IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

In re Testosterone Replacement Therapy Products Liability Litigation Coordinated Pretrial Proceedings	)	**Case No. 14 C 1748** **MDL No. 2545**
(This document applies to *Martin v. Actavis, Inc.*, Case No. 15 C 4292)	)	

CASE MANAGEMENT ORDER NO. 189
(Memorandum Opinion and Order on Post-Trial Motions in *Martin v. Actavis, Inc.*, No. 15 C 4292)

MATTHEW F. KENNELLY, District Judge:

In this case, which is part of a multidistrict litigation proceeding, plaintiff Brad Martin alleges that he suffered a myocardial infarction—a heart attack—caused by taking Androderm, a prescription testosterone replacement therapy (TRT) drug manufactured or sold by defendants Actavis, Inc., Actavis Pharma, Inc., and Actavis Laboratories UT, Inc. (collectively, Actavis). Most of the plaintiffs who sued Actavis settled their claims under a global settlement agreement. In August 2019, Martin advised that he would not join the settlement. Two years later in August 2021, after a two-week trial, a jury returned a verdict finding that Actavis was not liable.

Martin has moved for a new trial under Federal Rule of Civil Procedure 59. He contends that Actavis impermissibly introduced as part of its defense the warning label of another drug taken by Martin, Etodolac. Martin also contends that Actavis improperly failed to produce a March 2018 letter from the FDA in which the agency ordered Actavis to conduct a post-marketing study on the relationship between Androderm and elevated blood pressure. For the reasons stated below, the Court denies Martin's motion.

Background

The Court assumes familiarity with this case and its prior orders in the MDL. The Court will briefly discuss the context surrounding the two key pieces of evidence that are relevant to this motion: the Etodolac label and the FDA letter.

At trial, Actavis introduced an Etodolac warning label on cross-examination to rebut the notion that Martin would have heeded a stronger Androderm warning label. Actavis did so by comparing the warning labels of the two drugs and asking Martin how he had responded to those labels. Actavis did not use the label to argue or suggest that Etodolac directly caused Martin's heart attack. Actavis had not disclosed the label as a potential exhibit prior to trial. Martin's counsel objected to the evidence on the basis that it violated a pretrial agreement he said the parties had made not to discuss other drugs that Martin had taken. The Court gave Martin's counsel time to offer proof of the claimed agreement, but he was unable to produce it. Counsel admitted that he did not "have the smoking gun" and instead contended only that his notes indicated that there had been an agreement. Trial Tr. vol. 3 at 438 (dkt. no. 362). Actavis's counsel, in response, represented to the Court that they had "no recollection of making such an agreement." *Id.* at 439. The Court overruled Martin's objection.

A few hours after trial concluded on August 17, 2021, Actavis produced a letter from the FDA to Martin's counsel in another case in the MDL in which counsel represented the plaintiff.[1] The FDA letter, dated March 22, 2018, indicated that the agency was aware that men receiving testosterone therapy in clinical trials had elevated blood pressure levels, and consequently, the agency required Actavis to conduct a post-

[1] This case is *Davis v. Actavis*, case number 17 C 3775.

marketing clinical trial to study the relationship between Androderm and blood pressure. Actavis produced this letter in the *Davis* case in response to an order by the Court that was based on targeted discovery requests in the *Davis* case concerning Androderm post-marketing studies. Actavis initially responded to the Court's order in June 2021 by producing more than 7,000 pages of documents, which included a related FDA letter dated August 23, 2019 that discussed the post-marketing study's existence and protocol in depth. Actavis then supplemented this production on August 17 (just after Martin's trial concluded), and this supplementation included the March 2018 FDA letter that is now at issue.

Discussion

As a preliminary procedural point, Martin has entitled his motion as one for a new trial, which typically falls under Federal Rule of Civil Procedure 59(a). But in discussing the relevant legal standard, Martin frames the inquiry as one under Rule 59(e), which concerns altering or amending a judgment. *See* Pl.'s Mot. for New Trial at 1 (dkt. no. 350). Actavis accordingly frames its analysis under Rule 59(e) as well. *See* Defs.' Resp. to Pl.'s Mot. for New Trial at 2 (dkt. no. 371).

