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

REPLY BRIEF

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There is a split between the Second Circuit Court of Appeals and other Circuit Courts of Appeals on the appropriate application of Federal Rule of Evidence 702 ("Rule 702"). The Second Circuit decision creates a wide divergence from other courts with a profound effect upon thousands of litigants, calling for this Court to grant this Petition for Writ of Certiorari.

Respondent Abbot Laboratories' ("Respondent") Brief in Opposition makes two primary arguments: first, that the Second Circuit's decision does not represent a split from the established law in other Circuit Courts of Appeals as to when an expert's specific causation opinion is admissible; and, second, that the Second Circuit found a distinct ground for upholding the District Court's decision which Petitioner has not sought to have reviewed, namely, that Petitioner's experts lacked the appropriate qualifications to render specific causation opinions in this matter. Respondent is wrong on both counts.

As set forth in the Petition, Petitioner's expert, Dr. Lewis, provided an explanation for her rejection of genetic defects as the cause of Petitioner's injuries as part of her differential diagnosis, and met the clear standard set by the other Circuits regarding the admissibility of expert testimony based on a differential diagnosis. Separating itself from other Circuits, the Second Circuit established a new and higher standard in deciding that since additional genetic testing could have been conducted to further rule out genetic causes, Dr. Lewis' differential diagnosis was unsound, and her testimony inadmissible under Rule 702. This stringent and draconian standard stands in marked contrast to other Circuits, which have held that an expert's causation opinion is admissible where the expert employs

a reliable methodology such as a differential diagnosis (as employed by Dr. Lewis), and can reasonably explain why an alternative cause raised by defendants was rejected.

Importantly, the Second Circuit did not hold that Petitioner's experts lacked the qualifications or expertise to testify as to specific causation in this matter. The only way in which the Second Circuit stated that these experts were not "qualified" was that they failed to meet the new and onerous methodology requirements imposed by the Second Circuit in this case under Rule 702. Respondent thus errs in suggesting that the Second Circuit separately found Petitioners' experts' qualifications lacking, and that any such finding renders the Petition academic.

Notably, what is absent from the Brief in Opposition is any dispute as to the importance of this Court resolving the proper standard of admissibility for expert testimony under Rule 702. In addition to the importance of addressing a split among the Circuits, the question as to when expert specific causation testimony is admissible is of broad and general importance to the thousands of litigants for which specific causation is the overriding issue. The Second Circuit's new approach imposes an unreasonably high bar on the admission of expert testimony, and will lead to courts usurping the jury's role in weighing expert testimony. It will kill in the crib immeasurable claims or defenses that rely upon an expert's use of the ubiquitous method of differential diagnosis. The Supreme Court should grant the Petition since confusion among the Circuits mandates that a uniform standard be applied throughout the federal court system.

I. The Second Circuit's Decision Diverges Crucially From Other Circuits' Application of Rule 702

Contrary to Respondent's claims, Petitioner has not manufactured a split in authority between Circuits, but rather demonstrated that the Second Circuit's decision dangerously diverges from how other Circuits have addressed the admissibility of expert causation testimony based on differential diagnosis. Respondent's Brief in Opposition cites several of the same cases raised in the Petition, trumpeting that a differential diagnosis, to be reliable, must take into account alternative causes. (Brief in Opposition at 9). What Respondent fails to discuss is the standard applied by other Circuits to determine how an alternative cause is to be addressed by an expert. An expert explaining why an alternative has been rejected need 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). Furthermore, a "physician need not conduct every possible test to rule out all possible causes of a patient's illness." Heller v. Shaw, 167 F.3d 146, 156 (3d Cir. 1999). To the contrary, "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." Kudabeck v. Kroger Co., 338 F.3d 856, 862 (8th Cir. 2003) (quoting Heller, 167 F.3d at 156-67); see also United States v. Chikvashvili, 859 F.3d 285, 295 (4th Cir. 2017) (finding alternative causes suggested by a defendant affect the weight, not the admissibility, of an expert's testimony, unless the expert can offer "no explanation for why she has concluded that an alternative cause was not the sole

cause.") (quoting Westberry v. Gislaved Gummi AB, 178 F.3d 257, 265 (4th Cir. 1999) (quoting Heller, 167 F.3d at 156-67)).

