UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE: Acetaminophen – ASD-ADHD Products Liability Litigation	:	22md3043 (DLC) 22mc3043 (DLC) 22cv8830 (DLC)
This Document Relates To: Chapman et al. v. Walmart, Inc. et al., 22cv8830	:	OPINION AND ORDER

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DENISE COTE, District Judge:

Johnson & Johnson Consumer Inc. ("JJCI") has moved for certification of an interlocutory appeal under 28 U.S.C. § 1292(b) of two of the Opinions denying motions to dismiss in this litigation. For the following reasons, the motion for certification is denied.

Background

Familiarity with the decisions issued in this litigation, including those identified below, is presumed, and therefore the background for this motion is summarized only briefly. Cherise Chapman, individually and on behalf of her minor child D.C. (together, "Plaintiffs"), has sued JJCI and a retailer, alleging that her child has autism spectrum disorder ("ASD") and attention-deficit/hyperactivity disorder ("ADHD") because Chapman took one of JJCI's acetaminophen products, Tylenol Extra Strength ("Tylenol"), while pregnant. This action is one of many cases in this multidistrict products liability litigation ("MDL").

JJCI manufactures Tylenol. Acetaminophen has long been marketed as the only safe over-the-counter pain reliever for pregnant women. At the time Chapman took Tylenol, the label contained one FDA-required warning related to pregnancy: "**If**

pregnant or breast-feeding, ask a health professional before use." (Emphasis in original.) There was no specific warning about the risk of developing ASD or ADHD.

On June 7, 2022, the Plaintiffs filed this action in the U.S. District Court for the District of Nevada. On October 5, the Judicial Panel on Multidistrict Litigation consolidated this action with others asserting claims that prenatal exposure to acetaminophen causes ASD and ADHD in children and transferred the cases to this Court under 28 U.S.C. § 1407. On November 14, motions to dismiss two actions within the MDL on the ground of preemption were denied.[1] In re Acetaminophen - ASD-ADHD Prods. Liab. Litig., No. 22md3043 (DLC), 2022 WL 17348351 (S.D.N.Y. Nov. 14, 2022).

On December 16, the MDL plaintiffs filed a master complaint against JJCI ("Master Complaint"). On January 20, 2023, Chapman filed her short form complaint ("SFC"), and on February 3, timely amended it. The SFC asserts Nevada state law claims against JJCI, to wit, claims for strict liability for failure to warn, strict liability for design defect due to inadequate

[1] On April 27, 2023, a motion for reconsideration and request for certification under 28 U.S.C. § 1292(b) of the November preemption opinion were denied. In re Acetaminophen - ASD-ADHD Prods. Liab. Litig., No. 22md3043 (DLC), 2023 WL 3126574 (S.D.N.Y. Apr. 27, 2023). JJCI, which was not a party in the actions addressed by the November preemption opinion, opposed certification of that Opinion under 28 U.S.C. § 1292(b).

warnings and precautions, negligence, negligent misrepresentation, breach of implied warranty, and violation of Nevada's consumer protection laws.[2] On February 10, JJCI moved to dismiss all of the SFCs filed against it, including Chapman's.

On April 20, 2023, JJCI's motion to dismiss this action on the ground of preemption was denied. In re Acetaminophen - ASD-ADHD Prods. Liab. Litig., No. 22md3043 (DLC), 2023 WL 3026412 (S.D.N.Y. Apr. 20, 2023) ("Preemption Opinion"). On April 27, JJCI's motion to dismiss this action for failure to plead causation and knowledge as required by Rule 8, Fed. R. Civ. P., was also denied.[3] In re Acetaminophen - ASD-ADHD Prods. Liab. Litig., No. 22md3043 (DLC), 2023 WL 3126589 (S.D.N.Y. Apr. 27, 2023) ("Rule 8 Opinion").

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[2] The Plaintiffs also assert a strict liability misrepresentation claim under the laws of states in which the Plaintiffs do not reside, including California. The SFC does assert, however, in its claim against a retailer, that Chapman purchased the retailer's store-branded acetaminophen in Sacramento, California.

