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IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

No. 09-10079

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D. C. Docket No. 07-00133-CV-3-MCR-EMT

RHONDA HENDRIX,
Parent and Guardian of G.P.,
a minor child,

Plaintiff-Counter Defendant-Appellant,

versus

EVENFLO COMPANY, INC.,
a foreign corporation

Defendant-Counter Claimant-Appellee,

FORT WALTON BEACH MEDICAL CENTER,
a Florida corporation,

Defendant.

Appeal from the United States District Court
for the Northern District of Florida

(June 22, 2010)

Before CARNES, HULL and ANDERSON, Circuit Judges.

ANDERSON, Circuit Judge:

Plaintiff-Appellant Rhonda Hendrix alleges that her son, G.P., sustained traumatic brain injuries when a child restraint system manufactured by Defendant-Appellee Evenflo Company, Inc., (“Evenflo”), malfunctioned during a minor traffic accident. Hendrix further alleges that those brain injuries caused G.P. to develop autism spectrum disorder (“ASD”) and a spinal cord defect known as syringomyelia. The district court excluded testimony from two of Hendrix’s expert witnesses that the accident caused G.P.’s ASD. The district court concluded that the methods used by Hendrix’s experts were not sufficiently reliable under *Daubert v. Merrell Down Pharmaceuticals, Inc.*, 509 U.S. 579, 113 S. Ct. 2786 (1993). *Hendrix v. Evenflo Co., Inc.*, 255 F.R.D. 568 (N.D. Fla. 2009). The district court then granted partial summary judgment to Evenflo on Hendrix’s compensatory damages claim, determining that without the excluded testimony there was no reliable evidence to support Hendrix’s theory that the accident caused G.P.’s ASD. Hendrix voluntarily dismissed, with prejudice, her remaining damages claims and filed a notice of appeal.

I. FACTS AND PROCEDURAL HISTORY

The product at issue in this product liability case is the Evenflo Discovery Model 212 Child Restraint System (“the CRS”) owned by Hendrix. The CRS, which was manufactured in December 2000, consists of a plastic base that is

secured to the vehicle's seat by the safety belt and a padded plastic carrier. The carrier is either locked into the base or secured directly to the vehicle's seat with a safety belt. The CRS meets the requirements imposed by federal regulations. *See* 49 C.F.R. § 571.213. When used properly, the base is positioned in a rear seat with the carrier locked into the base so the child faces the rear of the vehicle.

On April 17, 2002, Hendrix and her fifteen-day-old son, G.P., were involved in a minor traffic accident (“the accident”) while traveling at a speed of 10-12 mph. Hendrix claims that G.P. was properly strapped into the CRS, and that the CRS was located in the rear center position of her SUV.¹ Hendrix's theory is that during the accident the seat dislodged from its base because it had been “false-latched.” A false-latch occurs when the mechanism that attaches the carrier to the base fails to properly latch even though the latch makes an audible click leading the person installing the seat to believe the seat is properly installed. Hendrix argues that because of the false-latch the carrier separated from the base at impact and struck the console between the SUV's front seats.

¹ For purposes of this appeal, we assume Hendrix's version of the facts that the carrier and the child were snapped into the base in the rear center position of the SUV. It is undisputed that the base of the CRS was in the rear center seat, secured by a safety belt. However, Evenflow's theory is that the carrier and the child were actually positioned in the front passenger seat of the SUV in contravention of the CRS safety instructions and in violation of state law. Evenflow argues that, due to the incorrect positioning of the carrier, during impact the carrier struck or was struck by the front passenger-side airbag.

It is undisputed that the carrier fractured during the accident. While it is also undisputed that G.P. suffered a closed-head injury as a result of the accident, the parties do dispute the severity of the injury and whether G.P. suffered brain damage. G.P.'s medical records reveal that he suffered, at the very least, a contusion on his forehead and bleeding in his brain. G.P.'s injuries do not appear to have caused immediate neurologic impairment, as G.P. exhibited no developmental problems at his 2, 4, or 10-month check-ups.

Nearly eighteen months after the accident, G.P. began to exhibit developmental problems. When occupational therapy failed to cause improvement, G.P. was referred to Dr. Suhrbier, a pediatric neurologist. Dr. Suhrbier administered a neurologic evaluation to address G.P.'s severe neurodevelopmental delay, impaired social interactions, and history of seizures.

Approximately three years after the accident, Dr. Suhrbier diagnosed G.P. with an asymptomatic spinal cord cyst. Hendrix argues that the cyst is a syringomyelia, which can be caused by trauma but may not appear for several years following the causative trauma.²

Dr. Suhrbier diagnosed G.P. with ASD in April 2007, when G.P. was five

² Evenflo suggests that, instead, the cyst is a hydromyelia resulting from a congenital defect in G.P.'s brain.

years old. There is little information in the record regarding G.P.'s current impairments related to his ASD diagnosis. A report filed in December 2007 by Hendrix's second medical expert, Dr. Hoffman³, describes G.P. as completely nonverbal, aggressive, lacking fine motor skills, and refusing or unable to use utensils, and as suffering from delayed sleep-onset, hyperactivity (i.e., constant motion, running away), and decreased response to pain. Based on information provided by Hendrix and his personal examinations of G.P., Dr. Hoffman concluded that G.P. has "autism spectrum disorder, a behaviorally defined disorder with qualitatively impaired social interaction, qualitatively impaired communication (not compensated by gesture), and restrictive repetitive and stereotyped patterns of behavior, interests and activities." Evenflo's medical expert, Dr. Epstein, also examined G.P. and described impairments consistent with those described by Dr. Hoffman. The experts all agree that, as a result of his ASD, G.P. will never be gainfully employed.

On April 12, 2006, Hendrix filed suit against Evenflo both individually and on behalf of G.P., claiming the defective CRS caused G.P. to sustain injuries that ultimately led him to develop ASD and syringomyelia. Evenflo removed the case

³ Dr. Hoffman is a medical doctor who is board-certified in neurodevelopmental disabilities and developmental-behavioral pediatrics.

to the Northern District of Florida on the basis of diversity jurisdiction. The parties then commenced discovery.

Hendrix sought to introduce testimony by Dr. Suhrbier and Dr. Hoffman that the injuries G.P. sustained in the accident caused him to develop ASD and syringomyelia. Evenflo moved to exclude this testimony, citing as one basis for exclusion the fact that there is no scientifically reliable basis for the experts' opinions, as required by *Daubert*.

The district court assessed the admissibility of Dr. Suhrbier's testimony based on Dr. Suhrbier's deposition taken by Evenflo in July, 2007, and Dr. Suhrbier's post-discovery affidavit prepared on September 9, 2008. In his deposition, Dr. Suhrbier stated that "recognized causes of autism include genetic disorders, metabolic disorders, epileptic encephalopathies, structural injuries and malformations to the brain, as well as reasons that have not been fully elucidated." Dr. Suhrbier also claimed that autism had been associated with severe head injury and stated his opinion that there was a "high probability" the accident had caused G.P.'s ASD. When asked for scientific or medical literature relating autism spectrum disorders and trauma, however, Dr. Suhrbier stated that he could not cite from memory any specific articles.

