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

UNITED STATES, *ex rel.* RONALD J. STRECK,	
Plaintiff,	**Case No. 14 C 9412**
v.	**Judge Harry D. Leinenweber**
TAKEDA PHARMACEUTICALS AMERICA, INC., *et al.*,	
Defendants.	

MEMORANDUM OPINION AND ORDER

Relator Ronald J. Streck, on behalf of the United States of America and twenty-six states, brings a Partial Summary Judgment Motion against Defendant Eli Lilly and Company. (Dkt. No. 311.) The Relator argues the undisputed material facts show that Defendant Lilly knowingly submitted false statements and certifications to the United States and several states as part of its Medicaid rebate program in violation of the False Claims Act. Defendant Lilly moves for full summary judgment against the Relator, arguing caselaw establishes affirmative defenses that prevent liability. (Dkt. No. 314.) The parties also move, under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), to strike various experts that would otherwise be relied upon in trial. (Dkt.

Nos. 293, 295, 297, 299, 301.) For the reasons stated herein, the Court denies Defendant Eli Lilly's Motion for Summary Judgment, denies in part and grants in part Relator's Motion for Summary Judgement, and grants in part and denies in part the Motions to exclude expert opinions and testimony.

I. BACKGROUND

As discussed in the Court's Memorandum Opinion and Order denying the motion to dismiss (Dkt. No. 122), this lawsuit arises from Lilly's participation in the Medicaid Drug Rebate Program ("MDRP"). The United States historically has been the single largest payer of prescription drugs, primarily through the MDRP. For a drug manufacturer to have the benefit of selling drugs to patients enrolled in Medicaid, that manufacturer must pay a rebate back to the state and federal government to lower the cost of the program. The rebate computations are based on the "Average Manufacturer's Price," or "AMP." Congress defined the AMP in the 1991 National Rebate Agreement as "the average unit price paid to the Manufacturer for the drug in the [United] States by wholesalers for drugs distributed to the retail pharmacy class of trade." (Relator's Resp. to Def.'s Stmt. of Facts ("RSOF") ¶ 25, Dkt. No. 330.) As set forth in the definition, the AMP "must be adjusted by the Manufacturer if

cumulative discounts or other arrangements subsequently adjust the prices actually realized." (*Id.*)

The 1991 National Rebate Agreement also stated that "[i]n the absence of specific guidance in section 1927 of the Act, Federal regulations, and the terms of this agreement, the Manufacturer may make reasonable assumptions in its calculations of AMP and Best Price, consistent with the intent of section 1927 of the Act, Federal regulations and the terms of this agreement." (*Id.* ¶ 30.) An early dispute in the history of the program focused on whether fees paid by a drug manufacturer to drug distributors should be incorporated as part of the AMP calculations. Following a request from Congress, in 2007 the Center for Medicare and Medicaid Services of the Department of HHS ("CMS") provided the following definition of "bona fide service fees" and stated that these fees were exempt from the AMP calculations:

> fees paid by manufacturer to an entity; that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement; and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.

42 U.S.C. § 447.502 (2007).

Upon the passage of the Patient Protection and Affordable Care Act of 2010, CMS removed its definition and directed

manufacturers to comply with the newly promogulated statute, which had a similar provision excluding bona fide service fees. In 2012, CMS proposed regulation that contained the preamble, "retroactive price adjustments, sometimes known as price appreciation credits, do not meet the definition of bona fide service fee as they do not reflect any service or offset of a bona fide service performed on behalf of the manufacturer." 77 Fed. Reg. 5318, 5332 (Feb. 2, 2012). This advice was not formally adopted, however, until 2016. As set forth under the 2016 regulations, CMS stated in its preamble:

> We continue to believe that price appreciation credits would likely not meet the definition of bona fide service fee. Based on our experience with the program, it is our understanding that price appreciation credits are not issued for the purposes of payment for any service or offset for a bona fide service performed on behalf of the manufacturer, but rather are issued by the manufacturer to adjust (increase) the wholesaler's purchase price of the drugs in such instances when the drugs were purchased at a certain price and are remaining in the wholesaler's inventory at the time the manufacturer's sale price of the drug increased. In such situations, these credits would amount to a subsequent price adjustment affecting the average price to the manufacturer and should be recognized for purposes of AMP in accordance with § 447.504(f).

81 Fed. Reg. 5170-01. Starting in 2017, Lilly began including price increase value as part of its AMP submissions. (Def.'s Resp. to Relator's Stmt. of Mat. Facts ("DSOF") ¶ 77, Dkt. No. 334.)

While perhaps counterintuitive, "service fee payments" paid by the drug manufacturer to the drug distributer, if included in the AMP calculations, would reduce the cost of the Average Manufacturer's Price. The service fee essentially offsets the price of the drug product on paper, which would reduce the "average price unit paid . . . by wholesalers for drugs" and thus would decrease the amount due to the government. Prior to CMS clarification, some drug manufacturers were using service fees to artificially lower the AMP calculations, and as stated above, CMS issued a regulation in 2007 to prevent unrelated service fees from being bundled with the price of the unit to manipulate AMP calculations to a lower price. When "service" or "service-related" payments are made in the opposite direction, *i.e.*, by drug distributer to the drug manufacturer, this increases the "average price unit paid . . . by wholesalers" and thus increases the amount of the rebate due to the government. Defendant Eli Lilly has excluded all "service-related" payments since 2005. (RSOF ¶ 57.)