These Rule 59 subsections, however, are not perfect substitutes. *Compare* 11 Charles Alan Wright & Arthur R. Miller, *Federal Practice and Procedure* § 2805 (3d ed. 2022) ("Grounds for New Trial"), *with id.* § 2810.1 ("Grounds for Amendment or Alteration of Judgment"); *see also Black & Decker Inc. v. Robert Bosch Tool Corp.*, No. 04 C 7955, 2007 WL 108412, at *1–2 (N.D. Ill. Jan. 12, 2007) (discussing the two different standards). Under Rule 59(a), "[a] new trial is appropriate if the jury's verdict is against the manifest weight of the evidence or if the trial was in some way unfair to the

moving party." *Venson v. Altamirano*, 749 F.3d 641, 656 (7th Cir. 2014). Rule 59(e), on the other hand, requires the movant to "demonstrate a manifest error of law or fact or present newly discovered evidence." *Boyd v. Tornier, Inc.*, 656 F.3d 487, 492 (7th Cir. 2011).

Despite these differences, to the extent that Martin's motion is premised on the discovery of new evidence, the distinction does not matter. The Seventh Circuit has endorsed the same test under both Rule 59(a) and (e) when new newly discovered evidence is at issue:

> [A] party must show that: (1) it has evidence that was discovered post-trial; (2) it had exercised due diligence to discover the new evidence; (3) the evidence is not merely cumulative or impeaching; (4) the evidence is material; and (5) the evidence is such that a new trial would probably produce a new result.

Cincinnati Life Ins. Co. v. Beyrer, 722 F.3d 939, 955 (7th Cir. 2013) (quoting *Envtl. Barrier Co., LLC v. Slurry Sys., Inc.*, 540 F.3d 598, 608 (7th Cir. 2008)).

To the extent that Martin's motion is premised on evidentiary error—in this case, the admission of the Etodolac label—the Court will follow the course set out by the parties and assess the issue under Rule 59(e). The Seventh Circuit has stated that manifest error under Rule 59(e) entails the "wholesale disregard, misapplication, or failure to recognize controlling precedent." *Oto v. Metro. Life Ins. Co.*, 224 F.3d 601, 606 (7th Cir. 2000) (quoting *Sedrak v. Callahan*, 987 F. Supp. 1063, 1069 (N.D. Ill. 1997)). Furthermore, Rule 59(e) motions are "not appropriately used to advance arguments or theories that could and should have been made before the district court rendered a judgment, or to present evidence that was available earlier." *Miller v. Safeco Ins. Co. of Am.*, 683 F.3d 805, 813 (7th Cir. 2012) (quoting *LB Credit Corp. v.*

Resolution Tr. Corp., 49 F.3d 1263, 1267 (7th Cir. 1995)). Accordingly, if a Rule 59(e) movant "does not object to the admission of evidence during the trial, the objection is waived and cannot be raised for the first time in a motion for new trial." *Naeem v. McKesson Drug Co.*, 444 F.3d 593, 610 (7th Cir. 2006).

A. Etodolac label

At trial, Actavis introduced the label of another drug, Etodolac, as an exhibit that it had not disclosed in its pretrial exhibit list. Martin argues that he was prejudiced by this surprise exhibit, in part because the Etodolac label encouraged the jury to infer that Etodolac, not Androderm, caused Martin's heart attack. Additionally, according to Martin, Actavis introduced the wrong version of the Etodolac label, and Actavis had agreed to not argue anything related to other drugs Martin had taken. Taking these points together, Martin contends that the admission of the Etodolac label created manifest error.