In his post-discovery affidavit, Dr. Suhrbier stated that his diagnosis of G.P.

was based on:

personal examinations, interaction with and observations of [G.P.], testing that I had performed on him, my review of some of his medical records, multiple interviews with his primary caregiver, my training, education and experience, my own base of knowledge and the utilization of the generally accepted medical methodology referred to as ‘differential diagnosis.’

Dr. Suhrbier explained that “[d]ifferential diagnosis, or differential etiology, is a standard scientific technique of identifying the cause of a medical problem by eliminating the likely causes until the most probable cause is isolated.” Dr.

Suhrbier further stated that in performing his differential diagnosis, he determined that G.P. did not have the Fragile X genetic disorder, “the most common ‘known’ cause of autism,” and therefore concluded “[t]his means, based on our current knowledge, that the cause of his autism is most likely not genetic in nature.” In addition to the differential diagnosis method, Dr. Suhrbier also stated that he sought a unifying mechanism to explain both G.P.’s ASD and his syringomyelia.

According to Dr. Suhrbier, it was important and “consistent with generally accepted methodologies within the field of pediatrics—to the extent possible—to look for unifying theories of diagnosis in an effort to explain a presentation of symptoms.” Dr. Suhrbier stated that he was “quite familiar with the concept that trauma is a recognized cause of autism and syringomyelia in very young patients.”

Again, Dr. Suhrbier provided no research or literature to support this statement.

Dr. Suhrbier stated: “I concluded that the most likely cause of [G.P.]’s autism and syringomyelia was the trauma that he sustained in that motor vehicle accident in April of 2002. It was, and still is, my opinion that trauma was a substantial factor in causing the disabilities that [G.P.] is experiencing today.”

Dr. Hoffman first examined G.P. on March 22, 2006, approximately four years after the accident. The district court assessed the admissibility of Dr. Hoffman’s testimony based on Dr. Hoffman’s Independent Medical Evaluation & Report prepared on December 14, 2007; a deposition taken by Evenflo on January 16, 2008; and a Supplemental Report prepared on June 18, 2008.

In his Independent Report, Dr. Hoffman stated:

[G.P.] has multiple neurodevelopmental impairments that will be handicapping lifelong. My medical opinion, to a reasonable degree of medical certainty, is that [G.P.’s] medical conditions and neurodevelopmental impairments (syringomyelia, autism, impaired adaptive behaviors) are related and secondary to the closed head and central nervous system injury he sustained in the [accident] at age 2 weeks.

In his Supplemental Report, Dr. Hoffman presented ten points that he believes explain how the accident caused both G.P.’s ASD and syringomyelia:

First, that the brain, including the cerebellum, is actively developing during the perinatal/neonatal age that the injury occurred. Second, that this active brain development particularly includes developing

connections between the cerebellum and different regions of the cortex. Third, that abnormalities in the cerebellum and in the connections between the cerebellum and the cortex, are strongly linked to autism. Fourth, that the presence of syringohydromyelia presupposes abnormal cerebral spinal fluid pressure around the cerebellum at the site of the obex and foramen magnum. Fifth, that neither syringohydromyelia nor borderline Chiari I abnormalities were present when [G.P.] was age 2 weeks and were certainly not present in utero when the target ultrasound was performed. Sixth, that hydromyelia is almost always associated with hydrocephalus, which [G.P.] has never had, and Dr. Zimmerman's opinion that [G.P.] does have hydromyelia goes against the clinical records in this case and against the accepted knowledge about the difference between hydromyelia and syringomyelia. Seventh, that the perinatal and neonatal intensive care follow-up literature does support the association between injury to the developing brain, including traumatic brain injury, and later occurrence of autism spectrum disorder. Eighth, that [G.P.] did experience at age 2 weeks . . . enough head injury to cause, among other things, a forehead bruise, irritability, poor feeding, reduced opening of left eye, subarachnoid and subdural hemorrhage, and soft tissue swelling in the parietooccipital region as well as likely hyperflexion neck injury. Ninth, that taken together (rather than in coincidental, idiopathic "we-don't-know" isolation) the sequence of the injury to the brain, spinal cord, and surrounding tissues at that time then resulted in changes to CSF flow in the cervical spinal cord and around the foramen magnum with subsequent development of syringohydromyelia and also related altered and impaired subsequent development of the cerebellum and cerebellar connections to the cerebral cortex resulting in autism spectrum disorder . . . Tenth, there is no evidence in the medical record of any specific genetic disorder as a cause for [G.P.]'s autism.

Dr. Hoffman further stated that G.P.'s autism "is not a result of chromosome abnormality nor of Fragile X syndrome, nor of perinatal distress or insult, nor of neonatal illness. There is no sign or other indication of prenatal or perinatal insult

or other apparent etiology for his autism.” Dr. Hoffman concluded: “G.P.’s autism is a direct result of the injuries he sustained to his head and developing brain during the motor vehicle accident.”

In his deposition, Dr. Hoffman stated that he has never been involved in any scientific studies on the causes of autism. When asked if he could cite any scientific research to support his opinion that traumatic brain injury or close-head injury causes autism, Dr. Hoffman responded:

I haven’t pulled stuff for this report directly. I have thought about this before because I noted clinically, which is not what you are asking, that when I have done neonatal followup or seen children in followup from birth problems, as part of my clinical practice that have autistic features, wondering is there evidence in the literature linking brain injury or trauma to this. And so I have done some literature searches and there are reports, both animal models and persons showing this link. . . . I didn’t include that in my report, so I could find you some of those.

If you ask what scientific basis, and what I was looking for was am I just coming up with this myself, or are there other people seeing this, too, and I reassured myself that other people are and it’s starting to show up in the literature. There is not, that I am aware of, like a major chapter or major article in the New England Journal saying this is a primary cause.

Prior to trial, the district court granted Evenflo’s motion to exclude testimony by Hendrix’s experts regarding the purported cause of G.P.’s ASD. The court reasoned that the methods by which Dr. Suhrbier and Dr. Hoffman arrived at the conclusion that the accident caused G.P.’s ASD were not sufficiently reliable

under *Daubert*. The district court also ruled that it *would* permit the expert testimony with regard to the cause of G.P.’s alleged syringomyelia. As a result of these rulings, the district court granted partial summary judgment to Evenflo on Hendrix’s compensatory damages claim for G.P.’s ASD, while allowing Hendrix’s compensatory damages claim for syringomyelia and her punitive damages claim to proceed to trial. Instead of proceeding to trial on her remaining claims, Hendrix chose to voluntarily dismiss with prejudice her remaining claims and file this appeal.

