[PUBLISH]

IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

No. 12-14502

D.C. Docket Nos. 1:09-md-02051-CMA; 9:09-cv-80625-CMA

MARIANNE CHAPMAN,
DANIEL CHAPMAN,

Plaintiffs - Appellants,

versus

THE PROCTER & GAMBLE DISTRIBUTING, LLC,
THE PROCTER & GAMBLE MANUFACTURING CO.,

Defendants - Appellees.

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

(September 11, 2014)

Before PRYOR, JORDAN and FAY, Circuit Judges.

FAY, Circuit Judge:

Marianne and Daniel Chapman appeal summary judgment for The Proctor & Gamble Distributing, LLC and The Proctor & Gamble Manufacturing Company (collectively "P&G") in their products liability case concerning Fixodent, a denture adhesive. We affirm.

I. FACTUAL AND PROCEDURAL BACKGROUND

Marianne Chapman suffers from myelopathy, a neurological condition or spinal-cord disorder that affects the upper and lower extremities. She developed a number of neurological symptoms from April 2006 through January 2009.[1] The Chapmans maintain Marianne Chapman's symptoms were caused by zinc-induced, copper-deficiency myelopathy ("CDM") from her use of two to four 68-gram tubes of Fixodent denture adhesive each week for eight years. P&G counters that the testimony of the Chapmans' experts should not be admitted, because their methodologies are unreliable and do not substantiate the conclusion that Fixodent caused Marianne Chapman's CDM.

[1] These symptoms included loss of feeling in her hands and feet, a progressive gait ataxia that caused her to trip when walking in the dark and subsequently confined her to bed, a burning pain in her hands and feet requiring opiod management, blood dyscrasias with anemia and neutropenia (low red and white blood-cell counts), and subacute bilateral asymmetric wrist and finger drop in both hands, limiting her ability to extend her fingers and thumbs. *In re Denture Cream Prods. Liab. Litig.*, 795 F. Supp. 2d 1345, 1348 (S.D. Fla. 2011).

While zinc is an essential element for human growth, it is not found separately in nature but occurs in various compounds, such as zinc acetate and zinc sulfate. In 1990, P&G reformulated Fixodent to include a calcium-zinc compound to improve its adhesion. The calcium-zinc compound in Fixodent is less bioavailable than other zinc compounds, like zinc acetate.[2] A case report in 2008 hypothesized zinc in denture adhesives may lead to copper deficiency, which could cause neurologic injury. S.P. Nations, et al., *Denture Cream: An Unusual Source of Excess Zinc, Leading to Hypocupremia and Neurologic Disease*, 71 Neurology 639 (2008). Thereafter, various individuals filed lawsuits nationwide against GlaxoSmithKline ("GSK"), manufacturer of Poligrip, and P&G, manufacturer of Fixodent.

The Chapmans originally filed their case in Florida state court on April 1, 2009, against P&G, which removed it to federal court in the Southern District of Florida on diversity jurisdiction.[3] On June 9, 2009, the United States Judicial Panel on Multidistrict Litigation ("MDL") transferred these similar cases against

[2] The zinc in Fixodent enters a user's digestive tract, when food is chewed and swallowed. The absorption of zinc occurs in the small intestine, where the Chapmans contend it blocks copper assimilation into the body, resulting in CDM. Bioavailability refers to accessibility to metabolic and physiological body processes, while dissociation references how a compound separates into component parts under particular conditions.

[3] The Chapmans' Amended Complaint, filed on November 9, 2009, contains seven causes of action, including state-law claims: (1) strict products liability, (2) negligence, (3) intentional misrepresentation, (4) breach of express warranty, (5) implied warranty, (6) violation of the Florida Deceptive and Unfair Trade Practices Act, Florida Statutes §§ 501.201, *et seq.*, and (7) loss of consortium. This appeal concerns only the products liability claim.

GSK and P&G to Judge Cecilia M. Altonaga in the Southern District of Florida for coordinated pretrial proceedings. *In re Denture Cream Prods. Liab. Litig.*, No. 09-2051-MD-Altonaga. Following the conclusion of pretrial proceedings, the individual MDL plaintiffs had the right to transfer their cases back to their respective district courts. Because this case was the only one filed in the Southern District of Florida, it provided the judge with jurisdiction to proceed to trial.

The Chapmans sought to prove causation primarily through four expert witnesses.[4] Dr. George J. Brewer, Dr. Joseph R. Landolph, and Dr. Ebbing Lautenbach would have testified generally whether Fixodent could cause CDM. Dr. Steven A. Greenberg would have testified Marianne Chapman's myelopathy specifically was caused by her use of Fixodent. P&G moved to exclude the Chapmans' expert testimony under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 113 S. Ct. 2786 (1993). Briefing, supplemental briefing, and a hearing addressed the issues raised by P&G's motions. On June 13, 2011, one week before trial was to begin on June 20, 2011, the district judge issued a comprehensive order granting P&G's motions to exclude the Chapmans' expert testimony. *In re Denture Cream Prods. Liab. Litig.*, 795 F. Supp. 2d 1345 (S.D. Fla. 2011).

[4] P&G also sought to exclude the testimonies of three additional experts for the Chapmans: Dr. Frederick Raffa, Dr. J. Anthony Von Fraunhofer, and Dr. Michael S. Wogalter.

A. First Appeal

1. District Court

At the previously scheduled calendar call on June 14, 2011, the parties discussed with the judge the best route to this court to decide whether the judge's *Daubert* order was correct—interlocutory appeal or summary judgment. P&G argued the other MDL cases should be "stayed pending the appeals," because "it would make no sense for the parties to be litigating anything in those cases while the issues that are set forth squarely in the Court's order yesterday are addressed by the 11th Circuit." Hr'g Tr., June 14, 2011, at 6:3-10. The judge commented it would be "futile" and "a waste of everyone's resources" to have full briefing on summary judgment "just so [the parties] could get to the 11th Circuit on the correctness of [her] decision on the *Daubert* motions." *Id.* at 7:8-12. Instead, the judge suggested the parties "consent to an entry of judgment with the right to appeal the adverse *Daubert* ruling." *Id.* at 7:13-14.

On June 16, 2011, the judge held a scheduling conference to discuss further the proper way to get her *Daubert* decision before this court. The judge recognized "the problem is how do you get [the *Daubert* order] to the Appellate Court [because] you can't . . . appeal . . . a *Daubert* ruling. You need a final order." Hr'g Tr., June 16, 2011, at 6:21-23. She suggested "the way to do it is to have me

enter judgment against [the Chapmans] with the understanding of the parties that you are reserving your right to appeal . . . my adverse ruling on *Daubert*, but you need a final order." *Id.* at 7:5-8. Since both parties wanted the *Daubert* order reviewed by this court, the judge ordered the parties to "present to [her] a proposed order that contemplates" an appealable final judgment. *Id.* at 9:10-13.

On June 23, 2011, the parties submitted a Joint Stipulation of Dismissal with Prejudice, agreeing to "1) the entry of judgment against [the Chapmans] on all claims alleged against [P&G]; and, 2) the entry of dismissal with prejudice on all [the Chapmans'] claims alleged against [P&G]." Jt. Stip. of Dismissal at 1-2. The joint stipulation provided "the parties recognize that this stipulation is in the best interest of all parties and judicial economy" and expressly reserved the Chapmans' right to appeal to this court. *Id.* at 2. In accordance with the joint stipulation, the judge entered final judgment on June 24, 2011, and the Chapmans timely appealed.