Lilly is a pharmaceutical company based in Indianapolis, Indiana. (RSOF ¶ 1.) In 2005, Lilly changed its contract with its three major drug distributors. (RSOF ¶ 7.) Lilly refers to the post-2005 contracts as "fee-for-service" or FFS Agreements.

(*Id.*) The FFS Agreements had two provisions that are relevant to the suit.

First, the FFS Agreement included a "service fee" or "distribution fee" that Lilly paid the drug distributers. (*Id.* ¶¶ 9, 13.) This fee paid for distribution services, inventory management services, and data reporting services. (*Id.* ¶ 9.) The service fee was calculated "by multiplying Lilly's quarterly sales of Products . . . invoiced to the wholesaler, less Products returned by Wholesaler during the same quarter, by the appropriate Distribution Fee percentage." (*Id.* ¶ 13.) In other words, the more product that the distributors sold, the higher the fee provided by Lilly.

The FFS Agreement also included a "price increase value," ("PIV") also referred to in the Court's prior opinion and throughout this opinion as a "price appreciation credit" or a "PACs." (*Id.* ¶ 11.) The PIV was an adjustment to the "price of Products after Wholesaler has taken possession, but before such Products are purchased by Customers." (*Id.* ¶ 17.) The price adjustment value would be multiplied by the number of products in inventory to create the final PIV. (*Id.*)

The FFS Agreement combined (1) the distribution fee cost to Lilly and (2) the price increase benefit to Lilly as follows:

> Wholesaler shall receive the Distribution Fee through a combination of (1) the value of any price increase

> by Lilly during the quarter for Products in Wholesaler's inventory ("Price Increase Value") and (2) a payment or credit by Lilly. The Price Increase Value for a Product shall be calculated by multiplying the price increase for the product by the amount of inventory for such Product Wholesaler has on the date of the price increase. … If the Price Increase Value for all Products for a quarter is greater than the total Distribution Fee, any excess shall be carried forward and netted out of future quarterly payments.

(*Id.*) In this way, Lilly would not have to pay any distribution fee unless the drug distributor's sales of Lilly's products were relatively and consistently higher than any drugs remaining in the inventory that were in the process of being "price adjusted" by Lilly. As testified to by Lilly, this was setup was used to prevent wholesalers who, if anticipating price increases, "increased their stock of a particular drug at the lower, then-current price." (*Id.* ¶ 5.) Lilly's updated 2009 agreements had a substantially similar structure, except Lilly was now entitled to payment of the excess PIV by the drug distributors instead of having the excess carried over onto future distribution fee payments. (*Id.* ¶¶ 13—14.)

The 2016 FFS Agreements noted that the distribution fee and the PIV were "administered together for efficiency." (*Id.* ¶¶ 15—22.) After netting the payments together, any excess in either direction was to be paid within 45 days. (*Id.*) Under all variations of the FFS Agreements, the "economic substance of the transaction" remained unchanged. (*Id.* ¶ 23.)

On September 7, 2018, Relator filed an Amended Complaint alleging three counts under the federal False Claims Act, 18 U.S.C. §§ 3279(a)(1)(A) and (a)(1)(B) (Count 1), § 3729(a)(1)(D) (Count 2), § 3729(a)(1)(G) (Count 3), and twenty-nine claims under various state False Claims Acts. On September 7, 2021, Relator filed a Motion to exclude the opinions and testimony of Charlene Frizzera (Dkt. No. 293), the opinions and testimony of Marcy Imada (Dkt. No. 295), certain opinions and testimony of Heather Bates, (Dkt. No. 297) and the opinions and testimony of Dr. Louis Rossiter. (Dkt. No. 301.) That same day, Eli Lilly filed a Motion to exclude the testimony of Brian C. Becker. (Dkt. No. 299).

On October 7, 2021, Relator filed a Motion for Partial Summary Judgment (Dkt. No. 311) and Defendant Eli Lilly filed a Motion for Full Summary Judgment. (Dkt. No. 314.) The Court now decides all seven pending Motions.

II. STANDARD

Summary judgment is appropriate when there are no genuine issues of material fact, and the moving party is entitled to judgment as a matter of law. FED. R. CIV. P. 56(a). A genuine issue of material fact exists only if "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Pugh v. City of Attica*, 259 F.3d 619, 625 (7th Cir. 2001)

(quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)). A court uses substantive law to "identify which facts are material." *Anderson*, 477 U.S. 248. Viewing the record in a light most favorable to the nonmoving party, a court then determines whether there is a genuine issue for trial. *Id.* at 242.

Expert testimony is permitted under Federal Rule of Evidence 702. Under the Rules, "the trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant but reliable." *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 589 (1993). As a result, a court reviews the following requirements prior to admittance at trial: (1) the witness must be "qualified as an expert by knowledge, skill, experience, training or education," and (2) "the subject matter of the expert's testimony must consist of specialized knowledge that will be helpful or essential to the trier of fact in deciding the case." FED. R. EVID. 702; *United States v. Lanzotti*, 205 F.3d 951, 956 (7th Cir. 2000). "The party seeking to offer expert testimony has the burden of establishing that the pertinent admissibility requirements are met by a preponderance of the evidence." *Rasmusen v. White*, 970 F.Supp. 2d 807, 813 (N.D. Ill. 2013).