II. STANDARD OF REVIEW

We review the district court’s exclusion of expert testimony for abuse of discretion. *Rink v. Cheminova, Inc.*, 400 F.3d 1286, 1291 (11th Cir. 2005). We will defer to the district court’s ruling unless it is “manifestly erroneous.” *Id.* “Because the task of evaluating the reliability of expert testimony is uniquely entrusted to the district court . . . we give the district court ‘considerable leeway’ in the execution of its duty.” *Id.* (quoting *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152, 119 S. Ct. 1167, 1176 (1999)) (internal citation omitted).

We review the district court’s ruling on a motion for summary judgment *de novo*, applying the same legal standards that bound the district court. *Nat’l Fire Insur. Co. of Hartford v. Fortine Const. Co.*, 320 F.3d 1260, 1267 (11th Cir. 2003).

Motions for summary judgment should only be granted when the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, show there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322, 106 S. Ct. 2548, 2552 (1986).

III. DISCUSSION

Hendrix raises several issues on appeal. First, she argues that the district court erred in finding unreliable under *Daubert* the experts' testimony that the traumatic brain injury G.P. sustained in the accident caused him to develop ASD. Preliminary to this argument, Hendrix objects to the district court's focus on G.P.'s ASD diagnosis, arguing that the court should instead have assessed the experts' testimony as it pertains to G.P.'s individual neurologic impairments. Second, Hendrix argues that the district court erred in excluding a portion of the opinion of Hendrix's expert, Gary Whitman, relating to the lack of sufficient energy-absorbing padding on the CRS, thus eliminating one of Hendrix's theories of defective product. Third, Hendrix argues that the district court erred in denying her request for discovery on a recall of Evenflo safety seats.

Upon thorough review of the record and with the benefit of oral argument, we conclude that the district court did not abuse its discretion in excluding the

expert testimony of Dr. Hoffman and Dr. Suhrbier based on the insufficient reliability of that testimony under *Daubert*. Because without the testimony of those two witnesses summary judgment was proper on Hendrix’s compensatory damages claim for G.P.’s ASD, and because Hendrix voluntarily dismissed the remainder of her claims with prejudice, we do not reach the additional issues presented in this appeal.⁴

A. Characterizing G.P.’s Neurologic Impairments

As a preliminary matter, we must address Hendrix’s argument that the district court erred by asking whether the experts had established that traumatic brain injury could ever cause ASD. Hendrix argues that, instead, the district court should have determined whether traumatic brain injury could ever cause one or more of the individual neurologic deficits that led to G.P.’s ASD diagnosis. As the experts in this case testified, ASD is a disorder that is recognized and diagnosed based on its underlying impairments. The district court, however, did not discuss G.P.’s underlying neurologic deficits separately. Instead, the court noted that “[a]ccording to Hendrix, [G.P.] suffers from ASD” and then went on to analyze the

⁴ In other words, Hendrix’s second and third arguments relate solely to liability, and Evenflo has no liability on Hendrix’s claim for damages for G.P.’s ASD. Therefore, because Hendrix’s ASD claim is the sole claim remaining after Hendrix dismissed all other claims, Hendrix’s second and third arguments are moot.

experts' testimony in terms of that ASD diagnosis generally. *Hendrix*, 255 F.R.D. at 577.

Hendrix argues that the district court was required to assess the reliability of the expert testimony regarding causation of each of G.P.'s neurologic impairments. Because ASD is defined by its underlying deficits and behaviors, it might be difficult to isolate the deficits underlying G.P.'s ASD diagnosis and determine whether traumatic brain injury could have caused each deficit individually. After a thorough review of the record, however, we conclude that the district court was not required to undertake that complicated task because Hendrix herself failed to fairly present this issue to the district court.

Hendrix's experts both referred to G.P.'s individual deficits, but opined only that there was a causal link between traumatic brain injury and G.P.'s ASD. Neither expert described whether or how traumatic brain injury could cause G.P.'s individual deficits. For example, Dr. Hoffman refers in passing to G.P.'s "multiple neurodevelopmental impairments"; however, in describing his theory of how the accident contributed to G.P.'s injuries, Dr. Hoffman stated the following:

abnormalities in the cerebellum, and in the connections between the cerebellum and the cortex, are strongly linked to autism

...

the perinatal and neonatal intensive care follow-up literature does support the association between injury to the developing brain,

including traumatic brain injury, and later occurrence of autism spectrum disorder

...

the sequence of the injury to the brain, spinal cord, and surrounding tissues at that time then resulted in changes to CSF flow in the cervical spinal cord and around the foramen magnum with . . . impaired subsequent development of the cerebellum and cerebellar connections to the cerebral cortex resulting in autism spectrum disorder

...

there is no evidence in the medical record of any specific genetic disorder as a cause for [G.P.]'s autism

Thus, Dr. Hoffman applied his elaborate causation theory explicitly and unambiguously to G.P.'s ASD diagnosis generally and not to G.P.'s impairments individually.

Similarly, Dr. Suhrbier notes G.P.'s underlying impairments but refers exclusively to "ASD" and "autism" when discussing causation. Dr. Suhrbier stated during his deposition that he had diagnosed G.P. with autism and that there "is a high probability given the severe nature of [G.P.]'s injury and his subsequent development of other neurologic sequela," that the accident had caused G.P.'s ASD. In his affidavit, Dr. Suhrbier said he had "diagnosed [G.P.] with [a]utism (which is on the spectrum of [a]utistic [s]pectrum [d]isorder)," and that "we can reasonably conclude that it is more likely than not that [G.P.] suffered damage to his brain—particularly the posterior regions—which was, in turn, a substantial factor

in causing his autism.” Dr. Suhrbier also stated that “[t]rauma of various kinds is a known cause for . . . autism. . . . as part of my treatment of [G.P.], I concluded that the most likely cause of G.P.’s autism . . . was the trauma that he sustained in that motor vehicle accident in April of 2002.”

Not only did Hendrix’s two medical experts opine only about the cause of GP’s ASD diagnosis taken as a whole, Hendrix’s arguments to the district court also did not attempt to parse the causation issue with respect to any of GP’s individual impairments. Accordingly, we cannot conclude that the district court abused its discretion in focusing on the issue which was fairly presented to it – i.e., the reliability Dr. Hoffman’s and Dr. Suhrbier’s testimony that traumatic brain injury caused G.P.’s ASD. Moreover, in her initial brief before this Court, Hendrix did not argue that it was appropriate to focus on causation of G.P.’s neurologic impairments separately. Therefore, we conclude that she has abandoned this argument on appeal. We now turn to the issue of whether the district court properly excluded testimony from Hendrix’s experts that traumatic brain injury caused G.P.’s ASD.