2. Court of Appeals

This court recognized "our jurisdiction 'must be both (1) authorized by statute and (2) within constitutional limits.'" *Chapman v. Proctor & Gamble Distrib., LLC*, No. 11-13371 at 2 (11th Cir. Jan. 4, 2012) (per curiam) (quoting *OFS Fitel, LLC v. Epstein, Becker & Green, P.C.*, 549 F.3d 1344, 1355 (11th Cir.

2008)). While the district judge's order was final under 28 U.S.C. § 1291, "to be within constitutional limits," it had to be "'adverse as to the final judgment' . . . to satisfy the Article III case or controversy requirement." *Id.* (quoting *OFS Fitel*, 549 F.3d at 1356). We noted "three 'distinct factual ingredients that are critical to the adverseness issue.'" *Id.* (quoting *OFS Fitel*, 549 F.3d at 1357). Those factual requirements are: (1) the appealed order was "'case-dispositive because it foreclosed plaintiff from presenting the expert testimony required to prove [the cause of action], which was a core element in all of its claims,'" (2) "plaintiff's attorney 'candidly informed the district court of the impact of its sanctions ruling on the plaintiff's case,'" and (3) "'importantly, the district court . . . agreed with plaintiff's counsel's suggestion that the [appealed] ruling was case-dispositive.'" *Id.* (alterations omitted) (quoting *OFS Fitel*, 549 F.3d at 1357, 1358).

We concluded the Chapmans did not meet the second and third *OFS Fitel* requirements. Although the parties had informed the district judge her *Daubert* order might be dispositive, the Chapmans "also argued that they could still muster enough evidence to prove causation at trial even without the expert testimony, specifically by presenting testimony from treating doctors." *Id.* at 3. Not only did the Chapmans fail "'candidly'" to inform the judge of the consequence of the *Daubert* order, but also they "disputed that it was dispositive." *Id.* (quoting *OFS Fitel*, 549 F.3d at 1357). Regarding the third requirement, we determined the

district judge's dismissal was not case-dispositive. It was unclear whether the interlocutory appeal from the *Daubert* order excluding the Chapmans' expert witnesses was "the only basis for dismissal, or if the Chapmans could otherwise have proceeded to trial and proved causation despite the exclusion, as they initially conte[nd]ed." *Id.* at 3-4. In addition, the Chapmans' representation that it was undisputed that the *Daubert* order was case-dispositive was belied by their persistently "claiming that the order was not case-dispositive." *Id.* at 4. Accordingly, we dismissed the appeal of the *Daubert* order for lack of standing, because the Chapmans were not adverse to the final judgment. *Id.*

B. Second Appeal

Following dismissal of the Chapmans' first appeal by this court, the district judge granted their motion to vacate the stipulated final judgment under Federal Rule of Civil Procedure 60(b). P&G then moved for summary judgment, which the Chapmans opposed, and P&G replied. Because the district judge had determined none of the Chapmans' proffered experts qualified as experts under *Daubert*, P&G maintained the Chapmans could not use treating physicians as experts at trial. Since these doctors had never been designated as experts, the judge determined they were not qualified to testify regarding general or specific causation of Marianne Chapman's CDM. Accordingly, she granted P&G's

summary judgment motion and entered final judgment. The Chapmans appealed, which is the case we now decide. We necessarily first must address the merits of the district judge's *Daubert* order, because it is incorporated by reference in the Chapmans' opposition to P&G's summary judgment motion,[5] and the parties' first appeal to this court was dismissed for lack of jurisdiction without addressing the merits of the *Daubert* order.

II. DISCUSSION

A. *Daubert* Analysis

1. Distinguishing *Daubert*-Applicable Cases

For analyzing cases involving alleged toxic substances, we have delineated two categories. *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1239 (11th Cir. 2005). The first category consists of "cases in which the medical community generally recognizes the toxicity of the [substance] at issue" to "caus[e] the injury plaintiff alleges." *Id.*; *Hendrix ex rel. G.P. v. Evenflo Co.*, 609 F.3d 1183, 1196 (11th Cir. 2010). In this category are "toxins like asbestos, which causes asbestosis and mesothelioma; silica, which causes silicosis; and cigarette smoke,

[5] In their opposition to P&G's summary judgment motion, the Chapmans stated: "Plaintiffs explicitly reserve their right to appeal this Court's June 13, 2011 decision and preserve all arguments previously set forth in opposition to Defendants' *Daubert* motions. All such arguments are hereby incorporated herein by reference." Chapmans' Opp'n to P&G's Summ. J. Mot. at 7 n.11.

which causes cancer." *McClain*, 401 F.3d at 1239. For judicial economy, federal courts need not consider expert opinions for diagnoses "medical doctors routinely and widely recognize as true, like cigarette smoking causes lung cancer and heart disease, too much alcohol causes cirrhosis of the liver, and . . . the ingestion of sufficient amounts of arsenic causes death." *Id.* at 1239 n.5. In cases where the cause and effect or resulting diagnosis has been proved and accepted by the medical community, federal judges "need not undertake an extensive *Daubert* analysis on the general toxicity question."[6] *Id.* at 1239.

In contrast, the second category contains cases, where the medical community generally does not recognize the substance in question as being toxic and having caused plaintiff's alleged injury. *Id.* These cases require a two-part *Daubert* analysis, comprised of (1) general causation, "whether the [substance] *can* cause the harm plaintiff alleges," *id.*, and (2) specific causation, whether experts' methodology determines the substance "caused the plaintiff's *specific* injury," *Hendrix*, 609 F.3d at 1196 (citing *McClain*, 401 F.3d at 1239). For cases in category two, a district judge "must assess the *reliability* of the expert's opinion on *general*, as well as specific, causation." *Id.* (first emphasis added). The two categories economize the time of a trial judge, who "does not need to waste time

[6] The focus for cases in the first category is "individual causation to plaintiff"—"was plaintiff exposed to the toxin, was plaintiff exposed to enough of the toxin to cause the alleged injury, and did the toxin in fact cause the injury?" *McClain*, 401 F.3d at 1239.

with a *Daubert* hearing 'where the reliability of an expert's methods is properly taken for granted, and to require appropriate proceedings in the less usual or more complex cases where cause for questioning the expert's reliability arises,'" *McClain*, 401 F.3d at 1239 n.5 (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152, 119 S. Ct. 1167, 1176 (1999)).

The Chapmans represent the district judge should have analyzed this case under *McClain* category one, because there is a general consensus in the medical community that ingestion of zinc causes CDM. They cite medical textbooks and journals as well as their experts[7] and those of P&G, who have recognized an association between excess zinc and copper deficiency. *See Rider v. Sandoz Pharm. Corp.*, 295 F.3d 1194, 1199 (11th Cir. 2002) ("[W]hile they may support other proof of causation, case reports alone ordinarily cannot prove causation."). But they fail to show that the zinc compound in Fixodent is in *McClain* category one of medically accepted, cause-and-effect toxins, such as asbestos causing asbestosis and cigarette smoking causing lung cancer and heart disease. *Id.* at 1239

[7] For example, the Chapmans quote from the report of their only expert unchallenged by P&G in the *Daubert* proceedings, Dr. Joseph Prohaska, that "it is well understood in the scientific community that excess zinc can result in low plasma copper." Appellants' Br. at 31 n.8 (citation, internal quotation marks, and alteration omitted). The Chapmans, however, did not advance Dr. Prohaska with their other seven proffered experts they argued could establish general and specific causation, all of whom the district judge disqualified in her *Daubert* order. Moreover, Dr. Prohaska was limited by his report to opining on "the hematological changes associated with copper deficiency as well as the impact of zinc on copper status." Prohaska Report at 2.