III. DISCUSSION

A. Motions to Exclude

1. Motion to Exclude the Opinions and Testimony of Charlene Frizzera

Relator first moves to exclude the opinions and testimony of Charlene Frizzera ("Frizzera"). Frizzera's main qualification is her long tenure at Centers for Medicare and Medicaid Services ("CMS"), where she served, *inter alia*, as Executive Project Officer of Health Care Reform, CMS Acting Administrator, and CMS Chief Operating Administrator, Deputy Director, and Regional Administrator of Philadelphia's Regional Office. (Frizzera CV, Frizzera Expert Report, Ex. B, Dkt. No. 294-1.) Frizzera proffers three opinions, all of which Defendants seek to exclude:

> 1. CMS did not issue any final rule or published guidance clearly instructing manufacturers how to treat price appreciation credits;
>
> 2. CMS charges manufacturers with making reasonable assumptions on AMP calculations in the absence of clear guidance, allowing for more than one reasonable interpretation of AMP rules, including regarding price appreciation credits; and
>
> 3. Information was available to CMS that would have allowed CMS to take action if it wanted Lilly to change its conduct.

(Frizzera Expert Report at 1, Mem., Ex. 1, Dkt. No. 294-1.) Relator begins by arguing that all three opinions provide improper legal conclusions. Allowing an expert witness to testify as to a legal conclusion creates a risk that a jury may

"accord too much weight to that testimony" and use it as legal guidance. *Naeem v. McKesson Drug Co.*, 444 F.3d 593, 610 (7th Cir. 2006). This is particularly true when the legal opinion "determine[s] the outcome of a case." *Id.* (quoting *United States v. Sinclair*, 74 F.3d 753, 757–58 n. 1 (7th Cir.1996). When, as here, the case hinges on a violation of statute, "an expert may not offer opinion testimony as to whether a defendant violated a statute or regulation." *Klaczak v. Consol. Med. Transp. Inc.*, No. 96 C 6502, 2005 WL 1564981, at *4 (N.D. Ill. May 26, 2005).

In support of his argument, Relator cites to Frizzera's testimony, where she asserts the following:

> Q: In your report, you provide opinions about the Medicaid Drug Rebate Program; is that fair?
>
> A: I provide opinions about whether Lilly met the requirements of the rules.

(Frizzera Dep. 65:20—24, Mem. to Exclude Frizzera, Ex. 2, Dkt. No. 494-2.) To the extent that Frizzera intends to testify to that "Lilly met the requirements of the rules," the Court excludes her testimony. Frizzera cannot testify as to how the jury should apply the statute and CMS rules to the case at hand.

On these grounds, the Court also grants the Motion to Exclude Opinion 3 in its entirety. In the third section of the report, Frizzera recounts the facts involved with Lilly's communications with the Federal Government and determines that

Lilly "appropriately sought guidance." This applies the recited facts to the case and reaches a legal conclusion as to Lilly's obligations. Building on this conclusion, Frizzera opined that CMS is required to "take action" to create liability once Lilly seeks the appropriate guidance. The Court finds this to be a legal conclusion and, further, a legally unsound opinion. Under the False Claims Act, the burden is on the individual submitting claims to provide accurate information, not on the government entity to act in response to other communications. *Heckler v. Cmty. Health Servs. of Crawford Cty., Inc.*, 467 U.S. 51, 63 (1984) ("[T]hose who deal with the Government are expected to know the law and may not rely on the conduct of Government agents contrary to law.")

The first two opinions of Frizzera's report, when read at face value, do not necessarily reach a legal conclusion. An expert who opines regarding the regulatory process for creating (1) CMS guidance to drug manufacturers generally, and (2) CMS's requirement that drug manufacturers to make "reasonable assumptions" as part of their submissions specifically, would be useful at trial. As an employee of CMS for thirty years, Frizzera has the background necessary to provide this information.

Relator next argues that Frizzera did not employ a reliable methodology. When evaluating methodology, "the trial court is

limited to determining whether expert testimony is pertinent to an issue in the case and whether the methodology underlying that testimony is sound." *Smith v. Ford Motor Co.*, 215 F.3d 713, 719 (7th Cir. 2000). The trial court does not evaluate the underlying facts, but instead evaluates the test administered and the source of information employed. *Walker v. Soo Line R. Co.*, 208 F.3d 581, 587 (7th Cir. 2000).

Relator argues that Frizzera's methodology was to review whether a statute and agency regulation contained the words "average manufacturer price," "price appreciation credits" or "bona fide service fees." Frizzera then opined (1) that there were no clearly published guidelines on price appreciation credits (Opinion 1), and (2) that there could be multiple valid ways to interpret the guidelines as applied to price appreciation credits (Opinion 2).

Relator has two arguments regarding Frizzera's methodology. First, Frizzera's review of the regulations, i.e., searching for "mentions" of the words in the text of the statute, is surface-level and ultimately insufficient to understand the obligations of drug manufacturers. Second, Frizzera does not understand what a "price appreciation credit" means, making her unable to analyze the regulations. In support, Relator highlights the following questions presented at the deposition:

Q. To make that opinion, do you have to have some sort of understanding of what price appreciation credits are?

A. I have to have an understanding of what the CMS rules and guidance were around price appreciation credits.

Q. And to apply those rules and regulations to price appreciation credits, do you need to know what price appreciation credits are?