B. Exclusion of Expert Testimony on Causal Link Between Traumatic Brain Injury and ASD

1. Legal Standards for Admitting Scientific Evidence of Causation

Hendrix seeks to admit expert testimony that the traumatic brain injury G.P. sustained in the accident caused his ASD. Because this is a diversity case, we apply Florida’s substantive law regarding a plaintiff’s burden of proof on causation. *McLeod v. Am. Motors Corp.*, 723 F.2d 830, 832 (11th Cir. 1984). Under Florida law, Hendrix may recover damages upon showing that the trauma was a “substantial factor” causing G.P.’s ASD. *Gross v. Lyons*, 763 So.2d 276, 279 (Fla. 2000); *Hart v. Stern*, 824 So.2d 927, 929-30 (Fla. 5th DCA 2002). A purported cause is a substantial factor if it operates in combination with another cause, such as the negligent act of another or the plaintiff’s pre-existing physical condition, to cause an injury. *Gross*, 763 So.2d at 279; *Hart*, 824 So.2d at 929-30.

Although the standards for finding causation are governed by Florida law, we apply federal law to determine whether the expert testimony proffered to prove causation is sufficiently reliable to submit it to the jury. *Flury v. Daimler Chrysler Corp.*, 427 F.3d 939, 944 (11th Cir. 2005) (noting that in diversity cases, the Federal Rules of Evidence govern the admissibility of evidence in federal court).

The Federal Rules of Evidence provide:

If scientific . . . knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is

the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702. “Unlike an ordinary witness . . . an expert is permitted wide latitude to offer opinions, including those that are not based on firsthand knowledge or observation.” *Daubert*, 509 U.S. at 592, 113 S. Ct. at 2796. “[T]his relaxation of the usual requirement of firsthand knowledge . . . is premised on an assumption that the expert’s opinion will have a reliable basis in the knowledge and experience of his discipline.” *Id.* A trial court assessing the reliability of an expert’s evidence must therefore perform a “gatekeeping” function by conducting “a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue.” *Id.* at 592-93, 113 S. Ct. at 2796. We have offered district courts the following general guidance in determining whether to admit scientific evidence under *Daubert*:

Given time, information, and resources, courts may only admit the state of science as it is. Courts are cautioned not to admit speculation, conjecture, or inference that cannot be supported by sound scientific principles. “The courtroom is not the place for scientific guesswork, even of the inspired sort. Law lags science; it does not lead it.”

Rider v. Sandoz Pharms. Corp., 295 F.3d 1194, 1202 (11th Cir. 2002) (quoting *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 319 (7th Cir. 1996)).

This circuit requires trial courts acting as gatekeepers to engage in a “rigorous three-part inquiry” assessing whether:

(1) the expert is qualified to testify competently regarding the matters he intends to address; (2) the methodology by which the expert reaches his conclusions is sufficiently reliable as determined by the sort of inquiry mandated in *Daubert*; and (3) the testimony assists the trier of fact, through the application of scientific, technical, or specialized expertise, to understand the evidence or to determine a fact in issue.

United States v. Frazier, 387 F.3d 1244, 1260. The proponent of the expert testimony bears the burden of showing, by a preponderance of the evidence, that the testimony satisfies each prong. See *Boca Raton Cmty. Hosp., Inc. v. Tenet Health Care*, 582 F.3d 1227, 1232 (11th Cir. 2009). Here, the parties raise no issues regarding the first and third prongs. Therefore, our analysis will focus on whether the district court abused its discretion in excluding the expert testimony of Dr. Hoffman and Dr. Suhrbier upon finding that the testimony was not sufficiently reliable under *Daubert*.

The *Daubert* Court described several factors trial judges may use to assess the reliability of proffered scientific testimony, including: (1) whether the theory or technique “can be (and has been) tested,” (2) “whether the theory or technique has been subjected to peer review and publication,” (3) “in the case of a particular scientific technique, . . . the known or potential rate of error,” and (4) whether the

theory or technique is generally accepted by the relevant scientific community. *Daubert*, 509 U.S. at 592-94, 2786 S. Ct. at 2796-97; *see also Rink*, 400 F.3d at 1292 (discussing these factors in the context of assessing an expert’s particular scientific technique). This list, however, is not exhaustive, and district courts “have substantial discretion in deciding how to test an expert’s reliability.” *Rink*, 400 F.3d at 1292.

In addition, the Supreme Court has noted that, in the context of this analysis, “conclusions and methodology are not entirely distinct from one another.” *General Elec. Co. v. Joiner*, 522 U.S. 136, 146, 118 S. Ct. 512, 519 (1997). Although experts “commonly extrapolate from existing data . . . nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert.” *Id.* Rather, the trial court is free to “conclude that there is simply too great an analytical gap between the data and the opinion proffered.” *Id.*

Hendrix’s experts rely primarily on the differential etiology method⁵ to link

⁵ Although the parties and other cases often refer to this method as “differential diagnosis,” throughout the opinion we will use the more precise term “differential etiology.” *See McClain v. Metabolife Int’l, Inc.*, 401 F.3d 1233, 1252 (11th Cir. 2005) (describing differential diagnosis and noting that “[t]he more precise but rarely used term is differential etiology”). Differential diagnosis is “the determination of which of two or more diseases with similar symptoms is the one from which the patient is suffering, by a systematic comparison and contrasting of the clinical findings.” *STEDMAN’S MEDICAL DICTIONARY*, 428 (25th ed. 1990). Etiology refers to the “science and study of the *causes* of disease and their mode of

G.P.’s traumatic brain injury to his ASD diagnosis. Differential etiology is a medical process of elimination whereby the possible causes of a condition are considered and ruled out one-by-one, leaving only one cause remaining. *See supra* n.5. Hendrix argues that the experts’ opinions were reliable because differential etiology is a well-recognized scientific method that has been accepted by many courts as a valid basis for expert testimony. *See, e.g., Best v. Lowe’s Home Centers, Inc.*, 563 F.3d 171, 178-84 (6th Cir. 2009); *McClain*, 401 F.3d at 1252-53; *Clausen v. M/V New Carissa*, 339 F.3d 1049, 1057 (9th Cir. 2003). We have previously noted that, when applied under circumstances that ensure reliability, the differential etiology method can provide a valid basis for medical causation opinions. *See McClain*, 401 F.3d at 1252. Here, the reliability of the method must be judged by considering the reasonableness of applying the differential etiology approach to the facts of this case and the validity of the experts’ particular method of analyzing the data and drawing conclusions therefrom. *See Kumho Tires*, 526 U.S. at 153-54, 119 S. Ct. at 1177 (“[T]he specific issue before the court was not the reasonableness *in general* of a tire expert's use of a visual and tactile inspection

operation.” *Id.* at 542 (emphasis added). It is undisputed that G.P. has been diagnosed with ASD; it is the cause of his condition that is at issue. Therefore, the relevant methodology used in this case is differential etiology, i.e., the process of determining which of two or more causes is responsible for the patient’s symptoms.

to determine whether overdeflection had caused the tire's tread to separate from its steel-belted carcass. Rather, it was the reasonableness of using such an approach, along with Carlson's particular method of analyzing the data thereby obtained, to draw a conclusion regarding *the particular matter to which the expert testimony was directly relevant.*") (emphasis in original); *see also Quiet Tech. DC-8 v. Hurel-Dubois UK LTD.*, 326 F.3d 1333, 1343 (11th Cir. 2003).