& n.5. P&G notes: "Millions of consumers have regularly used Fixodent for decades without complaint. Nevertheless, [the Chapmans] claim that Fixodent is toxic because it contains zinc in a calcium-zinc compound—even though zinc is undeniably an essential nutrient the body must have to function properly." Appellees' Br. at 1; *see Guinn v. AstraZeneca Pharm. LP*, 602 F.3d 1245, 1257 (11th Cir. 2010) (per curiam) (recognizing in a products liability case that two-thirds of patients who took an antipsychotic prescription drug, Seroquel, did not experience weight gain, which plaintiff alleged was the cause of her diabetes). Therefore, the district judge properly determined that Fixodent, containing zinc, was in *McClain* category two and conducted the requisite *Daubert* review of proffered expert testimony, which included a thorough hearing and consideration of "thousands of pages of filings by the parties, including the experts' reports and depositions, and scientific literature." *In re Denture Cream Prods. Liab. Litig.*, 795 F. Supp. 2d at 1348.

2. *Daubert* Review for Reliability of Expert Testimony

Under Federal Rule of Evidence 702, expert testimony is admissible if (1) the expert is qualified to testify regarding the subject of the testimony; (2) the expert's methodology is "sufficiently reliable as determined by the sort of inquiry mandated in *Daubert*"; and (3) the expert's testimony will assist the trier of fact in

understanding the evidence or determining a fact at issue. *United States v. Frazier*, 387 F.3d 1244, 1260 (11th Cir. 2004) (en banc) (citation and internal quotation marks omitted). In considering the proffered expert testimony, a trial judge is mindful "[t]he burden of establishing qualification, reliability, and helpfulness rests on the proponent of the expert opinion." *Id.* To determine the reliability and relevance of proffered expert testimony, the judge performs a "gatekeeping" function. *Daubert*, 509 U.S. at 589 n.7, 113 S. Ct. at 2795 n.7; *see Quiet Tech. DC-8, Inc. v. Hurel-Dubois UK Ltd.*, 326 F.3d 1333, 1342 (11th Cir. 2003) (recognizing "one may be considered an expert but still offer unreliable testimony"). We review a district judge's exclusion of expert testimony only for abuse of discretion. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 141-43, 118 S. Ct. 512, 517 (1997). This "considerable leeway" accorded to the district judge, *Kumho Tire Co.*, 526 U.S. at 152, 119 S. Ct. at 1176, requires us to defer to the judge's decision on expert testimony, "unless it is manifestly erroneous." *Rink v. Cheminova, Inc.*, 400 F.3d 1286, 1291 (11th Cir. 2005) (citation and internal quotation marks omitted). This deferential abuse-of-discretion standard is applied stringently, even if a decision on expert testimony is "outcome determinative."[8]

[8] We have "explain[ed] why it is difficult to persuade a court of appeals to reverse a district court's judgment on *Daubert* grounds[,] . . . where the abuse of discretion standard thrives." *United States v. Brown*, 415 F.3d 1257, 1264, 1266 (11th Cir. 2005). "[A] district court is more familiar with the procedural and factual details and is in a better position to decide *Daubert* issues," which "are not precisely calibrated and must be applied in case-specific evidentiary circumstances that often defy generalization." *Id.* at 1266. In "applying [the] abuse of discretion

Gen. Elec. Co., 522 U.S. at 142-43, 118 S. Ct. at 517; *United States v. Brown*, 415 F.3d 1257, 1266 (11th Cir. 2005).

The *Daubert* Court identified four factors to guide district judges in assessing the reliability of an individual expert's methodology:

> (1) whether the expert's methodology has been tested or is capable of being tested; (2) whether the theory or technique used by the expert has been subjected to peer review and publication; (3) whether there is a known or potential error rate of the methodology; and (4) whether the technique has been generally accepted in the relevant scientific community.

United Fire & Cas. Co. v. Whirlpool Corp., 704 F.3d 1338, 1341 (11th Cir. 2013) (per curiam) (citing *Daubert*, 509 U.S. at 593-94, 113 S. Ct. at 2796-97). These factors are not "a definitive checklist or test," *Daubert*, 509 U.S. at 593, 113 S. Ct. at 2796, and *Daubert* considerations are "applied in case-specific evidentiary circumstances," *Brown*, 415 F.3d at 1266. "[T]he trial judge must have considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable." *Kumho Tire Co.*, 526 U.S. at 152, 119 S. Ct. at 1176.

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standard, we must affirm unless we at least determine that the district court has made a clear error of judgment, or has applied an incorrect legal standard." *McClain*, 401 F.3d at 1238 (alteration in original) (citation and internal quotation marks omitted). Clearly, the abuse-of-discretion standard applied in *Daubert* cases is specialized and specifically addresses the narrow issue of the admission of reliable expert trial testimony rather than the general abuse-of-discretion standard implicated in other civil and criminal cases, which makes them not comparable.

While the inquiry is "a flexible one," *the focus "must be solely on principles and methodology, not on the conclusions that they generate*." *Daubert*, 509 U.S. at 594-95, 113 S. Ct. at 2797 (emphasis added); *see McDowell v. Brown*, 392 F.3d 1283, 1298 (11th Cir. 2004) (recognizing a trial judge "should meticulously focus on the expert's principles and methodology, and not on the conclusions that they generate"). "But conclusions and methodology are not entirely distinct from one another"; neither *Daubert* nor Federal Rule of Evidence 702 requires a trial judge "to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert." *Gen. Elec. Co.*, 522 U.S. at 146, 118 S. Ct. at 519. Instead, the judge "is free to 'conclude that there is simply too great an analytical gap between the data and the opinion proffered.'" *Hendrix*, 609 F.3d at 1194 (quoting *Gen. Elec. Co.*, 522 U.S. at 146, 118 S. Ct. at 519); *see McDowell*, 392 F.3d at 1299 (noting "there is no fit where a large analytical leap must be made between the facts and the opinion," such as proffering animal studies concerning a type of cancer in mice to establish a different cancer in humans (citing *Gen. Elec. Co.*, 522 U.S. at 146, 118 S. Ct. at 519)). The district judge has "the task of ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." *Daubert*, 509 U.S. at 597, 113 S. Ct. at 2799.

As gatekeeper for the expert evidence presented to the jury, the judge "must do 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." *Kilpatrick v. Breg, Inc.*, 613 F.3d 1329, 1335 (11th Cir. 2010) (citation and internal quotation marks omitted). It is "proper" and "necessary" for the trial judge "to focus on the reliability" of a proffered expert's "sources and methods." *Id.* at 1336. Under *Daubert*, the "district judge asked to admit scientific evidence must determine whether the evidence is genuinely scientific, as distinct from being unscientific speculation offered by a genuine scientist." *Allison v. McGhan Med. Corp.*, 184 F.3d 1300, 1316-17 (11th Cir. 1999) (citation and internal quotation marks omitted).

a. General Causation

General causation refers to the "general issue of whether a substance has the potential to cause the plaintiff's injury." *Guinn*, 602 F.3d at 1248 n.1. The district judge consolidated her consideration of the proffered testimonies of Dr. Brewer, Dr. Landolph, and Dr. Lautenbach regarding general causation. Neither the judge nor the parties questioned that these three experts were qualified to testify based on their credentials, the first part of the Rule 702 test for admission of expert testimony. *Frazier*, 387 F.3d at 1260. The judge, however, determined that their methodologies were not sufficiently reliable to satisfy part two of the test and therefore would not assist the trier of fact in understanding the evidence, part three

of the test. *Id.* We must review the judge's analysis that caused her to reach that conclusion.