A. No. CMS didn't issue any rules or guidelines about price appreciation credits.

Q. Did you do anything to educate yourself about how Lilly uses price appreciation credits?

A. I reviewed the documents that I reviewed -- I reviewed the documents I had.

Q. Can you provide the jury with an explanation of how Lilly's price appreciation credits operate?

A. My opinion is that CMS didn't issue any rules or guidance instructing them how to deal with price appreciation credits.

Q. I understand what you're saying with respect to CMS. Do you know sitting here today how Lilly's price appreciation credits function?

A. Can you repeat the question?

Q. Sure. Let me ask it in a more simple way. What is a price appreciation credit?

A. CMS did not issue any rule or guidance regarding price appreciation credits.

Q. Got it. I think I understand your opinion on that. But my question is, what is an actual price appreciation credit?

A. There is no definition of price appreciation credits in the federal rules or guidelines.

> Q. How does Lilly use the term price appreciation credits?
>
> A. Lilly made reasonable assumptions about what price appreciation credits were and how to use them.

(Frizzera Dep 103:21-106:5 (objections omitted).) In response, Lilly argues that Frizzera's methodology consisted of "appl[ying] her experience to a series of agency documents and statements." (Resp. at 13, Dkt. No. 304.) Lilly also argues that Relator is cherry-picking misleading deposition testimony, and that Frizzera demonstrated her knowledge of price appreciation credits from the following exchange:

> Q. And why are bona fide service fees relevant to your report?
>
> A. Lilly -- the reason why bona fide service fees are part of my report is because Lilly offset their bona fide service fees by their price appreciation credits.

(Frizzera Dep. 118:1—6.)

The Court finds that the methodology employed for Opinion 1, while simplistic, is straightforward and logical. Relator's arguments about better methods go to the weight of the testimony, and do not merit its exclusion.

Relator's concerns about Frizzera's knowledge of price appreciation credits are less about methodology and more appropriately raised during the second prong of the test. In addition to employing appropriate methodology, the Court must

also determine whether the expert has specialized knowledge that would be helpful for the trier of fact. Because Frizzera cannot articulate any definition of "price appreciation credit," the Court finds that, for Opinion 2, Frizzera lacks the specialized knowledge which is necessary for her to be an expert on price appreciation credits. In Opinion 2, Frizzera states that there is "more than one reasonable interpretation of . . . price appreciation credits." (Frizzera Rep. at 34.) The Court does not see how any expert can reliably analyze rules for price appreciation credits without first understanding how price appreciation credits work within the drug manufacturer's pricing system.

Lilly's explanation in response is that Frizzera does not need first-hand information to be an expert on price appreciation credits. Lilly's theory is that Frizzera is an expert through her longtime experience with CMS, similar to, for example, "experienced narcotics investigators [who] applied the knowledge gained through years of experience and, essentially, described for the jury what they knew about narcotics dealers." *United States v. Conn*, 297 F.3d 548, 556 (7th Cir. 2002). But if a narcotics investigator, after describing his or her knowledge of narcotics dealers, then was unable to provide information regarding a specific drug by name, the court would be remiss to

think the investigator had enough specialized knowledge to opine on the specifics of that drug. Here, Frizzera has worked for thirty years at CMS, and can provide information about CMS's regulatory processes. Her knowledge, however, does not reach to an understanding of "price appreciation credits," making her unable her to apply her experience to that term beyond her impressions set forth in Opinion 1. The Court grants the Motion to Exclude Opinion 2 and Opinion 3 in Frizzera's report and testimony and denies the Motion to Exclude Opinion 1. (Dkt. No. 293.)

2. Motion to Exclude the Opinions and Testimony of Marcy Imada

Relator next moves to exclude the opinions and testimony of Marcy Imada ("Imada"). Imada holds two bachelor's degrees and is a long-time consultant in the life sciences and health care industries. (Imada CV, Imada Expert Report, Ex. A, Dkt. No. 296-1.) Imada sets forth three opinions:

> A. Lilly's exclusion of price appreciation credits from is Average Manufacturer's Price calculation was a reasonable practice.
>
> B. Manufacturers often apply regulations and sub-regulatory guidance in differing, but reasonable, manners.
>
> C. Lilly's repeated disclosures and engagements with government agencies align with industry leading practices.

(Imada Expert Report at 16, 27, 29, Mem., Ex. 1, Dkt. No. 296-1.) At the outset, the Court notes that Opinion A is a legal conclusion, and specifically a legal conclusion that is at the heart of this case. If Lilly's price appreciation credits were reasonably excluded, then Lilly did not make a false claim. As a result, this expert testimony is inadmissible. *Good Shepherd Manor Found., Inc. v. City of Momence*, 323 F.3d 557, 564 (7th Cir. 2003) ("Expert testimony as to legal conclusions that will determine the outcome of the case is inadmissible."). The motion to exclude Opinion A is granted.

Relator provides a similar argument in his Motion to Exclude Imada's Opinion B. Relator argues that Opinion B is only relevant "if Lilly's purported interpretation was in fact reasonable, and for the reasons described above, Ms. Imada cannot provide this opinion." (Imada Mem. to Exclude at 11, Dkt. No. 296.) However, while Imada cannot testify as to whether Lilly's decision was reasonable, she can provide information from which the jury themselves can make that determination. As a result, Imada's expert testimony about regulations generally is relevant and admissible.