A reliable differential etiology analysis is performed in two steps. First, the expert must compile a "comprehensive list of hypotheses that might explain the set of salient clinical findings under consideration. . . . The issue at this point in the process is which of the competing causes are *generally* capable of causing the patient's symptoms." *McClain*, 401 F.3d at 1253 (quoting *Clausen v. M/V NEW CARISSA*, 339 F.3d 1049, 1057-58 (9th Cir. 2003)). Second, the expert must eliminate all causes but one. *See McCulloch v. H.B. Fuller Co.*, 61 F.3d 1038, 1044 (2d Cir. 1995).

With regard to the first step, the district court must ensure that, for each possible cause the expert "rules in" at the first stage of the analysis, the expert's opinion on general causation is "derived from scientifically valid methodology." *Hollander v. Sandoz Pharm. Corp.*, 289 F.3d 1193, 1211 (10th Cir. 2002) (quoting *Siharath v. Sandoz Pharms. Corp.*, 131 F. Supp. 2d 1347, 1362-63 (N.D. Ga.

2001)). This is because “a fundamental assumption underlying [differential etiology] is that the final, suspected ‘cause’ . . . must actually be capable of causing the injury.” *McClain*, 401 F.3d at 1253. Thus, the experts’ purported use of the differential etiology method “will not overcome a fundamental failure to lay the scientific groundwork” for the theory that traumatic brain injury can, in general, cause autism. *See McClain*, 401 F.3d at 1252 (“This approach, however, will not usually overcome the fundamental failure of laying a scientific groundwork for the general toxicity of the drug and that it can cause the harm a plaintiff suffered.”).

Some specific principles arise in the context of establishing general causation in cases dealing with medical injuries. In *McClain*, we distinguished cases in which the medical community generally recognizes that a certain chemical can cause the injury the plaintiff alleges from those in which the medical community has not reached such a consensus. 401 F.3d at 1239.⁶ We stated that in

⁶ Hendrix attempts to distinguish this case from *McClain* on the grounds that ours is an “ordinary trauma” case whereas *McClain* is a toxic tort case. Although we are not dealing with a toxic tort, which is “[a] civil wrong arising from exposure to a toxic substance, such as asbestos, radiation, or hazardous waste,” Black’s Law Dictionary (8th ed. 2004), we are dealing with a medical injury allegedly arising from use of a defective product. In *McClain*, as in our case, the court was required to analyze expert medical opinions regarding the cause of an injury; thus, the relevant inquiry was similar. *See McClain*, 401 F.3d at 1236 (holding that the district court erroneously admitted expert testimony that a weight-loss supplement caused the plaintiff’s medical problems). Because Hendrix has provided no reason to distinguish between the causation evidence in *McClain* and the instant case for the purposes of the *Daubert* analysis, we conclude that the principles articulated in *McClain* with regard to admitting expert medical testimony on the cause of an injury may properly guide our reliability inquiry on the causation issue.

the second category of cases, the district court must apply the *Daubert* analysis not only to the expert's methodology for figuring out whether the chemical caused the plaintiff's *specific* injury, but also to the question of whether the drug or chemical can, in general, cause the harm plaintiff alleges. *Id.* Thus, the district court must assess the reliability of the expert's opinion on *general*, as well as specific, causation. *Id.*

Hendrix does not contend that the medical community generally recognizes traumatic brain injury as a cause of autism. Therefore, the district court was correct to apply the *Daubert* analysis to the question of whether traumatic brain injury can, in general, cause autism.⁷ We afford the district court substantial discretion to decide how to test the reliability of the general causation evidence presented by Dr. Hoffman and Dr. Suhrbier. *Rink*, 400 F.3d at 1292.

In reviewing the district court's reliability determination, we note that we

⁷ Hendrix argues that Florida's "substantial factor" test absolves her of establishing general causation between traumatic brain injury and autism. This argument appears to be based on a misunderstanding that the "substantial factor" test means that a substantial *likelihood* of causation is sufficient to impose liability. That is not the case. Florida law's "substantial factor" requirement is best understood to mean that Hendrix could recover if a jury found that G.P.'s injuries were a partial or contributing cause of his ASD. The district court did not exclude the expert testimony on the basis that it did not show that the injury was the *only* cause of G.P.'s ASD; rather, the district court found that there was no scientifically reliable evidence that such brain injuries, in general, could *ever* cause autism. Even the "substantial factor" test requires the plaintiff to show a causal link based on reliable evidence between a purported cause and the alleged injury, as the district court required. *Gross*, 763 So.2d at 279-80. The district court's failure to explicitly articulate Florida's causation standard was neither prejudicial nor an abuse of discretion.

have previously identified some of the scientifically valid methods for establishing general causation. For instance, we will admit expert opinions pursuant to *Daubert* that are supported by epidemiological studies,⁸ provided the expert explains how the findings of those studies may be reliably connected to the facts of the particular case. *Rider*, 295 F.3d at 1198 (noting that, although they are not mandatory, “epidemiological studies may be powerful evidence of causation”); *see also*, *Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 882 (10th Cir. 2005) (“[E]pidemiology is the best evidence of general causation in a toxic tort case.”). An expert’s opinion will likely also survive *Daubert* if the expert describes the physiological process, derived by the scientific method, by which a particular cause leads to the development of a given disease or syndrome. *McClain*, 401 F.3d at 1253 (“The underlying predicates of any cause-and-effect medical testimony are that medical science understands the physiological process by which a particular disease or syndrome develops and knows what factors cause the process to occur.”) (quoting *Black v. Food Lion, Inc.*, 171 F.3d 308, 314 (5th Cir. 1999)); *see also* *Daubert*, 509 U.S. at 590, 113 S. Ct. at 2795 (noting that in order to qualify as “scientific

⁸ “Epidemiology is the ‘study of the distribution and determinants of health-related states and events in populations and the application of this study to control of health problems.’” *In re TMI Litigation*, 193 F.3d 613, 660 n.81 (3d Cir. 1999) (quoting Federal Judicial Center, Reference Manual on Scientific Evidence 174 (1994)).

knowledge” for the purposes of Fed. R. Evid. 702, “an inference or assertion must be derived by the scientific method”).

Courts have also identified other methods that, when used alone, are unable to provide scientifically valid proof of general causation. For instance, in *McClain*, we explained that the “*post hoc ergo propter hoc* fallacy assumes causality from temporal sequence. . . . It is called a fallacy because it makes an assumption based on the false inference that a temporal relationship proves a causal relationship.” *McClain*, 401 F.3d at 1243. Thus, a mere temporal relationship between an event and a patient’s disease or symptoms does not allow an expert to place that event on a list of possible causes of the disease or symptoms. Case studies and clinical experience, used alone and not merely to bolster other evidence, are also insufficient to show general causation. *See Rider*, 295 F.3d at 1199 (“Although a court may rely on anecdotal evidence such as case reports . . . courts must consider that case reports are merely accounts of medical events. They reflect only reported data, not scientific methodology.”) (internal citation omitted); *see also Norris*, 397 F.3d at 887 (“We cannot allow the jury to speculate based on an expert’s opinion which relies only on clinical experience in the absence of showing a consistent, statistically significant association between breast implants and systemic disease.”).

