

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF KANSAS**

**IN RE: EpiPen (Epinephrine
Injection, USP) Marketing,
Sales Practices and Antitrust
Litigation**

MDL No: 2785

Case No. 17-md-2785-DDC-TJJ

**(This Document Applies to
Consumer Class Cases)**

MEMORANDUM AND ORDER

This multi-district litigation presents itself at the class certification stage. Consistent with Scheduling Order No. 5 (Doc. 1263), plaintiffs already have filed their Motion for Class Certification (Doc. 1353) and defendants already have filed their Memorandum in Opposition to Class Certification (Doc. 1503-3). A class certification hearing is scheduled for June 11 and June 12, 2019 (Doc. 1421). Before the court is defendants Mylan's and Pfizer's Motion to Amend Scheduling Order No. 5 (Doc. 1486) to add a *Daubert*¹ briefing schedule to the class certification proceedings. Because the trend of authority supports challenges to expert witnesses at the class certification stage and because expert witnesses are likely to play an important role in the court's class certification analysis, the court grants defendants' Motion to Amend.

I. Procedural History and Arguments on Motion to Amend

In November 2018, the court issued Scheduling Order No. 5, establishing briefing deadlines for class certification consistent with those requested by the parties. Doc. 1263 at 1. Scheduling Order No. 5 established a December 7, 2018, deadline for plaintiffs to move for class certification; a March 18, 2019, deadline for defendants' response to the motion for class

¹ *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993).

certification; and an April 22, 2019, deadline for plaintiffs' reply. *Id.* Scheduling Order No. 5 didn't refer to challenges to experts at the class certification stage, through separate motion practice. *See id.* at 1–2.

Plaintiffs timely moved for class certification. Doc. 1353. On March 8, 2019, the court held a telephone status conference. Before the conference, defendants submitted a letter informing the court that the parties disagreed about adding a *Daubert* briefing schedule to Scheduling Order No. 5. Doc. 1486-1. The parties and the court discussed the matter during the status conference, and defendants filed a Motion to Amend, to which they attached the aforementioned letter. Doc. 1486. In their Motion to Amend, defendants contend a trend of authority supports allowing *Daubert* briefing at the class certification stage because the propriety of the experts offered by plaintiffs may affect the analysis that governs plaintiffs' burden at the class certification stage. Doc. 1486-1 at 2–3. Plaintiffs' Response advances three arguments: (1) a *Daubert* analysis either does not apply or is not required at the class certification stage; (2) Scheduling Order No. 5 does not provide for *Daubert* motions and briefing; and (3) defendants have not satisfied the good cause standard, established by Federal Rule of Civil Procedure 16(b)(4), for amending a scheduling order. Doc. 1494 at 3–8. Defendants' Reply argues that the proposed amendment satisfies the good cause standard because *Daubert* briefing will not delay the class certification process and will assist the court's analysis. Doc. 1513 at 5–6.

II. Analysis

Resolving defendants' Motion to Amend hinges on two questions: (1) does *Daubert* apply at the class certification stage; and (2) have defendants satisfied the Rule 16(b)(4), good cause standard for amending a scheduling order. The court addresses each question in turn, below.

A. Role of *Daubert* at Class Certification Stage

After reviewing the relevant case law, the court concludes that the trend of authority favors allowing *Daubert*-style challenges at the class certification stage. While it appears the Tenth Circuit has yet to address the matter, at least three other circuits have approved the practice in published opinions. See *Messner v. Northshore Univ. Healthsystem*, 669 F.3d 802 (7th Cir. 2012); *Ellis v. Costco Wholesale Corp.*, 657 F.3d 970, 982 (9th Cir. 2011); *In re Zurn Pex Plumbing Prods. Liab. Litig.*, 644 F.3d 604, 612–14 (8th Cir. 2011). A fourth has signaled its approval in an unpublished decision. *Sher v. Raytheon Co.*, 419 F. App'x 887, 890–91 (11th Cir. 2011). Plaintiffs, conversely, do not identify a single circuit that has rejected the role of *Daubert* at the class certification stage.