In the alternative, Relator argues the testimony is inadmissible under Rule 403 because any probative value is substantially outweighed by unfair prejudice, confusing the

issues, and wastes the jury's time. The Court finds none of these concerns in the proffered testimony. Imada provides examples of different calculations between drug manufactures under CMS regulations. In one example, some manufacturers calculate AMP using "standard" Average Manufacturer's Price, and some use the "5i" Average Manufacturer's Price. The jury can extrapolate whether differences in calculations between AMPs are similar to Lilly's decision to exclude price appreciation credits, or whether there is a difference in scale or intent such that it was not a reasonable decision. These are arguments that should be presented for the jury.

Finally, Relator moves to exclude Opinion C. Relator argues that Imada's methodology regarding "industry leading practices" is either impermissibly vague or nonexistent. Relator argues that Imada does not provide enough basis for her opinion on industry standards. For example, Imada does not cite to publications or other sources on which she bases this conclusion and does not provide examples of other companies who communicated with government agencies in a similar manner.

In response, Lilly cites to *Harms v. Laboratory Corporation of America*, 155 F.Supp. 2d 891 (N.D. Ill. 2001). In *Harms*, the district court found that Randy Chapman, Operation Manager for Defendant, and fact witness for the trial, could not testify

regarding general standards of care, reasoning that industry standards are "classic" expert testimony. *Id.* at 903. However, *Harms* does not allow each and every expert witness to opine on industry standards simply by being designated as experts. An expert witness, even one qualified through experience such as Imada, must explain the "'methodologies and principles' that support [her] opinion; [s]he cannot simply assert a 'bottom line.'" *Metavante Corp. v. Emigrant Sav. Bank*, 619 F.3d 748, 761 (7th Cir. 2010) (quoting *Minix v. Canarecci*, 597 F.3d 824, 835 (7th Cir.2010)).

After reciting the relevant facts, Imada's opinion regarding industry standards is three short paragraphs. She provides one principle, explaining that "[o]utreach to government agencies not only allows the manufacturers to confirm their interpretations or assumptions, but it can also direct the agency's attention to topics for which the rules are not clear or further guidance is needed." (Imada Expert Report at 35, Imada Mem. to Exclude, Ex. 1, Dkt. No. 296-1.) To the extent that there is a methodology, it is through Imada's assertion that she has "routinely advised [her] clients to reach out to regulators." (*Id.* at 34.) While this principle and this methodology, put together, edges slightly beyond a bottom-line assertion rejected by the Seventh Circuit, the Court finds even in the best light

these statements fall short of establishing an "industry standard." Ultimately, Imada's opinion cannot be based solely on her own personal prior practices and reasoning. By the nature of the words "industry standards," information beyond the ideas and practices of one expert is required to be established as a methodology.

The Court grants the Motion to Exclude Imada's Opinion A and Opinion C and denies the Motion to Exclude Imada's Opinion B. (Dkt. No. 295.)

3. Motion to Exclude Certain Opinions and Testimony of Heather Bates

Lilly has also proffered the expert Heather Bates ("Bates"), a managing director of a consulting group who holds a bachelor's degree in Economics. (Bates CV, Bates Expert Report, Ex. A, Dkt. No. 298-1.) Bates offers a rebuttal opinion to Relator's damages expert, Eric Kimelblatt. Relator moves to exclude Bates' Opinion 5, which states:

> Mr. Kimelblatt enumerated alleged damages to the Federal government under the Medicaid program but did not consider the impact of Relator's proposed change to Lilly's treatment of PIV credits on Federal government reimbursements under the Medicare and Veteran's Affairs ("VA") programs.

(Bates Expert Report at 22, Mem., Ex. 1, Dkt. No. 298-1.)

Relator first objects to the admissibility of Bates' counter-damages calculations, arguing that any benefits to

Government programs beyond Medicaid, such as Veteran's Affairs, are not relevant to this action. Under Seventh Circuit precedent, damages under the False Claims Act should be calculated by "net trebling," as opposed to "gross trebling." *United States v. Anchor Mortg. Corp.*, 711 F.3d 745, 749 (7th Cir. 2013). In other words, "[m]itigation of damages is almost universal." *Id.* Assuming the jury finds liability, the Federal Government is entitled to damages offset by the benefits, and Lilly is entitled to present evidence regarding the benefits of their calculations to other government departments.

Relator provides a variety of other arguments, most of which are speculations on how Bates' calculations will affect the state's payments in relation to the Federal Government. The basis of this suit is the failure to pay the Federal Government under Federal law. The Court fails to see how speculations on how the damages will be split constitutes any separation of power issues. The other reasons in Relator's Motion to Exclude do not attack Bates' methodology, but merely critique how her calculations were made. These arguments are appropriate for Relator to bring on cross-examination or in its own rebuttal report. The Court denies the Motion to Exclude certain opinions and testimony of Bates. (Dkt. No. 297.)

4. Motion to Exclude the Opinion and Testimony of Brian C. Becker

Dr. Brian Becker ("Becker") holds a PhD in applied economics and currently works at an economics consulting firm. (Becker CV, Becker Expert Report, Ex. A, Dkt. No. 300-1.) In his expert report, Dr. Becker provides an economic framework for understanding financials associated with Lilly's contract with drug manufacturers. Dr. Becker's opinion states that the economic difference between paying $100 initially and then a single additional dollar is the exact same as requiring a payment of $101. Lilly argues that Dr. Becker's opinion should be excluded because it is not relevant and outside the scope of an expert testimony.