In the second step of the differential etiology analysis, the expert must eliminate all causes but one. *See McCulloch*, 61 F.3d at 1044. While the first step focuses on general causation, in the second step the expert applies the facts of the patient’s case to the list created in the first step in order to form an opinion about the actual cause of the patient’s symptoms, i.e., to determine specific causation. In *Clausen*, the Ninth Circuit stated that an “expert must provide reasons for rejecting alternative hypotheses using scientific methods and procedures and the elimination of those hypotheses must be founded on more than subjective beliefs or unsupported speculation.” 339 F.3d at 1058 (internal quotation omitted). Thus, “[a] district court is justified in excluding evidence if an expert ‘utterly fails . . . to offer an explanation for why the proffered alternative cause’ was ruled out.” *Id.* (quoting *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 202 (4th Cir. 2001)).

With these principles in mind, we now review the district court’s determination that the experts’ testimony in this case was unreliable under *Daubert*.

2. Application of Standards to Dr. Hoffman’s Testimony

The district court determined that Dr. Hoffman’s testimony regarding ASD causation was insufficiently reliable under *Daubert* to warrant admission of that

testimony at trial. The district court identified errors in Dr. Hoffman’s differential etiology analysis at both the “rule in” and “rule out” steps. Specifically, the district court determined that Dr. Hoffman “fail[ed] to show how, by ‘scientifically valid methodology,’ traumatic brain injury could ever be a possible cause of autism in anyone.” *Hendrix*, 255 F.R.D. at 598. The court also found that Dr. Hoffman “failed to compile ‘a comprehensive list’ of all possible causes of ASD” and accordingly that “by failing to include all of the causes currently theorized in the medical literature in his ‘comprehensive list’ of the possible causes of ASD, Hoffman failed to ‘rule out’ all possible causes but one.”⁹ *Hendrix*, 255 F.R.D. at

⁹ Although the district court stated that the expert must make a list of “*all* possible causes for the condition,” *Hendrix*, 255 F.R.D. at 597, we note that *McClain* and *Clausen* merely require the list to be “comprehensive.” See *McClain*, 401 F.3d at 1253; *Clausen*, 339 F.3d at 1057-58. As the Supreme Court stated in *Daubert*, “it would be unreasonable to conclude that the subject of scientific testimony must be ‘known’ to a certainty; arguably, there are no certainties in science.” 509 U.S. at 590, 113 S. Ct. at 1795 (quoting Brief for Nicolaas Bloembergen *et al.* as Amici Curiae 9). Requiring experts to compile a list of all possible causes of a patient’s symptoms violates this principle. Thus, we think an expert performing a differential etiology need only compile a comprehensive list of known causes in order to adequately complete the first step of the differential etiology method. We do not, however, believe the district court’s misstatement of the first step of the differential etiology method led to any error in the court’s overall analysis, in part because the court determined that Dr. Hoffman did not even take into account all possible causes cited in the literature that Dr. Hoffman himself presented. Moreover, because we affirm the judgment of the district court only on the basis of its “ruling in” decision, even if there was error in its “ruling out” decision, our holding would not be affected. Therefore, the district court did not abuse its discretion in finding that Dr. Hoffman’s list of ASD causes was not comprehensive.

597-98. We agree with the district court that Dr. Hoffman failed to “rule in” traumatic brain injury as a possible cause of ASD. Because our holding in that regard is a sufficient ground upon which the district court ruling may be affirmed, we need not address the district court’s decision that Dr. Hoffman failed to rule out other known or plausible causes of ASD.

Dr. Hoffman’s sole support for his theory that, in general, traumatic brain injury can cause ASD came from certain medical textbooks and epidemiological studies submitted by Dr. Hoffman. The district court carefully considered all of the materials cited by Hoffman and concluded that “none of these works come close to providing useful evidence of a definitive¹⁰ causal link between traumatic head injuries and autistic disorders,¹¹ and none provide even marginal support for

¹⁰ Hendrix complains about the district court’s use of the word “definitive,” again accusing the district court of adopting an inflexible bright-line standard of certainty. For the reasons noted in the preceding footnote, we agree that *Daubert* does not require certainty; it requires only reliability. However, despite the district court’s inappropriate choice of the word “definitive,” the context of the district court’s opinion leaves us confident that the court required no more than reliability. As the district court said in the very same sentence, Dr. Hoffman’s cited literature provided not even “marginal support” for his theory of causation. Our own review of the cited literature amply confirms the lack of support.

¹¹ Hendrix objects to the district court’s rationale, arguing that medical literature proving a causal link between trauma and an illness is not a mandatory prerequisite to the admission of opinion testimony on causation from a qualified medical doctor. In general, we do not require medical doctors to support their expert opinions with medical literature. *See Rider*, 295 F.3d at 1198 (“It is well-settled that while epidemiological studies may be powerful evidence

Hoffman’s theory of a relationship between abnormal [cerebral spinal fluid] pressure and problems with cerebellum pressure, leading to autism.” *Id.* at 600-01. We have carefully and exhaustively reviewed the literature cited by Dr. Hoffman and conclude that the district court’s conclusion with regard to each piece of literature was reasonable. We hold that the district court reasonably concluded that none of the literature supported the reliability of Dr. Hoffman’s proffered physiological process, and that none of the literature supported Dr. Hoffman’s opinion that a traumatic brain injury like GP’s could have caused or contributed to the development of ASD. Thus, we conclude that the district court was reasonable

of causation, the lack thereof is not fatal to a plaintiff’s case.”). The proponent of such opinions, however, retains the burden of offering some proof that the expert’s testimony on general causation is reliable. In *Rider*, for example, we stated:

In the absence of epidemiology, plaintiffs may still prove medical causation by other evidence. In the instant case, however, plaintiffs simply have not provided reliable evidence to support their conclusions. To admit the plaintiffs’ evidence, the Court would have to make several scientifically unsupported “leaps of faith” in the causal chain. The *Daubert* rule requires more.

295 F.3d at 1202.

Here, Dr. Hoffman chose to rely exclusively on medical literature to establish general causation between traumatic brain injury and ASD. Therefore, the medical literature must provide enough support for Dr. Hoffman’s general causation opinion to satisfy *Daubert*’s reliability requirement. *See McClain*, 401 F.3d at 1239-40 (concluding that expert’s opinions on general causation should be excluded because the expert did not “support his opinions with sufficient data or reliable principles, as identified by the *Daubert* rubric . . .”).

in determining that the literature overall does not provide the necessary support for Dr. Hoffman's opinions to render those opinions admissible under *Daubert*.

