

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

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

Plaintiff,

v.

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

Defendants.

Case No. 14 C 9412

Judge Harry D. Leinenweber

MEMORANDUM OPINION AND ORDER

I. BACKGROUND

After a jury verdict, the Court entered judgment in favor of the Relator on this federal False Claims Act (the "FCA") and various state false claim act complaints. Defendant Eli Lilly and Company ("Lilly") has now filed a post-trial Motion under Federal Rules of Civil Procedure 26(B), 54, and 59 for Judgment as a Matter of Law or for a New Trial. Lilly raises 12 points: (1) collateral estoppel; (2) statute of limitations; (3) jury awarded damages for claims conceded to be invalid; (4) failure to prove scienter; (5) failure to show objective knowledge; (6) government acquiescence to Lilly's conduct; (7) incorrect and prejudicial comments by the Relator; (8) failure to show the submissions by Lilly were false; (9) accuracy of Lilly's final

submissions; (10) failure to prove materiality; (11) the public disclosure bar; and (12) failure to prove causation.

## **II. DISCUSSION**

### **A. Collateral Estoppel**

This defense was raised for the first time immediately prior to trial when Lilly filed a Motion *in limine*, arguing that the Relator was collaterally estopped from arguing scienter. After extensive argument, the Court denied the Motion, reasoning that Lilly had waived the defense by waiting until the eve of trial. The record shows that the Relator filed this case in 2014. Lilly did not respond until 2018 when it moved to dismiss under Rule 12(b)(6) for failure to state a claim. In the Motion, Lilly's position was that this Court should follow the Third Circuit's decision in *U.S. v. Allergan, Inc.*, 746 Fed. App'x. 101 (3rd Cir. 2018) (*Streck 1*), as persuasive authority. Lilly did not argue collateral estoppel in either its Motion, its prayer for relief, or in the body of its brief. The Relator in response argued the lack of precedential authority of the Third Circuit's opinion and that a Third Circuit district court had refused to follow it because it did not consider the opinion binding authority. See *U.S. ex rel. Streck v. Bristol-Myers Squibb*, 370 F.Supp. 3d 491 (E.D. Pa. 2018). Although Lilly did raise collateral estoppel in a footnote to its brief but, as noted, it did not raise it in the Motion itself. Nor did it

argue collateral estoppel in its Reply brief. The Court denied the Motion to Dismiss, without mentioning collateral estoppel, on the basis that the Court disagreed with the Third Circuit's reasoning. Lilly did not move to reconsider. Lilly filed its Answer raising twenty-two boiler plate affirmative defenses, including "[p]laintiff's claims are barred by estoppel."

Lilly filed a Motion for Summary Judgment in 2021, on several issues, including a lack of scienter, government knowledge, a lack of materiality, and a lack of causality, but did not mention collateral estoppel. After the denial of Lilly's Summary Judgment Motion, the case was set for trial in March 2022, and a schedule for filing the pretrial order and motions *in limine* was set. In the fall of 2021, Lilly changed attorneys and asked for the trial to be rescheduled for a later date. Due to logistical problems associated with the COVID-19 pandemic and Lilly's request for postponement, the Court continued the case to July 2022 and reset the dates for filing the pretrial order and motions *in limine* for June 2022. Lilly filed its Motions *in limine*, together with the joint Pretrial Order on June 17, 2022.

The Joint Pretrial Order did include collateral estoppel in Lilly's list of defenses, but as noted above, it was raised for the first time in its Motion *in limine* No. 1. This Motion prayed for an Order prohibiting the Relator from arguing

scienter during the trial which, if granted, would constitute summary judgment due to the lack of scienter, which is contrary to the Court's previous summary judgment decision.

The Court denied the Motion *in limine*, concluding that Lilly had waived this defense through delay, citing *Carr v. O'Leary*, 167 F.3d 1124, 1126 (7th Cir. 1999). In *Carr*, Judge Posner, in finding a defendant had waived a defense, wrote: "Normally failure to plead a defense in a timely fashion is a waiver," and "a party's unreasonable delay in advancing a good ground for a change in a previous ruling is normally a compelling ground for deeming a good ground being waived." This Court also noted that Lilly had pled 22 separate affirmative defenses in its Answer, including "estoppel," but that such boilerplate language did not comply with Rule 8(a), citing *Manley v. Boat U.S. Inc.*, 216 WL 1213731 (N.D. Ill. March 9, 2016).

The Court also relied on the Supreme Court decision in *U.S. v. Mendoza*, 464 U.S. 154, 162-163 (1984), which refused to apply non-mutual offensive collateral estoppel to the government. Lilly argued that a subsequent Supreme Court decision, *U.S. ex rel. Eisenstein v. City of New York*, 556 U.S. 928 (2009) held that in *qui tam* cases in which the government does not intervene, it is not a party. Thus, the government was not entitled to the extended period to file a notice of appeal to

which the government is entitled. The Supreme Court noted that this "harsh" result was dictated by the legislative and not the judicial process and that a court lacked jurisdiction to grant relief. This Court distinguished *Eisenstein* noting that collateral estoppel is dictated by the judicial process and not the legislature, so lack of jurisdiction is not an issue.