In marked contrast to the standard applied in the other Circuits, the Second Circuit found Dr. Lewis' causation opinion inadmissible despite her providing an explanation as to why she had rejected genetic causes of Petitioner's injuries in favor of Petitioner's mother's use of Depakote. Respondent, in attempting to justify the Second Circuit's decision, asserts that Dr. Lewis did not perform a proper differential diagnosis since Dr. Lewis did not "rule out" a genetic cause of Petitioner's injuries. Respondent compounds its false assertion by quoting an out of context statement from Dr. Lewis' deposition testimony in an attempt to distract the Court from the fact that Dr. Lewis undisputedly provided an explanation for her rejection of a genetic cause.

By the majority standard discussed at length in the Petition and above, Dr. Lewis utilized a sufficiently adequate and reliable methodology of differential diagnosis. Dr. Lewis did not rely solely upon her initial professional assessment, but utilized the relevant literature that valproate embryopathy was the best fit for Petitioner's specific constellation of physical conditions. Her opinion was buttressed with the result of genetic testing, and consultation with geneticists.

As noted in the Petition, New York Presbyterian Hospital's genetics department conducted a series of genetic tests for genetic conditions they considered as

possible causes for Petitioner's injuries. (A1334-1337.)[1] Quite conclusively, these tests each came back negative, causing Dr. Lewis to reject genetic causes and resulting in the diagnosis that Depakote was the specific cause of Petitioner's injuries. (A1379 at 147). Moreover, when Petitioner's dermatologist suggested (based on "café au lait" spots on Petitioner's skin), that a genetic condition known as "NF1" should be ruled out, Dr. Lewis referred Petitioner to an ophthalmologist to determine whether Petitioner had the ocular nodules that present with "NF1." (A1400-1402, A1371 at 113-114). The eye exam revealed that Petitioner did not have the nodule (A1403), thus providing Dr. Lewis a sound and adequate basis to rule out NF1 (A1371 at 113-14). Dr. Lewis explained in detail when deposed how the testing, and its uncontroverted results, caused her to reject a genetic cause for Petitioner's condition in concluding that Depakote indeed was the specific cause. She does not make claims to an absolute certainty as to the cause of Petitioner's defects, nor claim that there is no possible, novel genetic test that might conceivably show Petitioner had a genetic abnormality. (A1380 at 149-151.) After having stated as much to Respondent's counsel, when badgered to provide a "yes" or "no" answer as to whether she can "rule out a genetic underlying cause of NK's cognitive and physical disabilities," Dr. Lewis reasonably acknowledged that if "[I] must provide [a] yes or no answer, I guess I have to say no." (A1380 at 149-152.) However, Dr. Lewis immediately noted that Respondent's counsel's question, "doesn't make much sense to me as a question." (A1380 at 152.) Even Respondent's own experts conceded that for children who

1. "A___" refers to pages in the Joint Appendix submitted with Petitioner's appeal to the Second Circuit in this matter.

have a clinical presentation similar to Petitioner's, "no specific genetic diagnosis can be made using currently available genetic tests…" (A1021-A1022.)[2]

Dr. Lewis' concession that, in an absolute sense, she could rule out a genetic cause, does not erase her explanation as to why and how she rejected a genetic cause in favor of the more probable diagnosis of valproate embryopathy caused by Petitioner's mother's use of Depakote. In essence, there is no "certainty" in the field of medical science, nor, as a matter of law, is such a finding required.

Respondent's argument serves to underscore the dangerous and extreme standard the Second Circuit's decision represents, and which Respondent would favor as the rule of law to be applied in the Second Circuit. The Second Circuit's new conditional requirement subverts the role of the District Court as gatekeeper into a "gate shutter", and snatches from the jury their right to assess the weight to be afforded to specific causation evidence. As noted, the Ninth Circuit has found it is an abuse of

2. Respondent cherry-picked a single question and answer plucked from Dr. Lewis's deposition transcript, a lengthy document in which she speaks to the methodology employed, her differential diagnoses, and opinion that Depakote was indeed the specific cause of Petitioner's deformities. The selection of Respondent's single quoted question and answer is totally misleading in that Dr. Lewis was steadfast throughout her deposition that Depakote was the specific causative factor that produced Petitioner's medical conditions. As Petitioner's pediatrician from 12 days of life to the present time (14 years), Dr. Lewis answered all questions with candor. Neither Dr. Lewis, nor any other specific causation expert, could state with absolute certainty that Depakote was the villain.