The trend of authority in favor of applying *Daubert* at the class certification stage is in accord with suggestions from the Supreme Court. See *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 354 (2011) (expressing doubt about district court's conclusion that *Daubert* did not apply at class certification stage). Likewise, several recent opinions from district courts within the Tenth Circuit have permitted, or signaled the availability of, *Daubert*-style challenges at the class certification stage. See *Beltran v. InterExchange, Inc.*, No. 14-cv-03074-CMA-CBS, 2018 WL 1509258, at *4 (D. Colo. Mar. 27, 2018) (adopting magistrate judge's order employing "relaxed *Daubert*-like standard"); *Miller v. Farmers Ins. Grp.*, No. CIV-10-466-F, 2012 WL 8017244, at *5 (W.D. Okla. Mar. 22, 2012) (relying on language from *Wal-Mart Stores, Inc.* to conclude it was appropriate to apply *Daubert*); *In re Cox Enters., Inc. Set-Top Cable Television Box Antitrust Litig.*, No. 09-ML-2048-C, 2011 WL 6826813, at *14 (W.D. Okla. Dec. 28, 2011) (same); see also *In re Syngenta AG MIR 162 Corn Litig.*, No. 14-md-2591-JWL, 2016 WL 5371856, at *7 (D. Kan. Sept. 26, 2016) (suggesting availability of *Daubert* challenge at class

certification stage: “Although Syngenta challenges the reliability of those experts’ opinions, it . . . did not raise a *Daubert* challenge, and the Court assumes the admissibility of those opinions at this stage”).

But, the case law contains some dissonance about the proper breadth of *Daubert*-style challenges at the class certification stage. Compare *Am. Honda Motor Co. Inc. v. Allen*, 600 F.3d 813, 815–16 (7th Cir. 2010) (requiring full *Daubert* analysis where expert opinion is “critical” to class certification determination), with *In re Zurn*, 644 F.3d at 611–13 (adopting “tailored *Daubert* analysis” rather than Seventh Circuit’s position). Thus, the court will synthesize the available, persuasive authority to establish its view of the scope and contours of *Daubert* proceedings at this stage of the litigation.

Federal Rule of Civil Procedure 23 establishes the requirements for class certification. Class “certification is proper only if ‘the trial court is satisfied, after a rigorous analysis, that the prerequisites of Rule 23(a) have been satisfied.’” *Wal-Mart Stores, Inc.*, 564 U.S. at 350–51 (quoting *Gen. Tele. Co. of the Sw. v. Falcon*, 457 U.S. 147, 161 (1982)). The court must not confuse the “rigorous analysis” required at the class certification stage with an exposition into the merits of the claim; but, “sometimes it may be necessary for the court to probe behind the pleadings before coming to rest on the certification question.” *Falcon*, 457 U.S. at 160. In accord with this latter sentiment, “[t]he class determination generally involves considerations that are enmeshed in the factual and legal issues comprising the plaintiff’s cause of action.” *Id.*

Expert opinions often play an important role at the class certification stage. See, e.g., *In re Urethane Antitrust Litig.*, 251 F.R.D. 629, 634 (D. Kan. 2008) (observing that both parties “submitted and rely heavily on competing expert affidavits”). Thus, before granting or denying class certification based on expert evidence, a court must “ensure that the basis of the expert