At the outset, the judge placed this case in *McClain* category two, where "the medical community does not generally recognize the agent as both toxic and causing the injury plaintiff alleges." *McClain*, 401 F.3d at 1239. To establish generally "Fixodent is capable of causing a myelopathy," the Chapmans proffered the testimonies of three experts. *In re Denture Cream Prods. Liab. Litig.*, 795 F. Supp. 2d at 1350. "Dr. Brewer would testify 'that zinc containing Fixodent denture adhesives are a health hazard and capable of causing severe hematological and neurological injury.'" *Id.* at 1350-51 (quoting Brewer Report). "Dr. Landolph would testify 'that long-term use of Fixodent (containing 1.69% zinc) will result in . . . neurotoxic, neurologic, and hematologic consequences.'" *Id.* at 1351 (quoting Landolph Report). Dr. Lautenbach would testify "that there is 'an association between Fixodent and myeloneuropathy' and he would 'consider the myeloneuropathy as a "probable" reaction related to denture adhesive use.'" *Id.* (quoting Lautenbach Report).

The judge reviewed reliable methodologies, including dose-response relationship, epidemiological evidence, background risk of the disease, physiological processes involved, and clinical studies. *Id.* at 1351-57. The judge

determined the Chapmans' experts did not satisfy any of these recognized methodologies. Failure to satisfy any of the four reliability factors recognized in *Daubert* is sufficient to preclude the testimony of any of the general causation experts from testifying at trial. 509 U.S. at 593-94, 113 S. Ct. at 2796-97. Recognizing all substances potentially can be toxic, the judge noted "'the relationship between dose and effect (dose-response relationship) is the hallmark of basic toxicology,'" and "'is the single most important factor to consider in evaluating whether an alleged exposure caused a specific adverse effect.'" [9] *In re Denture Cream Prods. Liab. Litig.*, 795 F. Supp. 2d at 1351-52 (quoting *McClain*, 401 F.3d at 1242). The judge noted, however, neither the Chapmans' general-

[9] The judge quoted the deposition testimonies of the three general-causation experts to show their inability to state the Fixodent dosage to put an individual at risk of developing myelopathy:

> Dr. Brewer:
>
> Q. Have you ever determined the dose of Fixodent necessary to consistently place individuals into a negative copper balance?
> A. Experimentally, no.
>
> . . . .
>
> Dr. Lautenbach:
>
> Q. Now, do you know how much below normal . . . serum copper has to be and for how long before you have myelopathies?
> A. I don't know.
>
> Dr. Landolph:
>
> Q. So no studies have been done to determine how low the copper must be in the serum and for how long to cause myelopathy?
> A. I had not seen such a precise curve . . . .

In re Denture Cream Prods. Liab. Litig., 795 F. Supp. 2d at 1352 n.16 (deposition citations omitted).

causation experts "nor the articles on which they rely determine how much Fixodent must be used for how long to increase the risk of a copper-deficiency, or for how long a copper-deficiency must persist before an individual is at an increased risk of developing a myelopathy." *Id.* at 1352. Similarly, the judge recognized "[e]pidemiology is the 'best evidence of causation'" in cases involving toxic substances. *Id.* at 1354 (quoting *Kilpatrick*, 613 F.3d at 1337 n.8). But she determined the Chapmans' "experts have no analytical epidemiological evidence on which to base their inference of causation."[10] *Id.*

The judge further noted "[b]ackground risk of disease 'is the risk a plaintiff and other members of the general public have of suffering the disease or injury that plaintiff alleges *without* exposure to the drug or chemical in question.'" *Id.* at 1355 (quoting *McClain*, 401 F.3d at 1243). While "'[a] reliable methodology should take into account the background risk,'" the judge found the Chapmans' "causation experts uniformly testified that they did not know the background risk of copper-

[10] The judge supported the lack of epidemiological evidence with Dr. Lautenbach's deposition testimony:

> Q. To the best of your knowledge, there are no controlled population-based epidemiologic studies testing whether there is an association between denture adhesive and the development of hematologic or neurologic disease. Correct?
> A. That's correct.

In re Denture Cream Prods. Liab. Litig., 795 F. Supp. 2d at 1354 n.21 (deposition citation omitted).

deficiency myelopathy," which was "a serious methodological deficiency."[11] *Id.* (alteration in original) (quoting *McClain*, 401 F.3d at 1243). The judge explained:

> [T]he question of background risk is important because it could be coincidence that any particular denture-cream user has a myelopathy or copper-deficiency myelopathy. Some people use denture cream and some people have a myelopathy; it is possible (and depending on the incidence of myelopathies, likely) that some denture-cream users have an idiopathic myelopathy simply due to the background distribution of that disease. Without a baseline, any incidence may be coincidence.

[11] The Chapmans' general-causation experts testified concerning the lack of background risk of CDM at their respective depositions:

> Dr. Brewer:
>
> Q. Do you know the incidence of myeloneuropathies in the United States?
> A. No.
> Q. Do you know the incidence of myeloneuropathies, myelopathies, or myeloneuropathies [sic] amount uses of zinc-containing denture adhesives in the United States?
> A. No.
>
> Dr. Lautenbach:
>
> Q. Do you know what the incidence of myelopathy is in the general population?
> A. I don't. I'm not sure it's been well defined.
>
> Dr. Landolph:
>
> Q. You are unable to give me a number setting forth the incidence of myeloneuropathy among users of zinc containing denture adhesives in the United [S]tates, correct?
> A. That's correct, the precise number, I don't have that data.

In re Denture Cream Prods. Liab. Litig., 795 F. Supp. 2d at 1355 n.22 (first alteration in original) (deposition citations omitted).

Id. at 1356. The judge concluded the absence of background risk of disease was "a substantial weakness" in the Chapmans' experts' general-causation reasoning. *Id.*

Given the deposition admissions of Dr. Brewer, Dr. Lautenbach, and Dr. Landolph regarding their lack of knowledge of dose-response, epidemiological evidence, and background risk of disease, methodologies this circuit has recognized as indispensable to proving the effect of an ingested substance, we conclude that the testimonies of these proffered experts could not establish general causation of myelopathy by Fixodent. Because these experts have failed to demonstrate the primary methods for proving the zinc in Fixodent causes myelopathy, their secondary methodologies, including plausible explanations, generalized case reports, hypotheses, and animal studies are insufficient proof of general causation. This latter evidence could mislead the jury by causing it to consider testimony that was insufficient by recognized primary methodologies to prove using Fixodent causes myelopathy. As gatekeeper for the evidence presented to the jury, the judge did not abuse her discretion or commit manifest injustice by precluding the testimonies of Dr. Brewer, Dr. Lautenbach, and Dr. Landolph as experts on general causation.

b. Specific Causation

"Specific causation refers to the issue of whether the plaintiff has demonstrated that the substance actually caused injury in her particular case." *Guinn*, 602 F.3d at 1248 n.1. The Chapmans proffered only one expert to prove specific causation, Dr. Greenberg, who would testify at trial: "'[A] diagnosis of copper deficiency myelopathy is certain . . . [and] in this patient, it was precisely the ingested zinc in the denture cream that caused her copper deficiency.'" *In re Denture Cream Prods. Liab. Litig.*, 795 F. Supp. 2d at 1365 (alterations and ellipsis in original) (quoting Greenberg Report). His conclusion allegedly resulted from "the scientifically accepted methodology of differential diagnosis," *Guinn*, 602 F.3d at 1253, "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," *Hendrix*, 609 F.3d at 1195. Differential diagnosis includes three steps: (1) the patient's condition is diagnosed, (2) all potential causes of the ailment are considered, and (3) differential etiology is determined by systematically eliminating the possible causes. *McClain*, 401 F.3d at 1252. A reliable differential analysis "need not rule out all possible alternative causes," but "it must at least consider other factors that could have been the sole cause of the plaintiff's injury." *Guinn*, 602 F.3d at 1253. Differential diagnosis, "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." *McClain*, 401 F.3d at 1252.