discretion to exclude experts' testimony because "they could not completely rule out" a proposed alterative 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). Similarly, the Third Circuit has found that a "physician need not conduct every possible test to rule out all possible causes of a patient's illness." Heller v. Shaw, 167 F.3d 146, 156 (3d Cir. 1999). Dr. Lewis provided a clear explanation as to why Petitioner suffers from valproate embryopathy and not genetic defects. Most importantly, and for the purpose of reaching a reliable differential diagnosis, Dr. Lewis has sufficiently "ruled out" genetic causes. But here the Second Circuit agreed with the District Court that a "reliable differential diagnosis required the performance of additional generic tests," and that not having performed such, Dr. Lewis had failed to "eliminate the possibility that genetic defects caused" Petitioner's injuries.[3] (App. 7A-8A)[4] Such criticism in other Circuits goes to the weight of Dr. Lewis's testimony, and not to its admissibility. As stated earlier, it is the split in the Circuits that mandates a decision by the Supreme Court to bring uniformity to all Circuits.

Requiring Dr. Lewis to conduct unspecified tests beyond what she already had conducted in an attempt to "eliminate the possibility" raised by Respondent, far outstrips the requirements of other Circuits for a

3. Petitioner notes that these two quoted sections from the Second Circuit's Decision were inadvertently combined into a single quotation in the Petition, and regrets any confusion caused by this error.

4. "App. __" refers to pages in the Appendix submitted with the Petition.

sufficiently reliable, and admissible, differential diagnosis. It places an unreasonably heavy burden upon litigants, and sets courts on a risky path to take over the role of juries in weighing evidence and expert testimony.[5] This is a perilous course, and totally inconsistent with the fair and judicious application of Rule 702.

II. Establishing a Uniform Standard for Applying Rule 702 Would Not Constitute an Advisory Opinion:

Respondent claims that Petitioner seeks an advisory opinion, here asserting that Petitioner failed to address the Second Circuit's affirmance of the Eastern District of New York's "alternative ground" for excluding Petitioner's experts, their supposed lack of "qualifications" to render their differential-diagnosis opinions. The Second Circuit made no such ruling.

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5. Although not discussed in the Argument section of Respondent's Brief in Opposition, Respondent mischaracterizes the opinions of Petitioner's other Expert, Dr. Stodgell, in its "Factual Background" discussion. Contrary to Respondent's claims, Dr. Stodgell did not base his specific causation testimony solely on Dr. Lewis having ruled out genetic factors. Instead, as noted in the Petition, Dr. Stodgell reviewed Petitioner's mother's medical records and history, including the records of the prenatal and postnatal genetic testing performed on Petitioner; and conducted a comprehensive review of scientific literature regarding the effects of exposure to valproate, as well as Respondent's admissions concerning the effects of Depakote on birth defects. (A894-916.) In any event, as noted in the Petition, the Second Circuit's determination that Dr. Stodgell's opinion is inadmissible to the extent it relies on Dr. Lewis' differential diagnosis must be reversed upon this Court's finding that Dr. Lewis' differential diagnosis was reliable, and her testimony admissible.

Respondent's false assertion that Petitioner seeks an "advisory opinion" is both fantasy and a distraction from the real issue before this Court. The Second Circuit provides only one basis and explanation for upholding a finding that Petitioner's experts are not "qualified" to provide specific causation testimony: their supposed failure to perform an adequate differential diagnosis. (App. 6A-7A.) The Second Circuit does not discuss the extraordinary educational background of Dr. Lewis (Harvard Medical School, Department of Pediatrics, Morgan Stanley Children's Hospital of NY, Columbia University) or her areas of expertise. Nor does the Second Circuit suggest that the District Court was correct regarding Petitioner's experts' credentials or expertise.

The only manner in which the Second Circuit found Petitioner's experts not "qualified" was in their not adhering to the differential diagnosis standards established by the Second Circuit in its decision. (App. 7A-8A.) This issue is at the heart of the Petition, and the Second Circuit's relevant finding is precisely what Petitioner would appeal. The Petition is thus not academic nor does it seek an advisory opinion. While the District Court did find alternative grounds to exclude Petitioner's experts based on its evaluation of their background qualifications, the Second Circuit did not rule on this issue, basing its affirmance instead on its mistaken opinion that Petitioner's experts' were required to conduct additional genetic testing rendered to be fit to provide expert testimony. Should this Petition be granted and the Second Circuit's decision overturned on the grounds requested, the Second Circuit may be required to render a separate ruling as to Petitioners' experts' background qualifications, an issue vigorously briefed by Petitioner before the Second Circuit.

CONCLUSION

For the reasons stated and those set forth in the Petition, and in the interest of justice, a Writ of Certiorari should be granted.

Dated: Mineola, New York
November 27, 2018

Respectfully submitted,

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