opinion is not so flawed that it would be inadmissible as a matter of law.” *In re Visa Check/MasterMoney Antitrust Litig.*, 280 F.3d 124, 135 (2d Cir. 2001) (superseded by statute on other grounds); *see Vickers v. Gen. Motors Corp.*, 204 F.R.D. 476, 479 (D. Kan. 2001) (“[A] court should not ‘certify a class on the basis of an expert opinion so flawed that it is inadmissible as a matter of law.’” (ellipsis omitted) (quoting *In re Visa Check/MasterMoney Antitrust Litig.*, 192 F.R.D. 68, 75 (E.D.N.Y. 2000))). Beyond this most basic threshold, the role and scope of the *Daubert* analysis increases in step with the importance of the expert opinion to plaintiff’s showing of Rule 23(a)’s requirements. If, for instance, a plaintiff relies entirely on expert evidence to satisfy a Rule 23(a) requirement for certification, a nearly full-fledged *Daubert* analysis may be appropriate. *See Sher*, 419 F. App’x at 890 (“[I]f the situation warrants, the district court must perform a full *Daubert* analysis before certifying the class.”) (citing *Am. Honda Motor Co., Inc.*, 600 F.3d at 816). In raising a *Daubert*-style challenge to expert evidence at the class certification stage, it is therefore incumbent on the challenging party to establish the importance of the expert relative to the putative class plaintiff’s Rule 23(a) burden. Only once the expert’s importance is established can the court determine the appropriate scope of its *Daubert* analysis. *See Messner*, 669 F.3d at 814 (observing that *Daubert* hearing only necessary where challenged expert opinion was “critical” to motion for class certification).

Even where a challenging party establishes the importance of expert evidence relative to a Rule 23(a) requirement, the contours of Federal Rule of Evidence 702 and typical, pre-trial *Daubert* practice are not entirely applicable within the class certification setting. Rule 702 provides:

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

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

- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods; and
- (d) the expert has reliably applied the principles and methods to the facts of the case.

One of *Daubert*'s primary functions is to impart upon the trial judge a gatekeeping function so that juries do not hear evidence that is incompatible with Rule 702's requirements. *Bitler v. A.O. Smith Corp.*, 400 F.3d 1227, 1232 (10th Cir. 2005). But, a judge, not a jury, decides class certification. The concerns underlying *Daubert* thus are not fully in play and this may make a "less stringent application of *Daubert*" appropriate. *In re Zurn*, 644 F.3d at 613.

Also, as the parties remain engaged in merits discovery at the class certification stage, the information available to experts is limited. *Id.* at 612–13; *see also* Doc. 1517 at 2 (setting July 31, 2019, non-expert discovery deadline). As such, the requirements for admissibility announced in Rule 702(b) and 702(d) are not fully formed. A district court, thus, should apply "a focused *Daubert* analysis which scrutinize[s] the reliability of the expert testimony in light of the criteria for class certification and the current state of the evidence." *In re Zurn*, 644 F.3d at 614. As a consequence, any *Daubert* analysis performed by the court will focus primarily on: (1) the knowledge, training, experience, and qualifications of the expert; and (2) the methodology relied on by the expert in formulating the challenged opinion.

Finally, the forthcoming class certification determination is but a preliminary determination subject to reevaluation and amendment in light of developments in the case. *See Bennett v. Sprint Nextel Corp.*, 298 F.R.D. 498, 503 (D. Kan. 2014) (observing that a court "has authority to later redefine or even decertify the class if necessary"); *see also* Fed. R. Civ. P. 23(c)(1)(C) ("An order that grants or denies class certification may be altered or amended before final judgment."). It follows that any *Daubert* ruling specific to the class certification stage is subject to amendment for purposes of the class certification determination and is not finally

determinative of the admissibility of the expert's testimony at a trial on the merits. *See In re Zurn*, 644 F.3d at 610 (“We have never required a district court to decide conclusively at the class certification stage what evidence will ultimately be admissible at trial.”).