Lilly argues that Becker's opinion is not relevant because Dr. Becker does not attempt to answer the question as to "whether Medicaid regulations or statutes require price increase value to be included in average manufacturer price." (Mem. at 5, Dkt. No. 300.) However, the purpose of providing experts is not to advise the jury the answer to the ultimate question. It is inadvisable to submit expert testimony that advises on the final decision in the case as it will likely be excluded. The purpose of expert is to provide information which the jury can use to resolve the factual dispute. As explained in *Daubert*, "[t]he study of the phases of the moon, for example, may provide valid scientific

'knowledge' about whether a certain night was dark, and if darkness is a fact in issue, the knowledge will assist the trier of fact." 509 U.S. at 591. To extend the analogy, Lilly here argues that the expert must be excluded unless the expert testifies that the night was dark. But Lilly's requirement that the 'knowledge' be applied by the expert to the factual issue is wrong; instead, an expert should be providing background information from which the jury can deduce that the night was dark.

Becker does exactly that in his report. Assuming the jury learns of Lilly's obligation to provide an Average Manufacturer's Price to CMS from other testimony, the jury can use Dr. Becker's economic analysis of Lilly's contract with drug distributers to determine whether or not their "price increase value" should be considered part of the Average Manufacturer's Price, or if it was reasonable for Lilly to exclude them.

Lilly brings the Court's attention specifically to *Camelback Properties v. Phoenix Ins. Co.*, No. 10 CV 01467, 2013 WL 1568517 (N.D. Ill. Apr. 12, 2013). In *Camelback*, the magistrate court held that a party could not proffer an expert on real estate industry standards to help interpret an insurance contract. The magistrate court cited the lack of legal precedent incorporating real estate standards, such as the "BOMA code,"

into the separate body of insurance law, and noted that the expert failed to claim that "BOMA standards are commonly used in the insurance industry." *Id.* at *3. For this reason, the magistrate court excluded the expert on the grounds of relevance.

The Court finds this precedent inapplicable. Dr. Becker is not taking unrelated industry standards and applying them to the contract. Economics is a field that is well-suited to analyze the costs associated with the complicated financial transactions in a wide variety of legal settings. The economic result of the contract is useful information for the jury when resolving the factual disputes in this case.

In the alternative, Lilly argues that Dr. Becker did not apply any "scientific, technical, or specialized knowledge" under Federal Rule of Evidence 702. Lilly argues that the contract is straightforward, and Dr. Becker is not using any of his Ph.D. economics skills besides reading the contract. This argument is belied by the fact that Lilly actively disputes the economics of the contract and in fact hired its own economics professor who came to a markedly different opinion in its rebuttal of Dr. Becker's expert report. The Court denies the Motion to Exclude Dr. Becker's Testimony. (Dkt. No. 299.)

5. Motion to Exclude the Opinion and Testimony of Louis Rossiter

In response to Becker's report, Lilly proffers expert Dr. Louis Rossiter ("Rossiter") in rebuttal. Dr. Rossiter is a research professor at the public policy school at the College of William & Mary and holds a Ph.D. in Economics. (Rossiter CV, Rossiter Rebuttal Report, Ex. A, Dkt. No. 307-1.) Dr. Rossiter offers three opinions in rebuttal to Becker's economic analysis of Lilly's contract:

> A. The introduction of FFS contracts, including their PIV provisions, created a more efficient model for the distribution of pharmaceutical products and eliminated various inefficiencies and market distortions that existed under the prior contracts;
>
> B. Dr. Becker's opinion that the amount of PIV is simply a "part of the price of the drug" fails to consider and articulate the economic rationale and genesis of the PIV provisions as a mechanism for controlling wholesaler inventory levels, one of the specifically enumerated services that wholesalers provide to Lilly; and
>
> C. Without the PIV provision of the FFS contracts, wholesalers would have continued to engage in speculative buying and received significant additional compensation for performing the same set of services they are compensated for under the FFS contracts. This would have resulted in wholesalers being overcompensated for the services performed.

(Rossiter Rebuttal Report at 7—8, Resp., Ex. 1, Dkt. No. 307-1.) Relator argues that the opinions do not stick to the same subject matter as Dr. Becker's economic analysis and thus are outside the scope of a rebuttal opinion.

Under Federal Rule of Civil Procedure 26(a)(2)(D)(ii), rebuttal evidence is permitted "if the evidence is intended solely to contradict or rebut evidence on the same subject matter identified by another party." Relator reads the words "same subject matter" narrowly and argues that Lilly's rebuttal expert cannot rely on outside information in rebutting Becker's conclusions. The Court finds that Dr. Rossiter's analysis to be based on his own expertise as a health economics professor, and as a result his analysis will differ in sources and conclusions. *See Andersen v. City of Chicago*, 467 F.Supp. 3d 619, 631 (N.D. Ill. 2020) ("[I]t is permissible for [rebuttal expert] Dr. Reich to elaborate on how exactly his own practices and experience informed his opinion.") These differences are not a reason to exclude a rebuttal opinion.

Relator's remaining arguments are that Dr. Rossiter engages in flawed methodologies and that the introduction of Dr. Rossiter's testimony would confuse the jury. However, Relator's arguments are ultimately disagreements with Rossiter's conclusions. Relator states that Dr. Rossiter "ignores highly probative evidence" without "a single citation to any evidence." (Mem., Dkt. No. 302.) These critiques are better suited to cross-examination before the jury than any premature exclusion. The

Court denies the Motion to Exclude Dr. Rossiter's rebuttal report. (Dkt. No. 301.)