[3] Other Opinions have addressed motions to dismiss on other grounds brought by JJCI and the Retailer Defendants in this MDL. See In re Acetaminophen – ASD-ADHD Prods. Liab. Litig., No. 22md3043 (DLC), 2023 WL 3467057 (S.D.N.Y. May 15, 2023); In re Acetaminophen – ASD-ADHD Prods. Liab. Litig., No. 22md3043 (DLC), 2023 WL 3162623 (S.D.N.Y. Apr. 28, 2023); In re Acetaminophen – ASD-ADHD Prods. Liab. Litig., No. 22md3043 (DLC), 2023 WL 3126636 (S.D.N.Y. Apr. 27, 2023); In re Acetaminophen – ASD-ADHD Prods. Liab. Litig., No. 22md3043 (DLC), 2023 WL 3045802 (S.D.N.Y. Apr. 21, 2023).

On May 2, JJCI moved for certification of an interlocutory appeal under 28 U.S.C. § 1292(b) of the Preemption Opinion and the Rule 8 Opinion. The Retailer Defendants in this MDL support JJCI's motion. The Plaintiffs oppose the motion. The motion became fully submitted on June 7. In its reply brief, JJCI represents that it does not plan to seek a stay of this litigation should its motion for certification of an appeal be granted.

Discussion

Section 1292 is "a rare exception to the final judgment rule that generally prohibits piecemeal appeals." Koehler v. Bank of Bermuda Ltd., 101 F.3d 863, 865 (2d Cir. 1996). Section 1292(b) provides that

> When a district judge, in making in a civil action an order not otherwise appealable under this section, shall be of the opinion that such order involves a controlling question of law as to which there is substantial ground for difference of opinion and that an immediate appeal from the order may materially advance the ultimate termination of the litigation, he shall so state in writing in such order. The Court of Appeals which would have jurisdiction of an appeal of such action may thereupon, in its discretion, permit an appeal to be taken from such order, if application is made to it within ten days after the entry of the order.

28 U.S.C. § 1292(b) (emphasis added); United States v. Prevezon Holdings Ltd., 839 F.3d 227, 235 (2d Cir. 2016).

Section 1292(b) certification should be "strictly limited because only exceptional circumstances will justify a departure

from the basic policy of postponing appellate review until after the entry of a final judgment." Flor v. BOT Fin. Corp., 79 F.3d 281, 284 (2d Cir. 1996) (citation omitted). The proponents of an interlocutory appeal bear the burden of showing that all three of the substantive criteria are met. See Casey v. Long Island R.R. Co., 406 F.3d 142, 146 (2d Cir. 2005).

JJCI's motion for certification of an interlocutory appeal is denied. JJCI has not demonstrated that all of the § 1292(b) factors are met for an interlocutory appeal from either the Preemption Opinion or the Rule 8 Opinion. This Opinion will first address JJCI's motion to certify an interlocutory appeal of the Preemption Opinion, and then it will address the motion as to the Rule 8 Opinion.

I. Preemption Opinion

JJCI has failed to demonstrate that there is any ground for a substantial difference of opinion regarding the preemption of this litigation. Therefore, even though its motion identifies a controlling question of law and correctly argues that a reversal of the Preemption Opinion would terminate this action, and indeed would terminate this MDL, certification is not warranted.

The Preemption Opinion held that the Plaintiffs' state law claims are not preempted by FDA regulations that govern the label for acetaminophen or the prohibition in the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-399g, on misbranding. See

Preemption Opinion, 2023 WL 3026412, at *7. JJCI has not pointed to any authority to suggest that there is any ground for a difference of opinion on that issue. The preemptive effect of the pregnancy warning regulation, 21 C.F.R. § 201.63, has not been addressed by other courts. The issue's novelty, however, does not suggest that there is a substantial ground for disagreement about the Preemption Opinion's conclusions.

The arguments JJCI makes to demonstrate that a difference of opinion exists largely repeat the arguments it made unsuccessfully in its motion to dismiss. To the extent that JJCI finds support for its position in the FDA's interpretation of the pregnancy warning regulation, 21 C.F.R. § 201.63, and its exact language regulation, 21 C.F.R. § 330.1(c)(2), the Preemption Opinion already rejected JJCI's reading of those regulations and the relevant FDA regulatory history. See Preemption Opinion, 2023 WL 3026412, at *8-11. JJCI has not succeeded in showing that there is a reasonable basis to disagree with the analysis in the Preemption Opinion.