While differential diagnosis as a scientifically accepted methodology meets the *Daubert* guiding factors for district judges in deciding reliability, 509 U.S. at 593-94, 113 S. Ct. at 2796-97, Dr. Greenberg did not follow it. Marianne Chapman's treating physicians had not diagnosed her with CDM or informed her that her Fixodent use caused her neurologic symptoms.[12] Although her diagnosis generally was "neurological syndrome," she was not professionally diagnosed with CDM until Dr. Greenberg examined her in the course of this litigation as the Chapmans' specific-causation expert.[13] Greenberg Report at 10.

[12] Marianne Chapman's medical history reveals she had experienced neurologic ailments in her childhood, long before her Fixodent use began in 2001. Matthew E. Fink (P&G expert) Report at 4-5. As a child, she had suffered frequent migraine headaches and was treated for unexplained foot and ankle pain. *Id.* at 4. She was evaluated during her teen years for pain from her shoulder through her leg. *Id.* After a series of recurrent falls, some of which resulted in hospitalization, she complained of pain in her lower extremities, numbness, and decreased sensation. *Id.* at 5. In adulthood, before her use of Fixodent, Marianne Chapman was diagnosed with hereditary hemorrhagic telangiectasia, a genetic disorder often accompanied with spinal cord, neurologic ailments. Marianne Chapman Dep. at 39:20-25; Fink Report at 16.

[13] Marianne Chapman's husband first "diagnosed" her medical ailments as the result of her ingestion of zinc by researching the issue on the Internet. *See* Daniel Chapman Dep. at 57:15-24 ("A. I looked up her symptoms and I learned about zinc poisoning. Q. Now, prior to the time when you did that, had anybody suggested to you that it could be zinc poisoning? A. No. Q. So are you the first person that thought Marianne Chapman, your wife, might have zinc poisoning? A. Yes."); Marianne Chapman Dep. at 111:13-25 ("When did it first come to your attention that there might be some nerve problems that could result from the zinc in Fixodent or other dental adhesives? . . . A. In the beginning of '09 when my husband was looking up neuropathy, the browser log popped up with all different types of neuropathy, links to neuropathy and possible causes of neuropathy. And that's when he had brought it to my attention that the zinc in the denture cream could cause neuropathy."); Greenberg Report at 6 (noting Marianne Chapman and

Marianne Chapman's medical history included neurological ailments that occurred before and after her Fixodent use.[14] Notably, her neurological symptoms continued after she ceased using Fixodent.[15] "Temporal proximity is generally not a reliable indicator of a causal relationship." *Guinn*, 602 F.3d at 1254. "The temporal connection between exposure to chemicals and an onset of symptoms, standing alone, is entitled to little weight in determining causation." *McClain*, 401 F.3d at 1254 (citation, internal quotation marks, and alteration omitted). But Dr. Greenberg failed to explore fully other potential causes of Marianne Chapman's CDM, which he diagnosed in the course of this litigation. *In re Denture Cream Prods. Liab. Litig.*, 795 F. Supp. 2d at 1366. In addition to copper deficiency as the cause of Marianne Chapman's neurological ailments, Dr. Greenberg had identified "structural spinal cord injury, multiple sclerosis, and vitamin B12

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her husband "became concerned about the possibility of zinc poisoning after research on the Internet").

[14] After Marianne Chapman began using Fixodent, she again complained of pain in her lower extremities. Marianne Chapman Dep. 12:25-13:14. She was diagnosed with and treated for vitamin B12 deficiency, which has been associated with myelopathy. Fink Report at 14; Greenberg Dep. 75:1-9. Following brief improvement, her neurologic ailments returned in 2006, when she experienced burning and numbness in her legs, poor balance, and the eventual loss of motor control in her right hand. Fink Report at 14-15. In 2006, Marianne Chapman also developed anemia (low red blood cells) and neutropenia (low white blood cells). Greenberg Report at 5 (Table 3). She had normal red and white blood-cell measurements in May and November 2006, while she continued to use Fixodent; her neutropenia normalized permanently in September 2008, before she stopped using Fixodent in 2009. *Id.*; Fink Report at 15.

[15] Ten months after Marianne Chapman stopped using Fixodent, she reported worsening hand weakness and wrist drop. Fink Report at 15. Two years after she ceased using Fixodent, in 2011, she had a recurrence of a neurological problem, a positive Romberg sign of unsteady balance with her eyes closed, which was not present in 2010. Greenberg Report at 7; Fink Report at 13.

deficiency."[16] *Id.* Given her extensive medical history of neurological problems since childhood, it is entirely possible that Marianne Chapman had the myelopathy condition that she attributes to Fixodent prior to her use of the denture cream, because her symptoms occurred before and after using Fixodent. *See Guinn*, 602 F.3d at 1254 ("Because [plaintiff] was diagnosed with diabetes only four years after beginning to take Seroquel, the temporal relationship in this case does not provide strong evidence of causation; in fact, *it appears to equally indicate that [plaintiff] may have already developed diabetes before ever taking Seroquel*." (emphasis added)). In addition, Dr. Greenberg recognized lymphoproliferative disorders as possible causes of Marianne Chapman's hematological syndrome and "*malabsorption and gastric bypass surgery as potential causes for her copper-deficiency*." *In re Denture Cream Prods. Liab. Litig.*, 795 F. Supp. 2d at 1366 (emphasis added).

A reliable differential analysis requires an expert to "compile a comprehensive list of hypotheses that might explain" a plaintiff's condition.

[16] P&G contended to the district judge that Dr. Greenberg also should have considered other hereditary and acquired diseases that could have caused Marianne Chapman's myelopathy, including adrenomyeloneuropathy, complicated hereditary spastic paraplegia, Charcot-Marie-Tooth disease, hereditary motor and sensory neuropathy Type V, subtypes of spinocerebeller atrophy, hereditary ataxia with neuropathy, vitamin E deficiency, Sjogren's syndrome, sarcoidosis, HTLV-1, neuromylitis optica, and multiple-vitamin-deficiency syndrome. *In re Denture Cream Prods. Liab. Litig.*, 795 F. Supp. 2d at 1366. The judge noted P&G's argument concerning hereditary neuropathies, including myelopathies, "are far more common than copper-deficiency myelopathies," making Marianne Chapman's myelopathy "*more likely caused by a genetic condition than by Fixodent*, especially considering her personal medical history." *Id.* (emphasis added) (citation and internal quotation marks omitted).

Hendrix, 609 F.3d at 1195 (citation and internal quotation marks omitted). The "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." *Id.* at 1197 (citation and internal quotation marks omitted). An expert's failure to enumerate a comprehensive list of alternative causes and to eliminate those potential causes determines the admissibility of proposed specific-causation testimony. *See Guinn*, 602 F.3d at 1254 (determining no abuse of discretion in concluding the specific-causation expert's hypothesis was unreliable under *Daubert*, because of failure to consider possible alternative causes of plaintiff's diabetes).