Federal Rule of Civil Procedure 26 does not require evidence used for impeachment to be disclosed on an exhibit list. *Cf.* Fed. R. Civ. P. 26(a)(3); s*ee also Hammel v. Eau Galle Cheese Factory*, 407 F.3d 852, 869 (7th Cir. 2005). And this District's Local Rule 16.1.1 standing "Final Pretrial Order Form" expressly excepts rebuttal exhibits from pretrial disclosure. N.D. Ill. LR 16.1.1 (Final Pretrial Order Form); *see also DeBiasio v. Illinois Cent. R.R.*, 52 F.3d 678, 688 (7th Cir. 1995) (explaining that evidence "offered to impeach . . . [is] not demonstrative evidence" for the purposes of the local rules). The Seventh Circuit has further instructed that a court need not exclude nondisclosed evidence if the nondisclosure was justified. *David v. Caterpillar, Inc.*, 324 F.3d 851, 857 (7th Cir. 2003).

The record shows that Actavis used the Etodolac label to impeach Martin. To succeed on his failure to warn claim, Martin had to prove that he would not have taken Androderm if it had a stronger warning. Martin accordingly took the stand and testified to that effect. For example, he said, "Every medication that I get or suggested that I take . . . at the very minimum, I look up the side effects." Trial Tr. vol. 2, 323 (dkt. no. 361). On cross-examination, Actavis introduced the Etodolac label to rebut the notion that Martin would not have taken Androderm if it had a stronger warning. That is textbook impeachment evidence. *See United States v. Boswell*, 772 F.3d 469, 476 (7th Cir. 2014) ("Impeachment can be effected in a number of ways, including contradiction, which involves presenting evidence that the substance of a witness's testimony is not to be believed."). This means that Actavis was not required to identify the Etodolac label as an exhibit in advance of trial.

Martin's argument that Actavis proactively used the label to encourage the jury to infer lack of causation also lacks merit. Both before the initial admission of the Etodolac label and before closing arguments, the Court asked Actavis how it planned to use the Etodolac label. *See* Trial Tr. vol. 3 at 439–41 (dkt. no. 362); *Id.* vol. 9 at 1737–39 (dkt. no. 368). Actavis assured the Court on both occasions that it only planned to argue that Martin's reaction to the warning on the Etodolac label undermined the proposition that he would have heeded a stronger Androderm warning. Actavis never suggested that it planned to argue that Etodolac caused Martin's heart attack. Critically, the record reflects that Actavis adhered to its assurances. As such, Actavis is correct in its contention that the Etodolac label was only used for impeachment. This means that the nondisclosure of the Etodolac label as an exhibit was justified, and a new trial is not

warranted on this basis.

The other issues that Martin raises—the label version and pretrial agreement—do not warrant a new trial either. Regarding the label version, Martin has not provided any concrete evidence that Actavis introduced the wrong version at trial; instead, Martin's argument rests on the *mere possibility* that the wrong label was used and the fact that Actavis did not authenticate the document with Martin. *See, e.g.*, Pl.'s Mot. for New Trial at 9 (dkt. no. 350) ("[T]he version being used very likely was not the correct version."); *id.* at 10 ("[I]f Actavis' counsel used a post-2015 label and represented to Mr. Martin, the Court, and the jury that it was in effect at the time he was using it, that would be untrue."). This sort of speculation, however, cannot provide the basis for a new trial, especially when Martin did not object to the wrong version being used at trial and expressly said the issue is "not with the document itself." Trial Tr. vol. 3 at 436 (dkt. no. 362); *see Naeem*, 444 F.3d at 610.

Regarding the pretrial agreement issue, Martin has still not provided anything that establishes the existence of such an agreement. Matin's evidence—a screenshot of counsel's notes and an accompanying affidavit—will not cut it, especially when he already referenced his notes when the point was raised during the trial. *See Vesely v. Armslist LLC*, 762 F.3d 661, 666 (7th Cir. 2014) (explaining that "a Rule 59(e) motion is not to be used to rehash previously rejected arguments" (internal quotation marks omitted)).