B. Motions for Summary Judgment

Relator alleges violations of three components of the federal False Claims Act and a variety of state False Claims Acts. The False Claims Act "prohibits the submission of false and fraudulent claims for payment to the government" and "authorizes private citizens (called "relators") to file civil actions on behalf of the government." *Glaser v. Wound Care Consultants, Inc.*, 570 F.3d 907, 912 (7th Cir. 2009).

Count I alleges violations of 18 U.S.C. §§ 3279(a)(1)(A) and (a)(1)(B). Under § 3279(a)(1)(A), a liable individual is one who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." Under § 3279(a)(1)(B), a liable individual is one who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." Count II alleges a violation of § 3729(a)(1)(D), which provides liability for any individual who "has possession, custody, or control of property or money used, or to be used, by the Government and knowingly delivers, or causes to be delivered, less than all of that money or property."

Count III alleges a violation of § 3729(a)(1)(G) which creates liability for any individual who "knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government." This is often referred to "reverse false claim." *United States ex rel. Garbe v. Kmart Corp.*, 73 F.Supp. 3d 1002, 1011 (S.D. Ill. 2014), *as amended* (Jan. 12, 2015), *on reconsideration in part sub nom. United States v. Kmart Corp.*, No. 12-CV-0881-NJR-PMF, 2015 WL 11181733 (S.D. Ill. Jan. 9, 2015), *aff'd in part, rev'd in part and remanded*, 824 F.3d 632 (7th Cir. 2016).

FCA civil claims require two primary elements: (1) scienter and (2) falsity. *United States ex rel. Schutte v. Supervalu Inc.*, 9 F.4th 455, 463 (7th Cir. 2021). Falsity is found in the common law meaning of fraud, either "express misrepresentations or 'misrepresentations by omissions.'" *Id.* (quoting *Univ. Health Servs., Inc. v. U.S. ex rel. Escobar*, 136 S.Ct. 1989, 1999 (2016)). Scienter requires the liable individual to mean "that a person, with respect to information (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless

disregard of the truth or falsity of the information." *Id.* (citing § 3729(b)(1)(A)). It does not require "proof of specific intent to defraud." *Id.* (citing § 3729(b)(1)(B)).

In addition to these two essential elements, the plaintiff "also must prove that the violation proximately caused the alleged injury" and that defendant's conduct meets "a strict materiality requirement." *United States ex. rel. Prose v. Molina Healthcare of Illinois, Inc.*, 17 F.4th 732, 740 (7th Cir. 2021). In sum, the relator must establish (1) scienter, (2) falsity, (3) causation, and (4) materiality.

In Lilly's motion for summary judgment, Lilly argues that that the Relator cannot meet either the scienter or falsity elements of the claim. Relator cross-motions and asks the Court to find summary judgment as to all four elements. Essentially, Lilly argues that the Relator has a very high burden, and Relator argues that the language is very clear. As is typical in summary judgment motions, both parties make valid points. Relator's burden is very high, and the definitions of "Average Manufacturer's Price" and "bona fide service fees" are also very clear. But while even high burdens are occasionally met, the Court is unable, upon careful review, to find any reasonable interpretation of the statute that would support Lilly's partial exclusion of the price of its drug from its Average

Manufacturer's Price. For the reasons set forth below the Court denies Lilly's Motion entirely and denies in part and grants in part Relator's Motion.

1. Scienter

Lilly argues that Relator cannot pass the threshold requirement for scienter set forth in *United States ex rel. Schutte v. Supervalu Inc.*, 9 F.4th 455, 463 (7th Cir. 2021). In *Schutte*, the Seventh Circuit adopted the Supreme Court's scienter standard for the Fair Credit Reporting Act from *Safeco Insurance Company of America v. Burr*, 551 U.S. 47, 127 (2007), and applied it to the False Claims Act's scienter provision. *Id.* In *Safeco*, the Supreme Court held that "[a] defendant who acted under an incorrect interpretation of the relevant statute or regulation did not act with reckless disregard if (1) the interpretation was objectively reasonable and (2) no authoritative guidance cautioned defendants against it." *Schutte*, 9 F.4th at 464. The Seventh Circuit held that this requirement reaches all three scienter terms that define "knowingly" in the False Claims Act, and as such is a threshold issue. *Id.* at 467.

Lilly argues that undisputed materials facts demonstrate Lilly was not objectively unreasonable in its interpretation of the MDRP requirements and that CMS provided no authoritative

guidance to warn Lilly away from its incorrect views. As a result, Lilly argues that the Relator cannot show any level scienter that would make Lilly liable under the False Claims Act.

The Court first reviews whether Lilly was objectively unreasonable in excluding "price increase value" from its AMP calculations. "The objectively reasonable inquiry hinges on the text of the statute or regulation that the defendant allegedly violated and as such is a question of law." *Id.* at 468. The Average Manufacturer's Price is defined as "the average unit price paid to the Manufacturer for the drug in the [United] States by wholesalers for drugs distributed to the retail pharmacy class of trade." The definition further states that AMP "must be adjusted by the Manufacturer if cumulative discounts or other arrangements subsequently adjust the prices actually realized." The Court then compares this text the definition of a "price increase value" in Lilly's FFS Agreements. A "price increase value" is the difference between the price the wholesaler originally paid for the drug and the current price, multiplied by the number of units. Lilly cannot and does not deny a "price increase value" or "price adjustment credit" was an "adjust[ment]" "paid to the Manufacturer" and "by the wholesalers" on a per unit basis. Instead, Lilly argues that the

statute was unclear as to whether Lilly needed to include the entire price or simply the initial price of the product in the AMP. As already explained, the definition of Average Manufacturer's Price states that subsequent price increases and decreases must be included. For this reason, the explicit text of the statute makes Lilly's position unreasonable.

