of Dr. Lewis', the EDNY found that his specific causation

opinion had to be excluded if Dr. Lewis' opinion was excluded. (App. 27a) (quoting *Mallozzi v. EcoSMART Tech., Inc.*, No. 11-CV-2884 (SJF) (ARL), 2013 U.S. Dist. LEXIS 77723, 2018 WL 2315677, at *13 n.8 (E.D.N.Y. May 31, 2013)) ("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.").

ARGUMENT

I. No Split Of Circuit Authority Exists.

Petitioner distorts both the Second Circuit's holding and the facts to manufacture a split of authority among the Circuits. In finding that the experts did not conduct an adequate differential diagnosis and could not reliably exclude a genetic syndrome as a cause of Petitioner's anomalies, the Second Circuit did not create a new, heightened standard under *Daubert*. To the contrary, its decision applies settled law regarding the predicate requirements for differential diagnosis (a diagnosis rendered by excluding other possibilities) to a straightforward set of facts.

The Second Circuit did *not* require that an expert's differential diagnosis must exclude all possibilities, even unreasonable possibilities. Instead, it merely affirmed that *Daubert* requires the district court to assess whether the expert performed an "adequate 'differential diagnosis'" and upheld the EDNY's determination that, by her own admission, Dr. Lewis "could not *reliably* eliminate the possibility that N.K's injuries were caused by genetic

defects." (App. 6a-7a) (emphasis added). This is a routine and wholly unremarkable *Daubert* ruling, and, indeed, many of Petitioner's cases stand for the same proposition: the admission of expert opinions must be based upon adequate and reliable differential diagnoses. *See, e.g., United States v. Chikvashvili*, 859 F.3d 285, 294 (4th Cir. 2017) (quoting *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 265 (4th Cir. 1999)) ("A differential diagnosis that 'fails to take serious account of other potential causes may be so lacking that it cannot provide a reliable basis for an opinion on causation.'"); *Kudabeck v. Kroger Co.*, 338 F.3d 856, 861 (8th Cir. 2003) (citing *Turner v. Iowa Fire Equip. Co.*, 229 F.3d 1202, 1208 (8th Cir.2000)) (affirming that a causation opinion based upon "a proper differential diagnosis" is sufficiently reliable under *Daubert* to be admitted); *Guinn v. AstraZeneca Pharm. LP*, 602 F.3d 1245, 1253 (11th Cir. 2010) (quoting *Best v. Lowe's Home Ctrs., Inc.*, 563 F.3d 171, 179 (6th Cir.2009)) (in conducting a differential diagnosis, the expert must be able to provide "'a reasonable explanation'" as to why alternative causes were ruled out); *see also Kannankeril v. Terminix Int'l, Inc.* 128 F.3d 802, 808 (3d Cir. 1997) (citing *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 762 (3d Cir.1994)) (stating that when a plausible alternative cause is identified, it is "necessary for the plaintiff's expert to offer a good explanation as to why his or her conclusion remains reliable.").

To manufacture a conflict among the Circuits, Petitioner resorts to the gross factual mischaracterization that Dr. Lewis could "rule out" genetics as a cause, arguing that the Second Circuit departed from other courts by second-guessing Dr. Lewis' differential diagnosis. But Dr. Lewis did not rule out genetics as a cause and indeed

lacked the requisite expertise to rule out genetics as a cause. This case thus is the polar opposite of *Ambrosini v. Labarraque*, 101 F.3d 129 (D.C. Cir. 1996), relied on heavily by Petitioner, where a qualified expert *was* able to rule out genetics because of (i) a prior chromosomal study to that effect and (ii) his conclusion that there were no known gene mutations that could create the birth defects at issue. *Id.* at 140. Here, Dr. Lewis could not rule out genetics, did not know if specific genetic syndromes identified by the geneticist had been ruled out by the testing, and did not testify that gene mutations could not cause the constellation of symptoms present in N.K. None of the cases cited by Petitioner involves the situation in which the expert admitted she could not and did not rule out a plausible alternative cause.

The Second Circuit faithfully applied *Daubert* to the facts of this case. Its opinion is completely unremarkable in its application of Rule 702.

II. The Petition Seeks An Advisory Opinion.

Petitioner has already lost this case. His Petition does not seek review of the Second Circuit's affirmance of the EDNY's alternative ground for excluding the experts due to their lack of qualifications to render their differential-diagnosis opinions. As the EDNY's grant of summary judgment in favor of Abbott would not be reversed even if the Petition were granted and the Second Circuit decision were vacated, the outcome of this case is settled. The Petition is moot and raises a non-justiciable issue for review. "Any decision on the merits of a moot case or issue would be an impermissible advisory opinion." *Fla. Ass'n of Rehab. Facilities, Inc. v. State of Fla. Dep't of Health*

& Rehab. Servs., 225 F.3d 1208, 1217 (11th Cir. 2000); *see Conway v. California Adult Auth.*, 396 U.S. 107, 110 (1969) ("In this state of affairs we decline to adjudicate this case. Were we to pass upon the purely artificial and hypothetical issue tendered by the petition for certiorari we would not only in effect be rendering an advisory opinion but also lending ourselves to an unjustifiable intrusion upon the time of this Court. Accordingly, the writ of certiorari is dismissed as improvidently granted.").

CONCLUSION

For the foregoing reasons, Respondent respectfully requests that the Court deny the Petition for a Writ of Certiorari.

Respectfully submitted,

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