Rather than duplicating the district court's persuasive analysis of the literature provided by Dr. Hoffman, *see Hendrix* 255 F.R.D. at 600-03, we will focus on those pieces of literature emphasized by Hendrix on appeal. At oral argument, Hendrix's counsel stated that the most compelling literature discussing the physiological process by which traumatic brain injury could cause autism is a chapter in a textbook edited by Evenflo's medical expert Dr. Joel Morgan. *See* Gerry A. Stefanatos & Wilson Q. Joe, *Autistic Disorder*, in *Textbook of Clinical Neuropsychology*, 185-260 (Joel E. Morgan & Joseph H. Ricker, eds., 2008). We read this chapter carefully and failed to discern any suggestion that brain damage resulting from post-birth traumatic brain injury can cause autism spectrum disorders. We also saw no support for Dr. Hoffman's theory that abnormal cerebral spinal fluid pressure in the cerebellum could cause ASD. The chapter states that certain learning and memory patterns found in autistic individuals have been "interpreted as reflection of cerebellar pathology," but also notes that "studies have shown that frontal lobe and basal ganglia are also involved" in learning a memory, and that "[c]onsequently, these findings could not rule out an explanation in terms

of a frontal-striatal dysfunction rather than anomalies of frontal-cerebellar circuits.” *Id.* at 202. Further on in the chapter, the authors discuss the role of the cerebellum in ASD in general, and note that “histological studies of the autistic brain have consistently implicated reduction of Purkinje cells of the cerebellum.” *Id.* at 221. They do not, however, opine as to what might cause such a reduction of those cells. While these statements provide some support for the idea that the cerebellum is linked to autism in a very general sense, they offer no reliable support for Dr. Hoffman’s theory that a traumatic brain injury like the one G.P. suffered could cause or contribute to the development of ASD. We found no mention at all in the Chapter of Dr. Hoffman’s proposed physiological process involving abnormal cerebral spinal fluid pressure leading to ASD.

Notably, although the chapter catalogues the known etiological factors involved in ASD, the section titled “Etiological considerations” does not mention acquired trauma in the perinatal brain. *Id.* at 213-17. The section discusses genetic factors at length, and then goes on to list “extrinsic factors” such as: viruses; the presence of other neurological conditions, such as epilepsy; birthing complications; teratogenic substances, such as cocaine; and autoimmune factors. *Id.* The section fails to mention traumatic brain injury, and the authors qualify even the factors they

do list by noting that “studies directed to examining etiologic factors in [autism] have suffered from limitations due to small sample sizes, inadequate specification of diagnostic categories, and significant heterogeneity of the autistic population.” *Id.* at 217.

Hendrix’s counsel also noted as particularly persuasive an article titled *Late Neurologic and Cognitive Sequelae of Inflicted Traumatic Brain Injury in Infancy*. Barlow *et al.*, *Late Neurologic and Cognitive Sequelae of Inflicted Traumatic Brain Injury in Infancy*, 116 *Pediatrics*, Aug. 2005. The article describes a variety of neurologic impairments, including many of the impairments from which G.P. suffers, found in children with inflicted traumatic brain injury (e.g., shaken baby syndrome). *Id.* at e174. While Hendrix criticizes the district court for discounting the article based on the distinction between inflicted (non-accidental) and accidental traumatic brain injury, the article itself supports the notion that the two types of injuries are distinct. For instance, the article notes that mortality rates for infants with inflicted traumatic brain injury are greater than those for infants whose injuries were accidental. *Id.* at e174. The article also self-limits its findings by pointing out the small sample size, the need for further study, and that the study lacked a control group. *Id.* at e184. In fact, the authors mention that previous

similar studies used children with an accidental traumatic brain injury as control subjects against which to compare those subjects with inflicted injuries. *Id.* Moreover, although one patient in the study developed autism spectrum disorder, the authors note that the ASD patient “may have had significant exposure to alcohol in utero.” *Id.* at e183. The district court identified these shortcomings and noted that “significantly, nothing in the study purports to show or explain the physiological process by which brain injury produces autism.” *Hendrix*, 255 F.R.D. at 601. The court therefore concluded that this study was insufficient to support Dr. Hoffman’s assertion that the literature supports his theory of causation or even a general causal link between accidental traumatic brain injury and ASD. We cannot say that this determination was an abuse of discretion.

We found the most direct statement supporting the theory that traumatic brain injury can cause ASD in a textbook submitted by Dr. Hoffman that was not brought to our attention on appeal. That textbook states:

Considerable precedent for deleterious effects of various perinatal insults on organizational events is provided by studies with experimental animals. Initial studies of later cortical neuronal development in “undamaged” areas adjacent to ischemic cortical injury in human infants show dendritic aberrations that could contribute importantly to subsequent cognitive deficits and epilepsy. It is a clinical truism that some children affected by one or more

perinatal insults may exhibit neurological sequelae that are more severe than might be predicted from the extent of injury recognized by the usual brain imaging or neuropathological techniques.

Volpe, *Human Brain Development* in Neurology of the Newborn at 82. In other words, this textbook provides some support for the idea that even minor injuries sustained by newborn brains can result in more severe neurologic impairments than one would expect from the initial extent of the injury. The textbook does not, however, link such injuries to ASD, or provide any support for Dr. Hoffman's theory of ASD causation involving abnormal cerebral spinal fluid pressure.

We are satisfied that the district court did not abuse its discretion in concluding, based on the literature Dr. Hoffman himself provided, that there is no reliable support for Dr. Hoffman's assertion that "perinatal and neonatal intensive care follow-up literature does support the association between injury to the developing brain, including traumatic brain injury, and later occurrence of autism spectrum disorder."¹² Because Dr. Hoffman offers no other scientifically reliable

¹² In addition to concluding from our own review of the medical literature that it does not support Dr. Hoffman's theory of causation, we also note that Dr. Hoffman himself was quite qualified in the support he claims from the literature. In his supplemental report, he noted that: "Thus, there is a general consensus by many in the scientific community that the etiology for autism spectrum disorders often does include environmental factors, and some researchers have reported specifically the association between insults to the perinatal-newborn brain and subsequent development of autism." In a similar vein, Dr. Hoffman testified that he had noticed

basis for his opinion, his testimony is the type of “speculation, conjecture, or inference” that we have cautioned district courts not to admit. *Rider*, 295 F.3d at 1202.

Hendrix attempts to sidestep the deficiencies in the medical literature by focusing on Dr. Hoffman’s experience and training. Merely demonstrating that an expert has experience, however, does not automatically render every opinion and statement by that expert reliable. As an Advisory Committee Note on Federal Rule of Evidence 702 states:

If the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts. The trial court's gatekeeping function requires more than simply “taking the expert's word for it.”