B. Rule 16(b)(4) Good Cause

Having identified the contours of *Daubert*-style challenges the court will apply at the class certification stage in this case, the question remains whether amending Scheduling Order No. 5 to add a *Daubert* briefing schedule is appropriate. “[T]he district court is afforded broad discretion in managing the pretrial schedule.” *Rimbert v. Eli Lilly & Co.*, 647 F.3d 1247, 1254 (10th Cir. 2011). Federal Rule of Civil Procedure 16 governs amendments to scheduling orders. Under Rule 16(b)(4), “[a] schedule may be modified only for good cause and with the judge’s consent.” “A scheduling order is not a frivolous piece of paper, idly entered, which can be cavalierly disregarded by counsel without peril.” *Johnson v. Mammoth Recreations, Inc.*, 975 F.2d 604, 610 (9th Cir. 1992) (internal quotation marks omitted). But, “while the pretrial order defines a lawsuit’s boundaries,” *Summers v. Mo. Pac. R.R. Sys.*, 132 F.3d 599, 604 (10th Cir. 1997) (quoting *Hull v. Chevron U.S.A., Inc.*, 812 F.2d 584, 588 (10th Cir. 1987)), the Tenth Circuit also has “recognized that a scheduling order can have an outcome-determinative effect on the case and ‘total inflexibility is undesirable,’” *Rimbert*, 647 F.3d at 1254 (quoting *Summers*, 132 F.3d at 604). In this latter vein, “[a] scheduling order which results in the exclusion of evidence is . . . ‘a drastic sanction.’” *Id.* (quoting *Summers*, 132 F.3d at 604).

Here, the court concludes the anticipated important role of expert testimony in the class certification determination and the authority supporting *Daubert* analysis at the class certification stage provide good cause for amending Scheduling Order No. 5. Based in part on the parties’ recent request to extend the deadline for expert discovery beyond the deadline for non-expert

discovery, it long has been evident that expert evidence will play a significant role in this case. *See* Doc. 1517 (adopting parties' proposal to delay expert discovery deadline to November 15, 2019). *Daubert* briefing, thus, may prove crucial to the court's ability to decide the class certification question. And, not amending Scheduling Order No. 5 to permit *Daubert* briefing would impose a drastic sanction because considering expert evidence that does not satisfy *Daubert* may have an outcome-determinative effect on class certification. And, in the Seventh Circuit at least, it is reversible error for a district court to refuse to address a *Daubert* challenge to an expert whose opinions are critical to class certification. *Messner*, 669 F.3d at 811–14; *see also Sher*, 419 F. App'x at 890–91 (adopting Seventh Circuit position). Accordingly, the state of the law and the importance of the issue suffices. It provides good cause for amending Scheduling Order No. 5 to permit *Daubert* briefing, as limited by this Order's discussion about the role of *Daubert* at the class certification stage.

III. Conclusion

Defendants Mylan and Pfizer have satisfied the court that Rule 702 and *Daubert* play a role at the class certification stage. The scope of that role, however, depends on the specifics of both the litigation and the challenged expert opinions relative to plaintiffs' Rule 23 burden. Thus, it is incumbent on the party raising the *Daubert* challenge to establish that a full-fledged *Daubert* analysis, as opposed to a tailored *Daubert* analysis, is appropriate. To focus briefing to the *Daubert* issue relative to Rule 23(a) and class certification, opening briefs and response briefs on the *Daubert* opinion shall not exceed 20 pages and reply briefs shall not exceed 10 pages.

IT IS THEREFORE ORDERED BY THE COURT THAT Mylan's and Pfizer's Motion to Amend Scheduling Order (Doc. 1486) is granted.

IT IS FURTHER ORDERED BY THE COURT THAT Scheduling Order No. 5 (Doc. 1263) is amended to add the following deadlines: (1) *Daubert* motions relating to the class certification stage shall be filed by **May 21, 2019**; (2) response briefs shall be filed by **June 7, 2019**; and (3) reply briefs shall be filed by **June 21, 2019**. Opening briefs in support of motions, as well as response briefs, shall be limited to **20 pages**. Reply briefs shall be limited to **10 pages**.

IT IS FURTHER ORDERED BY THE COURT THAT Scheduling Order No. 8, issued contemporaneous to this Memorandum and Order, supersedes Scheduling Order No. 5.

IT IS SO ORDERED.

Dated this 11th day of April, 2019, at Kansas City, Kansas.

s/ Daniel D. Crabtree
Daniel D. Crabtree
United States District Judge

s/ Teresa J. James
Teresa J. James
United States Magistrate Judge