The Court concludes that the admission of the Etodolac label as evidence was

not error and thus does not merit a new trial under Federal Rule of Civil Procedure 59.[2] Additionally, because the admission of the Etodolac label was not erroneous, the Court rejects Martin's argument that the cumulative effect of the label admission and the FDA letter merits a new trial. *See Christmas v. City of Chicago*, 682 F.3d 632, 643 (7th Cir. 2012) (explaining that a cumulative effect argument requires the plaintiff to show that "multiple errors occurred at trial").

B. FDA letter

Martin argues next that Actavis failed to produce a March 2018 letter from the FDA. Martin's counsel first received this letter hours after the jury returned its verdict on August 17, 2021, when it was produced to him in connection with the *Davis* case, which is part of the same MDL. The FDA letter directed Actavis to conduct a post-marketing trial to study the relationship between Androderm and blood pressure, due to observations of increased blood pressure in testosterone therapy clinical trials. Martin contends that he could have used this FDA letter at trial to undercut two of Actavis's arguments: first, that the fact the FDA had not stopped a related TRAVERSE study examining Androderm tended to establish that the drug was safe; and second, that Martin's poor health management, rather than Androderm, caused his heart attack.

The FDA letter has no bearing on the first of the two points advanced by Martin. Martin contends that the elevated blood pressure readings that the FDA letter referenced "could only have come from the TRAVERSE study," Pl.'s Reply at 11 (dkt.

[2] Although the Seventh Circuit uses a slightly different standard for a motion for new trial under Rule 59(a), the Court would nevertheless reach the same result if Martin had brought his motion under Rule 59(a) because the admission did not cause the trial to be unfair. *See Venson*, 749 F.3d at 656.

no. 374), but the letter's timing betrays this contention. The FDA sent the letter at issue on March 22, 2018; the TRAVERSE study did not begin until May 3, 2018. This alone proves that the FDA letter could not have been sent because of concerns with the TRAVERSE study. Martin's first contention accordingly lacks merit.

The letter's relevance on the second point—Actavis's contention that Martin's poor health management, rather than Androderm, caused his heart attack—is a closer call. As detailed above, a movant must establish five factors to receive a new trial on the basis of newly discovered evidence.[3] *See Cincinnati Life Ins.*, 722 F.3d at 955. Actavis disputes all five elements, but Actavis's arguments are best interpreted as disputes over whether Martin should have known about the letter and whether it should have been produced at all. Martin clearly has established three of the five elements: the letter was not produced until after trial, it was not cumulative or impeaching, and it directly pertained to at least one of Actavis's theories meaning it was material. As such, the Court turns to the elements of due diligence and the likelihood of a different outcome.

On the issue of due diligence, the parties largely focus on the question of whether Actavis was ever required to produce the letter. In Martin's opening new trial brief, he asserts, without further analysis, that the letter "is responsive to prior discovery requests and Actavis had an ongoing duty to supplement its discovery responses. Fed. R. Civ. P. 26(e)(1)." Pl.'s Mot. for New Trial at 17 (dkt. no. 350). Similarly in his reply,

[3] These elements are as follows: (1) the movant has evidence that was discovered post-trial; (2) it exercised due diligence to discover the new evidence; (3) the evidence is not merely cumulative or impeaching; (4) the evidence is material; and (5) the evidence is such that a new trial would probably produce a new result.

Martin again summarily contends that Actavis "provides absolutely no reason for [nondisclosure]." Pl.'s Reply at 12 (dkt. no. 374). It is only in the supplemental briefing directed by the Court that Martin finally makes two arguments explaining why he contends Actavis should have actually produced the letter: first, Actavis should have produced it in supplementing its earlier productions of records under Federal Rule of Civil Procedure 26(e); and second, the Court's May 27, 2020, discovery order in this case required Actavis to produce the letter.