JJCI argues that the very fact that this case presents an issue of first impression satisfies the requirement that there be a substantial ground for a difference of opinion on this question of law. That may be so if the legal issue were a close one. It is not a close question here.

JJCI also faults the Preemption Opinion for relying on Wyeth v. Levine, 555 U.S. 555 (2009), and Merck Sharp & Dohme Corp. v. Albrecht, 139 S. Ct. 1668 (2019), because those Supreme Court decisions arose in the context of the regulatory regime for prescription drugs, which is different from the regime governing acetaminophen. See Preemption Opinion, 2023 WL 3026412, at *7. This argument is unavailing. Wyeth and Albrecht are undoubtedly relevant, and JJCI's own motion to dismiss premised on the preemption doctrine discussed those opinions. Consulting established Supreme Court precedent on preemption, even if the precedent arose in a different context, however, does not provide a basis to find that a substantial difference of opinion exists on the Preemption Opinion's conclusions. Indeed, the Supreme Court's rejection of the preemption argument, made in the context of tightly regulated prescription drugs, provides strong confirmation of the conclusion reached in the Preemption Opinion regarding state laws when they are applied to drugs regulated under the monograph system.

II. Rule 8 Opinion

JJCI's motion to certify the Rule 8 Opinion for an interlocutory appeal is also denied. The Rule 8 Opinion held, inter alia, that the Plaintiffs adequately pled that in utero exposure to acetaminophen causes ASD and ADHD and that JJCI knew

or should have known about that risk. See Rule 8 Opinion, 2023 WL 3126589, at *3-4.

JJCI complains that neither the Master Complaint nor the SFC filed by the Plaintiffs cites a single study asserting that prenatal use of acetaminophen can "cause" ADHD or ASD. JJCI contends that that failure is easy to explain since "none exists; to the contrary, the relevant studies disclaim causation." It argues that allowing the litigation to proceed without adequate support pleaded for the essential element of causation will impose substantial burdens on the parties and the courts.

In connection with the Rule 8 Opinion, JJCI has not identified a question of law that is appropriate for certification. JJCI does not suggest that a standard other than that applied pursuant to Rule 8 governs the Master Complaint. Whether the Master Complaint plausibly pleads a claim as required by Rule 8 is not, at least in this case, a legal issue appropriate for certification. The application of the Rule 8 standard to the Master Complaint requires a careful review of the facts pleaded in and integral to the pleading.

For similar reasons, JJCI has not shown that there is a substantial ground for difference of opinion regarding the very fact-specific inquiry addressed in the Rule 8 Opinion. The degree to which the particular scientific studies cited in a

pleading enable the plaintiff to plausibly plead the elements of causation and knowledge is usually a question unique to the particular litigation.

JJCI insists that the question here is a pure legal one, to wit, whether the Master Complaint was required to identify scientific literature that finds a causal relationship between the product and the injury. But that begs the question. Whether the cited studies are sufficient to plausibly plead causation requires a careful examination of the studies and allegations. This application of Rule 8 standards to this particular complaint does not constitute a controlling question of law.

Nor has JJCI shown that certification will materially advance the termination of the litigation. Daubert motions addressed to expert reports relevant to the issue of general causation will be briefed this Fall and a hearing will be held in December, should one be necessary. Thus, whether current scientific research permits the plaintiffs to proceed with this litigation will be resolved in the near future. Any review of the Rule 8 Opinion pursuant to the certification process is unlikely to be completed by then, and in any event, even if the outcome from an interlocutory appeal is favorable to JJCI, the Plaintiffs may be given an opportunity to amend the Master Complaint.

Conclusion

JJCI's May 2, 2023 motion for certification of an interlocutory appeal pursuant to 28 U.S.C. § 1292(b) from the Preemption Opinion and the Rule 8 Opinion is denied.

Dated: New York, New York
August 3, 2023

DENISE COTE
United States District Judge