Significantly, after concluding his report on Marianne Chapman, Dr. Greenberg performed an additional, reasonable test on her to determine if she had arterial venous malformation in her thoracic spinal cord. The judge found Dr. Greenberg's "failure to perform a test he considered reasonable before opining on the cause of Ms. Chapman's disease shows a lack of methodological rigor in reaching the diagnosis in his report," because he "did not consider the possibility of an idiopathic cause for Ms. Chapman's myelopathy." *In re Denture Cream Prods. Liab. Litig.*, 795 F. Supp. 2d at 1367. Dr. Greenberg failed to consider obvious alternative causes for Marianne Chapman's CDM, such as hereditary and acquired conditions known to cause myelopathies. *See Guinn*, 602 F.3d at 1257

(affirming exclusion of plaintiff's expert witness following *Daubert* proceedings, when the expert's testimony revealed facts casting "substantial doubt on whether Seroquel contributed to [plaintiff's] development of diabetes," since plaintiff "had multiple risk factors that could have been the sole cause of [her] diabetes[,] and [the expert] was unable to determine the relative risk of each factor"). Instead, Dr. Greenberg pursued his view that zinc-associated copper deficiency was responsible for Marianne Chapman's neurological and hematological symptoms. Yet, he provided no support for his hypothesis that Marianne Chapman's anemia, neutropenia, and myelopathy resulted from a single cause rather than several causes. He also omitted consideration of idiopathic causes for Marianne Chapman's CDM, additionally rendering his differential diagnosis unreliable. *See Kilpatrick*, 613 F.3d at 1342 ("The failure to take into account the potential for idiopathically occurring [disease]—particularly when [the disease] is a relatively new phenomenon in need of further study—placed the reliability of [the expert's] conclusions in further doubt.").

Obviously, there were numerous potential causes for Marianne Chapman's CDM that Dr. Greenberg did not analyze or consider. The district judge determined "Dr. Greenberg's differential diagnosis is not reliable as a matter of law in the Eleventh Circuit because he ruled-in and considered an etiology—Fixodent-induced copper-deficiency myelopathy—that has not been established to

cause Ms. Chapman's disease." *In re Denture Cream Prods. Liab. Litig.*, 795 F. Supp. 2d at 1366. In reviewing the evidence presented and applying the applicable law, we conclude the district judge did not abuse her discretion or commit manifest error in precluding Dr. Greenberg's expert testimony regarding the specific causation of Marianne Chapman's CDM.

c. Exclusion of Other Expert Testimony

Because the judge determined neither the general nor specific-causation experts had proffered testimony that would prove the zinc in Fixodent had caused Marianne Chapman's CDM, she also excluded the testimonies of Dr. Wogalter and Dr. Von Frunhofer, whose testimonies were premised on the toxicity of Fixodent. *In re Denture Cream Prods. Liab. Litig.*, 795 F. Supp. 2d at 1367.

> In short, taking everything together, there is enough data in the scientific literature to *hypothesize* causation, but not to *infer* it. Hypotheses are verified by testing, not by submitting them to lay juries for a vote. It may very well be that Fixodent in extremely large doses over many years can cause copper deficiency and neurological problems, but the methodology [the Chapmans'] experts have used in reaching that conclusion will not reliably produce correct determinations of causation.

Id. The proposed testimony of Dr. Raffa concerned P&G's assets, which related to the punitive damages claim. Consequently, the judge precluded the proffered testimonies of these experts based on Rule 702 relevancy. We conclude there was

no abuse of discretion or manifest injustice in granting P&G's motions preventing the testimonies of these three experts for the Chapmans.

B. Summary Judgment

After this court dismissed the parties' first appeal for lack of jurisdiction, based on our conclusion the Chapmans did not consider the district judge's *Daubert* order case-dispositive, the judge granted their Federal Rule of Civil Procedure 60(b) motion for relief from the final judgment. Thereafter, P&G moved for summary judgment and argued the Chapmans did not have an admissible expert witness to establish general or specific causation. In opposition, the Chapmans argued they had alternative expert witnesses to testify at trial, irrespective of the district judge's *Daubert* order. Concluding under the governing law the Chapmans had no experts to prove their products liability case alleging Fixodent was the cause of Marianne Chapman's CDM, the district judge granted summary judgment to P&G and entered final judgment.

The Chapmans' notice of appeal states they are appealing the summary judgment order and final summary judgment entered on July 31, 2012, "as well as all orders and rulings that produced that final judgment," including the order granting P&G's motions to exclude the testimony of the Chapmans' seven general and specific expert witnesses. Notice of Appeal (Aug. 27, 2012). We have

considered fully the district judge's thorough *Daubert* order, which eliminated the Chapmans' expert witnesses, and concluded it was decided correctly under the controlling law. We now address the summary judgment order the Chapmans have appealed in conjunction with the *Daubert* order.[17]

We review a district judge's granting summary judgment de novo. *Williams v. Mast Biosurgery USA, Inc.*, 644 F.3d 1312, 1318 (11th Cir. 2011). Summary judgment is proper if the movant shows "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). When a party fails to proffer a sufficient showing "to establish the existence of an element on which that party will bear the burden of proof at trial," there is no genuine dispute regarding a material fact. *Williams*, 644 F.3d at 1318 (citations, internal quotation marks, and ellipsis omitted). The burden for laying the proper foundation for admission of expert testimony is on the party offering the expert; admissibility must be shown by a preponderance of the evidence. *Daubert*, 509 U.S. at 592 n.10, 113 S. Ct. at 2796 n.10 (citing *Bourjaily v. United States*, 483

[17] Procedurally, this case has been appealed from the district judge's order granting summary judgment to P&G. Her *Daubert* order, excluding the Chapmans' general and specific-causation experts, alone could not have provided the procedural basis for appellate jurisdiction, because it was not a final order. Consequently, the Chapmans have incorporated the judge's *Daubert* order in their appeal of summary judgment granted to P&G to have this court review the merits of the *Daubert* order. The Chapmans' reasons for appealing summary judgment granted to P&G were raised before the district judge and decided in her order. The Chapmans' opposition to P&G's summary judgment motion consisted of their proposing alternative experts for trial testimony, while the *Daubert* order had addressed and excluded their general and specific-causation experts. To the extent the Chapmans have appealed the same reasons for opposing P&G's summary judgment motion before the district judge, we address them.

U.S. 171, 175-76, 107 S. Ct. 2775, 2778-79 (1987)). "Evidence inadmissible at trial cannot be used to avoid summary judgment." *Corwin v. Walt Disney Co.*, 475 F.3d 1239, 1249 (11th Cir. 2007) (citation, internal quotation marks, and alteration omitted).

The Chapmans opposed summary judgment for lack of expert witnesses following the *Daubert* order for three reasons: (1) their expert, Dr. Joseph Prohaska, a biochemistry professor at the University of Minnesota Medical School, could testify at trial, because P&G had not contested his proffered testimony; (2) they could call P&G experts and witnesses to testify that excessive ingestion of zinc can lead to copper deficiency, which can cause CDM; and (3) Marianne Chapman's treating physicians for her neuropathy could testify regarding causation. Because of the Chapmans' "periodic and contradictory insistence on having enough evidence to proceed to trial," the judge analyzed the merits of P&G's motion to make her decision "perfectly clear" for this court.[18] Summ. J. Order at 6. In granting summary judgment to P&G, the district judge addressed the three possibilities for expert testimony the Chapmans had proffered following

[18] Because of the Chapmans' joining in the interlocutory appeal purporting to be a final judgment and her granting the Rule 60(b) motion, the judge was inclined to grant P&G's motion for summary judgment based on judicial estoppel under *New Hampshire v. Maine*, 532 U.S. 742, 121 S. Ct. 1808 (2001). *See id.* at 749, 121 S. Ct. at 1814 ("Where a party assumes a certain position in a legal proceeding, and succeeds in maintaining that position, he may not thereafter, simply because his interests have changed, assume a contrary position, especially if it be to the prejudice of the party who has acquiesced in the position formerly taken by him." (citation, internal quotation marks, and alteration omitted)).

her *Daubert* order, precluding the testimonies of their general and specific causation experts, and concluded their alternative expert witnesses also were unavailing.