Federal Rule of Civil Procedure 26(e) "impos[es] a duty to correct or supplement in a timely manner 'if the party learns that in some material respect the disclosure or response is incomplete or incorrect.'" *Morris v. BNSF Ry. Co.*, 969 F.3d 753, 765 (7th Cir. 2020) (quoting Fed. R. Civ. P. 26(e)(1)(A)). This duty stems from a party's disclosure obligations, which are delineated in Rule 26(a)(1) and apply unless "otherwise stipulated or ordered by the court." Fed. R. Civ. P. 26(a)(1)(A). In this MDL, the Court's Case Management Order (CMO) No. 7 supplanted Rule 26(a)(1) disclosure obligations with a standardized set of initial disclosures. *See* CMO No. 7 (Preliminary Discovery Plan and Procedures), MDL No. 2545, Case No. 14 C 1748, Dkt. No. 346. Actavis complied with CMO 7 by producing relevant Androderm materials, which included relevant FDA correspondence, dated between January 1, 2010 and December 31, 2014. Thus, the duty to supplement under Rule 26(e) would only be triggered if the FDA letter made those disclosures incomplete or incorrect.

Martin does not dispute Actavis's initial compliance with CMO 7, which makes sense seeing as how the March 2018 FDA letter did not exist in 2014. Instead, he contends that the duty to supplement under Rule 26(e) is not limited to situations where

production is incomplete or incorrect. *See* Pl.'s Mem. Regarding CMO 144 & Rule 26(e) at 4, 7–8 (dkt. no. 387). To support this contention, Martin cites *Morris v. BNSF Railway*, where the Seventh Circuit pointed out that "[p]arties who do not attend diligently to their obligation to supplement initial disclosures proceed at their own peril." *Morris*, 969 F.3d at 766. But *Morris* does not go so far as to say that Rule 26(e) requires anything more than what the text of Rule 26(e) demands, which is supplementation to address incorrectness or incompleteness. *See id.* To this point, the Rule 26 advisory committee notes further explain that "[s]ubdivision (e) provides that a party is *not under a continuing burden* except as expressly provided." Fed. R. Civ. P. 26(e) advisory committee's note to 1970 amendment (emphasis added). Put another way, Rule 26(e) does not require a party to supplement its production of records to include everything an opposing party might consider relevant, irrespective of whether the new item renders a party's earlier production "incomplete" in light of the party's obligations under Rule 26(a) or a court order or the opposing party's discovery request to which the item is claimed to be responsive. In this case, Rule 26(a)(1) did not apply (and even if it did, the FDA letter is not a document that *Actavis* intended to use to support its claims or defenses); its production was not required by CMO 7; and Martin cites no separate discovery request he made in this case to which the FDA letter would have been responsive. In sum, the Court is not persuaded that the Rule 26(e) duty to supplement obligated Actavis to produce the March 2018 FDA letter.

Martin also argues that the duty to supplement would have been triggered in connection with Actavis's custodian productions. But like the initial disclosures, Martin again has not demonstrated that Actavis's custodian productions were incomplete or

incorrect. Although Martin contends that these custodian searches were not date restricted, CMO 15 indicates otherwise, as it directed parties to use "date ranges as a means to identify relevant ESI for review and production." CMO No. 15 (Protocol for electronically stored information (ESI) production format), MDL No. 2545, Case No. 14 C 1748, Dkt. No. 469 ¶ C(2). Furthermore, CMO 15 specified that it would be in effect unless there was a written agreement between the parties, and the e-mail correspondence that Martin offers to show there was no date restriction does not establish that there was any agreement to the contrary. *See id.* ¶ F(2); Supp. to Pl.'s Mot., Ex. D (dkt. no. 382-4) (e-mail correspondence).

