

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS**

UNITED STATES ex rel. RONALD J.)
STRECK,)

Relator,)

v.)

TAKEDA PHARMACEUTICALS)
AMERICA, INC., et al.,)

Defendants.)

Case No. 1:14-cv-09412

Hon. Judge Harry D. Leinenweber

**ELI LILLY AND COMPANY’S MOTION PURSUANT TO FEDERAL RULES OF
CIVIL PROCEDURE 50(b) AND 59**

Defendant Eli Lilly and Company (“Lilly”) respectfully requests that the Court grant judgment as a matter of law in its favor under Federal Rule of Civil Procedure 50(b) on each of Relator’s claims or order a new trial under Federal Rule of Civil Procedure 59, for the following reasons:

First, collateral estoppel bars Relator’s claims based on conduct arising before February 1, 2012. Relator admitted at trial that his previous lawsuit—decided against him on the merits—concerned “exactly what [Lilly is] being accused of here in this courtroom.” Tr. at 119:11–12; *U.S. ex rel. Streck v. Allergan, Inc.*, 894 F. Supp. 2d 584 (E.D. Pa. 2012), *aff’d* 746 F. App’x 101 (3d Cir. 2018) (“*Streck I*”). Collateral estoppel therefore applies, and Relator cannot use claims of waiver, the *Mendoza* exception, or anything else to evade this result. Lilly is thus entitled to judgment on all claims prior to February 1, 2012, and a new trial on only those claims after February 1, 2012, for which Relator is not collaterally estopped.

Second, Lilly is entitled to judgment as a matter of law for all claims related to conduct prior to November 24, 2008 because they are barred by the FCA’s statute of limitations. 31 U.S.C. § 3731(b); *e.g.*, *U.S. ex rel. Leveski v. ITT Educ. Servs., Inc.*, 2010 WL 1936118, at *4 (S.D. Ind. May 12, 2010) (dismissing claims that were more than six years old at the time of filing).

Third, Relator has conceded that his state-law claims impermissibly seek damages and penalties from before relevant state statutes were enacted and suffer from other clear legal defects, but he nevertheless pursued these unsound claims at trial. Dkt. 100 at 30–31 (agreeing to dismissal of certain claims). The Court should grant Lilly judgment as a matter of law on these admittedly defective claims and order a new trial where Relator does not seek damages for claims he has already admitted are invalid. Relator’s state-law claims also fail on each of the other grounds raised in this motion. *See U.S. ex rel. Streck v. Allergan, Inc.*, 746 F. App’x 101, 105 n.3 (3d Cir.

2018) (explaining that its reasoning under the “federal FCA” applies “equally” to “the FCAs of the various states”).

Fourth, no reasonable jury could find that Lilly acted “knowingly” under the FCA. There is overwhelming evidence that Lilly genuinely believed that its conduct was lawful, and that Lilly diligently worked to understand and comply with the legal guidance available. Relator has not introduced legally sufficient evidence upon which a reasonable jury could find that Lilly acted with the scienter required for liability under the FCA. Lilly is thus entitled to judgment as a matter of law on scienter for all of Relator’s claims. *U.S. ex rel. Main v. Oakland City Univ.*, 426 F.3d 914, 917 (7th Cir. 2005); *U.S. ex rel. Rueter v. Sparks*, 939 F. Supp. 636, 638 (C.D. Ill. 1996). In the alternative, because the jury’s verdict is against the weight of the evidence, the Court should order a new trial.

Fifth, the Court should enter judgment as a matter of law for Lilly because Relator cannot show objective knowledge under *Safeco Ins. Co. of Am. v. Burr*, 551 U.S. 47 (2007). Lilly’s conduct was consistent with objectively reasonable interpretations of the law and no authoritative guidance warned Lilly away. *U.S. ex rel. Schutte v. Supervalu Inc.*, 9 F.4th 455, 468 (7th Cir. 2021); *see U.S. ex rel. Purcell v. MWI Corp.*, 807 F.3d 281, 289 (D.C. Cir. 2015) (overturning jury verdict for government, and entering judgment for defendant under *Safeco*). Moreover, although subjective intent is irrelevant under *Safeco*, trial proved Lilly subjectively held objectively reasonable interpretations of the law at the time.