On appeal, the Chapmans challenge both the district judge's *Daubert* order and summary judgment granted to P&G, because the cumulative effect of these orders eliminated all potential causation experts the Chapmans had proffered. Their arguments for alternative expert witnesses are combined in the Chapmans' initial and reply briefs with their *Daubert* arguments, regarding their contention the district judge erred in disqualifying their original causation experts. *See, e.g.*, Appellants' Br. at 18 n.5, 22-23, 25, 30-31, 40, 43, 44-46, 47, 48-49, 50, 56, 60; Appellants' Reply Br. at 4 n.1, 6, 8, 11, 14, 16-17, 18, 21, 22, 24, 30. The alternative expert witnesses the Chapmans propounded following the *Daubert* order and precluded by summary judgment granted to P&G necessarily had to satisfy the same *Daubert* review standards to testify concerning causation for the Chapmans to prove their case that Fixodent caused Marianne Chapman's CDM.

The Chapmans discuss Dr. Prohaska[19] and P&G experts and witnesses[20] in their initial and reply briefs in connection with their contention that the medical

[19] The Chapmans argue Dr. Prohaska's Report states his "unchallenged opinion [by P&G] that zinc excess causes copper deficiency and that copper deficiency caused [Marianne] Chapman's hematological symptoms." Appellants' Br. at 18 n.5.

[20] In their initial brief, the Chapmans argue P&G pre-litigation studies, demonstrating the bioavailability of zinc after ingestion, would support their position:

> Plaintiffs' experts relied on three internal P&G studies demonstrating that a large percentage of the Fixodent used by denture wearers is ultimately ingested into the body and that the zinc in Fixodent, once ingested, is highly bioavailable in the small intestine, ultimately being absorbed into the bloodstream and leading to elevated serum zinc levels. In 1993, P&G performed a study of 10 actual denture wearers "to obtain data on the quantity of Zinc ions ingested by the study subjects following daily administration of the maximum recommended amount of [denture] adhesive paste." P&G Clinical Study Report No. 003793, at 5 (Sept. 1993) ("1993 Study"). Even when the study subjects were instructed to apply only half of the label's recommended amount of adhesive, P&G found that the studied users ingested approximately 50% of the Fixodent applied. [Footnote 17 to this sentence states: "At that rate, someone like Ms. Chapman would ingest 247 mg of zinc daily (approximately 10 times the threshold for causing hypocupremia)."]
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> Moreover, P&G internal studies dating back more than two decades have demonstrated that, once ingested, most of the elemental zinc dissociates from the Fixodent polymer and becomes free-floating in the intestines, where it affects copper metabolism. First, in 1989, prior to the introduction of Fixodent, P&G conducted a "zinc dissociation experiment" in which it mixed Fixodent with laboratory-simulated saliva, gastric fluid, and intestinal proteins. P&G calculated that "nearly 100% [of the zinc] dissociated (96.6%)" from its polymer when mixed with the simulated gastric fluid. P&G Report on Zinc Dissociation Experiment at 5 (July 1989). P&G further recognized that the zinc ions would bind with proteins in the small intestine, the precise mechanism by which zinc interferes with copper absorption (binding to metallothionein).
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> Subsequently, in 1994, P&G performed an "[i]n vitro dialysis study" to further analyze the bioavailability of Fixodent. Consistent with its 1989 study, P&G found that 83.3% of the zinc in Fixodent became bioavailable when the denture cream was mixed with simulated gastric fluid (compared to 93% for zinc salt). P&G Dialysis Study on Denture Adhesives at 2 (Nov. 1994). The researchers responsible for the 1994 study noted that, "if the adhesive is ingested, . . . the majority of [the zinc will] be released" into the body, and as P&G had found the previous year, users ingest almost all of the Fixodent that they apply. As Dr. Brewer stated in his report, P&G's own studies provide reliable evidence that the zinc in Fixodent can, if the adhesive is consumed, "caus[e] copper depletion and its clinical manifestations." Brewer Rep. 9 & n.14.
>
> In excluding Plaintiffs' general-causation experts, the district court never mentioned these studies or explained why they were not reliable in demonstrating the bioavailability of zinc in Fixodent. The court thus erred by failing to do the kind of "exacting analysis of the proffered expert's methodology" that *Daubert* requires. That error was critical: given that it is well settled that zinc can cause

community generally accepts excess zinc can cause CDM. Appellants' Br. at 27-33; Appellants' Reply Br. at 3-6. Accepting this classification would place this case in *McClain* category one, which would eliminate the *Daubert* analysis of the Chapmans' experts, if it were generally accepted by the medical community that zinc causes CDM. We give the Chapmans "the benefit of the doubt" that these first two sources of alternative expert witnesses have been presented on appeal in their briefs. *Carmichael v. Kellogg, Brown & Root Servs., Inc.*, 572 F.3d 1271, 1293 (11th Cir. 2009). The district judge noted "Dr. Prohaska's report was limited to hematological disorders, not myelopathy, and is therefore irrelevant." Summ. J. Order at 7. Although the Chapmans "may show zinc blocks copper absorption, this alone cannot constitute a showing of general or specific causation." *Id.* at 8; *see Rider*, 295 F.3d at 1202 (noting causation evidence of one type of stroke "does not apply to situations involving" another type of stroke). Moreover, she decided "there was no mechanistic evidence regarding the absorption of zinc from Fixodent itself." Summ. J. Order at 8. In performing the requisite gatekeeping function, a trial judge's assessment of proposed testimony does not mean "'taking the expert's word for it.'" *Frazier*, 387 F.3d at 1261 (quoting Fed. R. Evid. 702 Advisory

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> CDM, P&G's own internal studies showing that Fixodent is ingested, and that when ingested exposes users to bioavailable zinc, constitute reliable evidence that zinc in Fixodent generally can cause CDM.

Appellants' Br. at 44-46 (alterations and ellipsis in original) (some citations omitted).

Committee Notes (2000 Amends.)). We also conclude that Dr. Prohaska's testimony cannot provide admissible proof the Chapmans need to establish their case at trial, because his expertise is hematology and not myelopathy at issue in this case.

In addition, the judge explained the Chapmans "cannot create a triable issue of fact as to causation" with P&G experts and witnesses, who have not submitted the requisite epidemiological or clinical reports. Summ. J. Order at 9. Expert witnesses, who are expected to testify at trial, must be identified in the Joint Pretrial Stipulation and must meet the procedural requirements of Federal Rule of Civil Procedure 26(a)(2), including time designations for supplying disclosures and reports, regarding expert testimony to be given. The Chapmans proposed their ability to use P&G experts and witnesses at trial almost six months *after* the judge's scheduled January 24, 2011, deadline for identifying experts, making complying with the procedural timely notice and disclosure requirements of Rule 26(a)(2), including reports of testimony, impossible.[21] *See* Fed. R. Civ. P. 26(a)(2)(D) (stating a party "must" disclose expert testimony "at the times and in

[21] Because the Chapmans had waited six months after the court-imposed deadline for naming expert witnesses before proffering P&G's experts to testify for them at trial, the district judge recognized that they were procedurally barred from using these alternative witnesses at trial. We are not saying parties may not use opposing parties' experts to prove their case at trial as a general proposition. We are recognizing that all experts, regardless of which party secured their services, must meet the qualifications established by *Daubert* and the procedural requirements of Rule 26(a)(2).

the sequence that the court orders"). "District courts have broad discretion to exclude untimely disclosed expert-witness testimony." *Pride v. BIC Corp.*, 218 F.3d 566, 578 (6th Cir. 2000).