At bottom, Actavis complied with its custodian production obligations, and the fact that a later search of a single custodian's e-mails would have turned up the FDA letter does not mean that the original custodian production was incomplete or incorrect. *See Barnhill v. Bos. Sci. Corp.*, No. 8:20CV182, 2021 WL 424441, at *2 (D. Neb. Feb. 8, 2021) (discussing the difference between supplementation and requesting ongoing discovery); *Adidas Am., Inc. v. TRB Acquisitions LLC*, No. 3:15-CV-2113-SI, 2018 WL 4849312, at *3 (D. Or. Oct. 5, 2018) (similar); *Our Children's Earth v. Leland Stanford Jr. Univ.*, No. 13-CV-00402-EDL, 2015 WL 12964638, at *3 (N.D. Cal. Oct. 29, 2015) (similar); *Kuhns v. City of Allentown*, No. CIV.A. 08-2606, 2010 WL 4236873, at *2 (E.D. Pa. Oct. 26, 2010) (similar). Thus, Martin has not demonstrated that these custodian productions triggered Rule 26(e) such that the FDA letter should have been produced to supplement the productions.

Martin's final point—that the Court's May 27, 2020 discovery order in the present case required Actavis to produce the FDA letter—also lacks merit. In this order, the

Court directed Actavis "to promptly update its discovery responses pursuant to Fed. R. Civ. P. 26(e) with respect to the matters referenced in Section III of plaintiffs' motion and items E.1 & E.2 of Actavis's response to the motion, concerning regulatory documents and annual reports." Order on Pls.' Mot. for Disc. at 2 (dkt. no. 142). As to the regulatory documents referenced in the motion and response, the subject matter consisted only of FDA inspection reports and annual reports, meaning the production obligations would *not* have included the FDA letter at issue. *See* Pls.' Omnibus Disc. Mot. at 7–8 (dkt. no. 122); Defs.' Mem. in Opp'n to Pls.' Mot. at 11–13 (dkt. no. 130). If the Court had more broadly ordered the production of *all* regulatory documents relating to Androderm, then Actavis would have had to produce the FDA letter. But as the issues were framed in the briefing—which is how the Court defined the supplemental production it was requiring—the order did not encompass the March 2018 FDA letter at issue. This argument therefore does not change the calculus either.

The Court acknowledges that the timing of Actavis's disclosure of the FDA letter is fishy. But that's not the issue here; the question is whether Actavis was required to produce it earlier. Martin has not demonstrated that this is the case. The Court notes that Martin could have requested additional discovery in this case under CMO 144, which is exactly what his counsel did in the *Davis* case. Yet Martin did not do so.

Moreover, as shown in the related *Davis* sanctions briefing, Martin's counsel received plenty of information regarding the post-marketing study's impetus, existence, and protocols at least by June 23, 2021—before the trial in the present case—when Actavis produced documents in connection with the aforementioned discovery request under CMO 144 in *Davis*. The information he received included a different letter from

the FDA, dated August 23, 2019, that discussed the same post-marketing study in depth and stated the following in its second sentence: "Sponsor also refers to the FDA's Postmarketing Requirements Notification letter Rec'd on March 22, 2018, requesting that sponsor conducts a 24-Hour Ambulatory Blood Pressure Monitoring Trial to assess whether Androderm increases blood pressure (BP) in hypgonadal men . . . ." Defs.' Mem. in Opp'n to Pls.' Mot. for Sanctions, Ex. 1 (dkt. no. 100-1). That's a reference to the very letter at issue on the present motion. In short, the post-marketing study and its genesis cannot be said to have been concealed in its entirety. The records produced in June 2021 brought the point to the attention of Martin's counsel sufficient that he could have sought further disclosures or discovery if he considered it important. But counsel did not do so. Martin has not shown that he exercised the due diligence required to establish a basis for a new trial under Rule 59(e).

Because Martin has not satisfied the due diligence element, the Court need not decide whether the FDA letter would have changed the outcome at trial.

Conclusion

For the foregoing reasons, the Court denies the plaintiff's motion for a new trial [dkt. no. 350]. The Court will enter a separate order on defendants' bill of costs.

MATTHEW F. KENNELLY
United States District Judge

Date: August 6, 2022