Sixth, the fact that Lilly knew that the government knew about Lilly’s conduct negates any inference that Lilly acted knowingly. *U.S. ex rel. Durcholz v. FKW Inc.*, 189 F.3d 542, 545 (7th Cir. 1999). The Court should therefore enter judgment as a matter of law for Lilly.

Seventh, Relator argued incorrect and highly prejudicial statements of law that “misled the

jury” as to the FCA’s scienter and materiality standards, and the jury was instructed incorrectly on the law, exasperating the prejudice. *Ruiz-Cortez v. City of Chicago*, 931 F.3d 592, 602-04 (7th Cir. 2019). Under binding Seventh Circuit law, a new trial is required. *E.g., id.*

Eighth, in light of the record at trial, Lilly renews its request for judgment as a matter of law on falsity. No binding law required Lilly to include PIV in AMP during the time that Lilly excluded it, let alone imposed a “clear obligation” to include PIV in its AMP calculation, as required to prove falsity. *U.S. ex rel. Quinn v. Omnicare Inc.*, 382 F.3d 432, 445 (3d Cir. 2004). In the alternative, there is clearly at least a genuine dispute of fact as to the falsity of Lilly’s AMP submissions, and the Court should vacate the judgment and order a new trial not tainted with the falsity ruling.

Ninth, the Court should grant Lilly judgment as a matter of law on falsity for any claims submitted after April 1, 2016. After that date, all final, operative, restated AMPs used by the government to determine Lilly’s Medicaid rebate liability included PIV, as Relator alleges was required. 42 C.F.R. § 447.510(b)(1) & (2).

Tenth, the Court should grant judgment as a matter of law to Lilly because no reasonable juror could conclude that Relator satisfied the FCA’s “demanding” and “rigorous materiality requirement.” *Universal Health Servs., Inc. v. U.S. ex rel. Escobar*, 579 U.S. 176, 181 (2016). In the alternative, the Court should order a new trial because the jury received a misleading and prejudicial instruction on the meaning of “material,” and Relator used that instruction to argue a standard that he admits is “exactly opposite of” what is in fact binding precedent. Tr. 1487:7-11.

Eleventh, Lilly is entitled to judgment as a matter of law on all of Relator’s claims prior to March 30, 2010 under the FCA’s public-disclosure bar, and Relator is not an “original source” in this lawsuit. *Bellevue v. Universal Health Servs. of Hartgrove, Inc.*, 867 F.3d 712, 717–18 (7th

Cir. 2017); *U.S. ex rel. Bogina v. Medline Indus., Inc.*, 2015 WL 1396190, at *2 (N.D. Ill. Mar. 24, 2015).

Twelfth, no reasonable jury could conclude that Lilly's exclusion of PIV from its quarterly AMP submissions were the "proximate cause" of any harm to the government. *United States v. Luce*, 873 F.3d 999, 1014 (7th Cir. 2017). Lilly is thus entitled to judgment on causation for all of Relator's claims.

CONCLUSION

For these reasons, and as set forth in the accompanying memorandum, the Court should grant Lilly's Motion Pursuant to Federal Rules of Civil Procedure 50(b) and 59.

Dated: August 31, 2022

Respectfully submitted,

/s/ Diana M. Watral

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CERTIFICATE OF SERVICE

I, Diana M. Watral, hereby certify that on August 31, 2022, a true and accurate copy of Eli Lilly and Company's Motion Pursuant to Federal Rules of Civil Procedure 50(b) and 59 was served upon counsel of record at the addresses indicated by CM/ECF electronic notification.

Dated: August 31, 2022

/s/ Diana M. Watral

Attorney for Defendant Eli Lilly and Company.