Even if the Chapmans had satisfied the procedural requirements of Rule 26(a)(2) to use P&G experts and witnesses to testify for them at trial, the district judge concluded the Chapmans could not prove their case with them. P&G's experts had "reached the conclusion that Fixodent does *not* cause CDM."[22] Summ. J. Order at 9. The judge determined the Chapmans had "not made a sufficient showing that [P&G's] expert testimony would withstand the *Daubert* analysis of [her] June 13 Order *and* yield the conclusion they seek, in view of [P&G's] experts' testimony as a whole." *Id.* Deciding the P&G witnesses ultimately did not support the Chapmans' conclusion that Fixodent caused Marianne Chapman's CDM, the judge explained the Chapmans "cannot perform an end run around the [*Daubert*] Order by calling witnesses who have not been vetted for reliability." *Id.* The judge also noted P&G's expert, Dr. Laura W. Katzan, cannot "establish

[22] For example, P&G expert, Dr. Timothy R. Koch, plainly disagreed with the Chapmans' general causation theory and stated: "It's my position, based on an independent review of the literature [and] based upon my own practice and experience, that there's not a sufficient amount of medical and scientific information and evidence available to support the statement that zinc induces myelopathy." Koch Dep. at 67:9-17. Similarly, the district judge noted the Chapmans contended P&G expert, Dr. Lara W. Katzin, "confirmed that zinc-induced CDM should be considered in the differential etiology for Ms. Chapman's condition," but failed to square that statement with the judge's discussion of Eleventh Circuit law stating general causation cannot be proved by differential diagnosis, "a necessary element of their claims." Summ. J. Order at 9 (citing *McClain*, 401 F.3d at 1253) (citation and internal quotation marks omitted).

general causation, a necessary element of their claims," by differential diagnosis. *Id.* (citing *McClain*, 401 F.3d at 1253). Considering the prospective testimonies of P&G experts and witnesses in context, the judge properly decided the Chapmans could not prove their case with admissible evidence from these alternative experts and witnesses.

At a status conference the day after issuance of the *Daubert* order, the Chapmans' counsel argued *for the first time* they still could try to prove causation through "*treating experts* who have opined [Marianne Chapman's] condition was caused by her use of Fixodent that were not the subject of the *Daubert* motion." Hr'g Tr., June 14, 2011, at 7:21-8:1 (emphasis added). In recasting Marianne Chapman's treating physicians as "treating experts," the Chapmans sought to have these doctors testify concerning their personal treatment of Marianne Chapman as well as their view of the cause of her CDM. The judge, however, explained in her summary judgment order that treating physicians, who diagnosed Marianne Chapman's CDM, are fact and not expert witnesses.[23] Summ. J. Order at 10

[23] A treating physician providing lay testimony can testify narrowly, limited to personal knowledge resulting from providing medical care, involving consultation, examination, or treatment of a patient plaintiff. *See United States v. Henderson*, 409 F.3d 1293, 1300 (11th Cir. 2005) (distinguishing between an oral surgeon's testimony that a patient had a fractured jaw as opposed to giving a hypothesis as to the cause). But "a treating doctor . . . is providing expert testimony if the testimony consists of opinions based on 'scientific, technical, or other specialized knowledge' regardless of whether those opinions were formed during the scope of

(citing *Hendrix*, 609 F.3d 1183). The Chapmans have not briefed on appeal their district-court argument in opposing summary judgment that Marianne Chapman's treating physicians could testify as experts at trial. "The 'law is by now well settled in this Circuit that a legal claim or argument that has not been briefed before the court is deemed abandoned and its merits will not be addressed.'" *Carmichael*, 572 F.3d at 1293 (quoting *Access Now, Inc. v. Sw. Airlines Co.*, 385 F.3d 1324, 1330 (11th Cir. 2004)). Consequently, we conclude the Chapmans have abandoned on appeal their argument that Marianne Chapman's treating physicians could have testified as experts at trial. Because none of the Chapmans' alternative sources for expert witnesses could provide evidence admissible at trial "to avoid summary judgment," the district judge appropriately granted summary judgment to P&G. *Corwin*, 475 F.3d at 1249 (citations and internal quotation marks omitted).

III. CONCLUSION

To prove Fixodent caused Marianne Chapman's CDM, the Chapmans were *required* to have *Daubert*-qualified, general and specific-causation-expert testimony that would be admissible at trial to avoid summary judgment. *Guinn*,

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interaction with a party prior to litigation." *Musser v. Gentiva Health Servs.*, 356 F.3d 751, 757 n.2 (7th Cir. 2004) (quoting Fed. R. Evid. 702(a)).

602 F.3d at 1252. With the district judge's properly analyzed *Daubert* order, the Chapmans lost their designated general and specific-expert witnesses, because of deficiencies in the experts' scientific-methodology reliability. Their attempts to proffer alternative causation-expert witnesses failed, because their prospective testimony was inadmissible substantively, procedurally, or abandoned on appeal. Summary judgment correctly was granted to P&G.

AFFIRMED.

JORDAN, Circuit Judge, concurring:

Given the "due deference" that the abuse of discretion standard embodies, *see Gall v. United States*, 552 U.S. 38, 59 (2007), and the "range of choice" permitted by that standard, *see In re Rasbury*, 24 F.3d 159, 168 (11th Cir. 1994), I agree that we should affirm the district court's exclusion of the Chapmans' general causation experts. I would, therefore, not address any of the other issues raised by the Chapmans.

Specifically, I would not suggest, as the court does in dictum, that the district court could have properly prevented the Chapmans from relying on Procter & Gamble's own experts. The district court addressed the Chapmans' reliance on some of the defense experts on the merits and did not exclude those experts under Rule 26 of the Federal Rules of Civil Procedure. So there is no need to hypothesize about how we would rule if the district court had decreed that such reliance by the Chapmans was procedurally improper. Moreover, P&G does not assert Rule 26 on appeal, and some cases hold that, because there is no surprise or prejudice, a party is permitted to use and rely on the expert testimony presented by the opposing party. *See, e.g.*, *Nat'l Railroad Passenger Corp. v. Certain Temporary Easements*, 357 F.3d 36, 42 (1st Cir. 2004) (no abuse of discretion in allowing plaintiff to call defense expert in its case-in-chief); *Kerns v. Pro-Foam of South Alabama*, 572 F.Supp.2d 1303, 1309-12 (S.D. Ala. 2007) (failure of plaintiff

to disclose defendant's expert as its own expert did not prevent plaintiff from calling that expert during its case-in-chief). If we are going to opine on this issue, we should wait for a case which directly presents it.

In closing, I recognize that the district court at times used language which might be seen as opining on the ultimate persuasiveness of the theories advanced by the Chapmans' experts. But given its numerous accurate statements of the correct standard under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), I do not think the district court applied an incorrect (or improperly onerous) legal standard.