Lilly now argues in its Post-Trial Motion that the Relator cannot rely on waiver because he has not shown that he was prejudiced by Lilly's late invocation of collateral estoppel. However, Lilly did not argue prejudice prior to this Post-Trial Motion. Also, Lilly did not, and has not to this day, offered any explanation why it failed to raise collateral estoppel earlier. While a court has some discretion in allowing a defendant to amend its answer after discovery is closed and even after summary judgment, a defendant seeking to present a new defense at such a late date needs to provide a reasonable explanation for its failure to seek to do so in a timely fashion.

Lilly waited until the eve of trial to file its motion, without seeking leave of court and without providing any justification for delay and used a motion *in limine* in lieu of a motion for summary judgment to raise collateral estoppel. Although Lilly's motion *in limine* seeks to "estop" Relator from litigating the issue of scienter, the motion clearly seeks to

relitigate Lilly's earlier Motion for Summary Judgment which did not raise collateral estoppel.

As this Court said in *Rainey v. Metropolitan Water Reclamation District*, 2012 WL 2192241 (N.D. Ill, 2012), motions *in limine* are intended to alert the court and the parties of evidentiary issues that may arise during the trial and to exclude anticipated prejudicial evidence before it is offered. They are considered preliminary in nature and subject to reconsideration at a later date on a more complete record. Motions for summary judgment are supposed to be presented early enough in the proceedings to allow the opposing party ample time to defend its position and the Court to consider the motion in an orderly manner. FED. R. Civ. P. 56(b) restricts filing motions for summary judgment without leave of court after 30 days past close of discovery. In addition, Local Rule 56.1 provides many requirements on the filing of motions for summary judgment. Motions *in limine* are not intended to be used as a substitute for an untimely summary judgment motion. To do otherwise encourages trial by ambush. See *Salinas v. Rock Island Boatworks, Inc.*, 2016 WL 3390664 at \*2 (C.D. Ill. June 17, 2016). The Court rejects Lilly's Motion for Judgment of Dismissal based on collateral estoppel defense.

### **B. Statute of Limitations Defense**

Similarly, the Court considered Lilly's statute of limitations defense as waived due to its untimely presentation. Although Lilly did assert the statute of limitations in one of its twenty-two boiler plate affirmative defenses in its Answer, it did not present this defense in either its Motion to Dismiss, in its Motion for Summary Judgment, or in the Pretrial Order. It also did not present the statute of limitations issue to the jury or request an instruction concerning its application. See *U.S. ex rel Landis v. Tailwind Sports Corp.*, 51 F.Supp. 3d 9, 40 (D.D.C. 2014). Other than its boiler plate assertion as an affirmative defense in its answer filed in 2018, the first time Lilly attempted to argue it substantively, was in its Rule 50(a) Motion filed at the conclusion of the Relator's case on August 31, 2022.

The question raised by Lilly's Motion is when the government received notice or constructive notice of the alleged false payments. The date of notice is when the statute of limitations commences. Lilly argues that the service of the *Streck 1* complaint on the government is notice on the government as a matter of law and is the date when the statute of limitation commences to run. However, a statute of limitations is an affirmative defense and can only be decided prior to trial, if there are no factual issues concerning notice. The

possession by the government of the *Streck 1* Complaint is certainly some evidence of notice, but the Third Circuit's dismissal would raise questions as to the validity of the Relator's claim. The statute of limitations was argued for the first time at the conclusion of the Relator's case, and Court declined to grant Lilly's motion. It should have been presented to the jury for its consideration. It was not submitted to the jury, and it is too late to relitigate the issue on post-trial motions. See *Elusta v. Rubio*, 418 F. App'x 552, 554 (7th Cir. 2011). The Court denies the Motion on the same basis it denied Lilly's Rule 50(a) motion.

### **C. Scienter**

Next, Lilly argues that it should receive a judgment as a matter of law or receive a new trial on the issue of scienter. However, as Lilly itself stated in its response to the Relator's motion for summary judgment on scienter, the evidence on scienter has been "heavily disputed." The Court agreed with Lilly then and still believes the same to be the case after the trial. The Court also believes the same to be true for the issues of "objectively reasonable interpretation" and "government knowledge." These issues were heavily disputed at summary judgment and at the jury trial. No new facts were elicited at the trial which had not been raised and considered in the cross-motions for summary judgment. The jury was



correctly instructed on these issues which resulted in a verdict in favor of the Relator. There is no basis to upset the jury's verdict and resulting judgment on these issues.