Committee Notes on Rules - 2000 Amendment (quoting *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1319 (9th Cir. 1995)). “Taking the expert’s word for

in his practice that some children with early brain injuries later develop autistic features, had wondered if others were seeing this too, and then “reassured [him]self that other people are, and it’s starting to show up in the literature.” In other words, Dr. Hoffman refers both to his own experience and to the literature as evidencing only a temporal relationship, or a mere correlation. However, we held in *McClain* that a mere temporal relationship, itself, would not ordinarily be sufficient to prove a causal relationship. See *McClain*, 401 F.3d at 1243 (“Proving a *temporal* relationship between taking Metabolife and the onset of symptoms does not establish a *causal* relationship.”)

it” is precisely what Hendrix suggests the district court should have done in this case; however, we have previously recognized that “[n]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert.” See *McClain*, 401 F.3d at 1244 (quoting *Joiner*, 522 U.S. at 146, 118 S. Ct. at 519 (1997)). Dr. Hoffman has not provided a reliable basis, derived by the scientific method, for concluding that traumatic brain injury can cause ASD. We decline to conclude that the district court abused its discretion in failing to admit Dr. Hoffman’s testimony based on his experience alone.

Because the medical literature adduced by Hendrix supports neither Dr. Hoffman’s theory of causation involving abnormal cerebral spinal fluid pressure nor his ultimate opinion that a traumatic brain injury like GP’s can cause autism, and because Dr. Hoffman offers no other scientifically reliable basis for his opinion,¹³ we hold that the district court did not abuse its discretion in concluding

¹³ For example, there is no evidence that Dr. Hoffman’s theory of causation has been tested or subject to peer-reviewed publication. See *Daubert*, 509 U.S. at 593-94; 2786 S. Ct. at 2796-97. And, other than Dr. Hoffman’s own unsupported and qualified assertion of general acceptance in the scientific community, there is no evidence that Dr. Hoffman’s theory is generally accepted in the relevant scientific community. See *McClain*, 401 F.3d at 1244 (with respect to the *ipse dixit* of an expert).

that Hendrix failed to establish general causation to support Dr. Hoffman's opinion. That is, Hendrix has failed reliably to "rule in" traumatic brain injuries like GP's as a plausible cause of autism.

Because this is a sufficient basis on which to affirm the district court's ruling excluding Dr. Hoffman's testimony, we need not address the district court's decision that Dr. Hoffman also failed to "rule out" other possible causes. The district court held:

Hoffman's claim that he ruled out genetics as a potential cause of [GP's] ASD based on [GP's] normal "Fragile X" tests ignores the possibility of other genetic conditions as a cause. Given the plethora of genetic theories for autism, "ruling out" Fragile X as a possible cause of [GP's] ASD far from eliminates all genetic causes of his ASD, let alone the other multitude of factors that have been linked to autism or ASD.

Hendrix, 255 F.R.D. at 598 (footnotes omitted). The medical literature indicates that there are a dizzying array of other factors that have been mentioned as possible causes, including as many as 90 gene mutations that could play a role in the development of autism. See Frank Polleaux & Gean M. Lauder, *Toward a Developmental Neurobiology of Autism*, 10 *Mental Retardation and Dev. Disabilities Research Rev.* 303, 309, 310-12 (2004). Dr. Hoffman conceded in his deposition testimony that, unless one of the genetic chromosome anomalies that is

known to cause autism is identified, medical science simply does not know what causes autism. Obviously, in such a situation, the task of “ruling out” other plausible causes is extremely complex. In light of our decision that Dr. Hoffman failed to reliably “rule in” his theory of ASD causation, we need not in this case venture into the quagmire of attempting to define the parameters of a reliable process of “ruling out” other possible causes of autism.

3. Application of Standards to Dr. Suhrbier’s Testimony

Hendrix also objects to the district court’s exclusion of Dr. Suhrbier’s testimony. Dr. Suhrbier, G.P.’s treating physician, sought to testify as an expert witness under Rule 702. In order to be admitted into evidence, Dr. Suhrbier’s opinions must also be based on a scientifically reliable methodology under *Daubert*. See *United States v. Henderson*, 409 F.3d 1293, 1299-1300 (11th Cir. 2005).

Dr. Suhrbier purported to both perform a differential etiology and to look for a unifying theory to explain G.P.’s ASD and syringomyelia. Like Dr. Hoffman, he concluded that the “most likely cause of [G.P.]’s autism and syringomyelia was the trauma that he sustained in that motor vehicle accident in April of 2002.” Unlike Dr. Hoffman, however, Dr. Suhrbier did not even attempt to provide any evidence

to support a general causal link between traumatic brain injury and ASD. He presented no medical literature, described no relevant physiological process, and provided no other support for his conclusion that traumatic brain injury can cause autism. Based on the *Daubert* requirements for admitting expert testimony, we cannot say that the district court abused its discretion in determining that there was too great an analytical gap between Dr. Suhrbier's evidence and conclusions regarding G.P.'s ASD diagnosis to submit those conclusions to the jury.¹⁴

IV. CONCLUSION

Under *Daubert*, it is the unique role of the district court to determine whether an expert's opinion is sufficiently reliable to allow it to be presented to a jury. Here, the district court concluded that Hendrix failed to present scientifically reliable evidence that traumatic brain injury can ever cause autism. Thus, the

¹⁴ Hendrix also argues that the expert testimony of Dr. Hoffman and Dr. Suhrbier is reliable because both sought to find a "unifying mechanism" explaining both G.P.'s ASD and syringomyelia. Both doctors came to the conclusion that the unifying mechanism was the traumatic brain injury G.P. sustained in the accident. This argument fails for the same reason Hendrix's argument related to differential etiology fails. There is no evidence that is scientifically reliable under *Daubert* indicating that traumatic brain injury can ever cause or contribute to ASD. Therefore, it follows that there is no scientifically reliable evidence that traumatic brain injury can cause or contribute to *both* ASD *and* syringomyelia. Moreover, regardless of the rarity of either condition or the probability that both conditions would be present in the same individual, Hendrix's experts have provided no support for the notion that the accident is a more likely unifying mechanism than some other common cause.

district court excluded the experts' theories because of a lack of reliable proof of general causation between the alleged injury and the purported cause of that injury.¹⁵ Upon thorough review of the record and with the benefit of oral argument, we conclude that the district court properly executed its gatekeeper function under *Daubert*, and therefore the court did not abuse its discretion in excluding the expert testimony.

We emphasize that we express no opinion regarding whether traumatic brain injury sustained in the perinatal or neonatal period can ever cause or contribute to later development of an autism spectrum disorder. Rather, as we have previously stated: "The courtroom is not the place for scientific guesswork, even of the inspired sort. Law lags science; it does not lead it." *Rider*, 295 F.3d at 1202 (quoting *Rosen*, 78 F.3d at 319). We emphasize also that our conclusion, and that of the district court, is based only on the evidence presented in this case. Given the current state of scientific knowledge regarding the causes of autism spectrum disorders (as it has been presented to us by the parties), we are unable to say that the district court abused its discretion in excluding this expert testimony. Because

¹⁵ We can reject summarily Hendrix's argument that the testimony of Evenflo's experts constituted reliable evidence of such general causation.

without this testimony there is no genuine dispute of material fact regarding causation of G.P.'s ASD, the district court's grant of summary judgment on Hendrix's sole remaining claim was appropriate.

Accordingly, the district court's exclusion of expert testimony and grant of summary judgment are

AFFIRMED.