#### **D. Materiality and Proximate Cause**

Lilly contends that no rational jury could have concluded that its false representations were material. The jury was instructed in the words of the statute that conduct is material if it had "a natural tendency to influence, or be capable of influencing, the payment or receipt of money." Lilly's position is that this is insufficient because the Relator must also prove that the government's receipt and acceptance of money was actually influenced by Lilly's failure to comply. However, the case relied upon by Lilly, *Universal Health Services, Inc. v. U.S. ex rel. Escobar*, 579 U.S. 176 (2016) does not require this. The Supreme Court in *Escobar* reviewed the common law definitions of materiality and determined that these definitions all included conduct that a "reasonable man" would attach importance to in determining a course of action or conduct that a defendant had reason to know that recipient attached importance even if a reasonable recipient would not have done so. What the Supreme Court did decide in *Escobar* is that the FCA is interested in serious misconduct, not in cases "where non-compliance is minor or insubstantial." The Supreme Court remanded *Escobar* to determine whether the Relator had actually pled a FCA violation.

In this case, the Court has determined that the Relator had adequately pled a FCA violation, and the Court now holds that the evidence submitted, showing Lilly's false statements caused a payment shortfall to the government of over \$61,000,000.00, was not of a "minor or inconsequential" nature. The Court finds that the Relator met the materiality requirement of the FCA.

The Court also finds that the evidence demonstrated a causal relationship between Lilly's conduct and the loss to the government. It appears that Lilly's contention that the Relator failed to prove causation is based on its position that the government was aware of Lilly's treatment of Price Incentive Value ("PIV") in its Average Manufacturer's Price ("AMP") submissions. While there was evidence to the contrary, the jury was entitled to make a finding of causation, under the Court's instruction.

**E. Relator's Statements in Opening and Closing**

Lilly contends that the Relator in his opening and closing statements made many assertions that were clear violations of the Court's rulings *in limine*. The Relator responds that whatever objections Lilly may have as to any alleged erroneous statements Relator may have made (and he disputes making any), are waived because Lilly failed to object and, in any event, the Court's instructions cured any harm to Lilly. Lilly denies that it waived any such objections and pointed to remarks of the

Court which it interpreted to mean that the Court's rulings *in limine* eliminated any need to object during the trial. The Court did tell the parties that *in limine* rulings constituted a continuing objection, but Lilly misses the point. The Court said that the parties did not need to object to any evidence, argument or statement that was either allowed or disallowed by the *in limine* rulings. However, the Court did not say that the parties did not have to make objections to violations of the *in limine* rulings. Where the Court ruled that certain evidence could not be introduced or that certain evidence could be introduced, the parties need not object to the evidence allowed in, nor make offers of proof of evidence that had been excluded. The Court's statement did not include violations of the *in limine* rulings because a court may need a reminder of the specific *in limine* ruling that is alleged to be violated, so that the Court could rule on the alleged violation and properly instruct the jury. The matters complained of by Lilly are alleged violations of the rulings *in limine* so that failure to object is a waiver. The main objection raised by Lilly is that the Relator argued to the jury that Lilly was a "big company" that could afford to devote the appropriate resources to conduct an adequate inquiry of its legal obligations, rather than rely on views of one person. This is arguably a violation of the

ruling *in limine* that excluded evidence and arguments related to Lilly's size. There was no objection, so the matter is waived.

#### **F. Alleged Invalid State Law Claims**

Lilly points out that the jury awarded damages to five states covering periods that predated the effective dates of the false claims' statutes of the five states. They include Colorado, Georgia, New Jersey, Oklahoma, and Rhode Island. The damages totaled \$147,364.00 (Colorado - \$37,622.00; Georgia - \$25,690.00; New Jersey - \$55,738.00; Oklahoma - \$15,991.00; and Rhode Island - \$8,320.00). The Relator argues that Lilly waived its objections by not countering the Relator's expert testimony. The better way to handle the matter is for the Court to order a Remittitur of the \$147,364.00. The Court therefore orders a Remittitur of \$147,364.00. If the Relator refuses to agree to the Remittitur, the Court will order a new trial as to the issue of damages as to these five (5) states.

#### **G. Other Objections**

The other matters raised by Lilly were considered by the Court previously in the Motions to Dismiss and Summary Judgment, and the Court sees no reason to reconsider its earlier rulings. Nor are these matters of sufficient consequence to cause the Court to grant a judgment in Lilly's favor or order a new trial. During the trial the Relator attempted multiple times to get Lilly's witnesses to admit that the "claw back" of the monetary

windfall that Lilly's customers resulting from the increase in value of the customer's inventory of Lilly products after Lilly increased its prices of these products (the "PIV"), needed to be accounted for in determining the "Average Manufacturer's Price" of its products. Lilly's witnesses repeatedly denied that the claw back had to be accounted for in determining the AMP. The jury heard the testimony and determined that Lilly's witnesses were wrong, and its AMPs must include the claw backs and that failure to so caused Lilly to make multiple false clais.

### **III. CONCLUSION**

For the reasons stated herein, the Post-Trial Motions of Defendant Eli Lilly and Company are denied with exception to the award of damages to Colorado, Georgia, New Jersey, Oklahoma, and Rhode Island. If the Relator refuses to agree to the Remittitur, the Court will order a new trial as to the issue of damages as to these five (5) states.

**IT IS SO ORDERED.**



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Harry D. Leinenweber, Judge  
United States District Court

Dated: 4/26/2023