Nevertheless, Lilly argues that the words "price increase value" are not present in the statute in that exact order and therefore the legal landscape was ambiguous. Lilly argues that, under the 1991 National Rebate Agreement, in the absence of "specific guidance," a drug manufacturer is permitted to "make reasonable assumptions in its calculations of AMP." This strains the meaning of "specific guidance." Under Lilly's standard, any creation and subsequent definition of a new phrase in a contract, as present here, would allow drug manufacturers to avoid its clear obligations under statute. Courts have recognized that "[b]y requiring regulations to be too specific [courts] would be opening up large loopholes allowing conduct which should be regulated to escape regulation." *Freeman United Coal Min. Co. v. Fed. Mine Safety & Health Rev. Comm'n*, 108 F.3d 358, 362 (D.C. Cir. 1997) (citing *Ray Evers Welding Co. v. OSHRC*, 625 F.2d 726, 730 (6th Cir.1980)). The Court declines to allow this loophole reasonable under a plain reading of the statute.

In the alternative, Lilly argues that the "price increase value" could reasonably be considered part of its bona fide service fees. In the FFS agreements drafted by Lilly, the price increase value calculation is in the same paragraph as the bona fide service fees calculation, and the transaction between the two parties happens simultaneously. Lilly argues that CMS has explicitly rejected bona fide fee services from AMP calculations, so Lilly was entitled to add "price increase value" as part of the services fees and thus also exclude them from the AMP.

By definition, bona fide service fees are "fees paid by manufacturer to an entity . . . for a . . . service." In contrast, a "price increase value" is never paid by the manufacturer and is never for a service. Therefore, the Court finds the proximity of the words "price increase value" to the words "bona fide service fee" in the FFS Agreements irrelevant to the Court's analysis. The history of the bona fide service fees in FFS Agreements furthers this conclusion. As recounted by Lilly in its briefing, CMS specifically rejected the bundling of "service fees" with product pricing in 2007. As noted by Lilly, some drug manufacturers tried to incorporate service fees with the full price of the product, which illegally lowered their AMP calculations and thus their payments to the government. Lilly,

characterizing itself as taking "a conservative approach," decided to only bundle price adjustments with service fees. (Mem., Dkt. No. 315.) However, there is nothing conservative about an approach where two distinct transactions that were explicitly not permitted to be coupled, the price of the product and the service fees, are nonetheless combined to lower AMP calculations. A fundamental truth in mathematics and law is that $10(price) - $1(fee) is equal to $9(price) - $1(fee) + $1(price adjustment). Although one uses more steps, they are the same equation and create the same result. Lilly readily admits that CMS prohibits the first equation ($10 - $1) because it artificially lowers the price of AMP. Therefore, it is decidedly not reasonable for Lilly to assume that it may instead use second equation ($9 - $1 + $1), simply because the steps take place a different or more complicated order.

To support its position, Lilly draws parallels to the findings in *United States ex rel. Schutte v. Supervalu Inc.*, 9 F.4th 455, 463 (7th Cir. 2021). There, the Seventh Circuit found that there were two reasonable ways to interpret the meaning of the word "Usual and Customary Price." *Id.* at 469. The Seventh Circuit found that the definition of "Usual and Customary" might mean the price that is "charged" most frequently for a drug, but it could also indicate the retail rather than discount price."

Id. As a result, the Seventh Circuit found that Defendant Supervalu did not have an objectively unreasonable interpretation of the statute. *Id.*

The Court finds this precedent inapplicable. Lilly has not proffered, nor has the Court been able to imagine, a reasonable alternative interpretation to both the mechanics and the definition of "price increase value" to be anything other than an adjustment of price and thus within the definition of Average Manufacturer's Price. Instead, the Court agrees with the district court in *United States ex rel. Streck v. Bristol-Myers Squibb Co.*, 370 F.Supp. 3d 491 (E.D. Pa. 2019), who found "nothing ambiguous" in the definition of bona fide service fees and agreed that *Streck* provided sufficient scienter, even under the "objectively unreasonable" standard. 370 F.Supp. 3d at 497. Having determined that Lilly's interpretation of Average Manufacturer Price is objectively unreasonable, the Court finds that Lilly reaches the threshold requirement of *Safeco* and denies the motion to grant summary judgment on the basis of scienter.

Relator, in response, moves for summary judgment in the opposite direction. Relator argues that Lilly, at a minimum, acted with reckless disregard or deliberate ignorance and thus knowingly violated the False Claims Act. As part of electing to participate in the National Rebate Agreement, Lilly has "a duty

to familiarize itself with the legal requirements for cost reimbursement." *Heckler*, 467 U.S. at 64. For the False Claims Act, reckless disregard holds liable "'only those who act in gross negligence,' that is, those who failed 'to make such inquiry as would be reasonable and prudent to conduct under the circumstances.'" *United States v. King-Vassel*, 728 F.3d 707, 713 (7th Cir. 2013) (quoting S. Rep. No. 99-345, at 20).

While the duty Lilly holds is clear, what Lilly did and the intent with which Lilly did them is hotly contested in the submitted Rule 56.1 statements of material fact. The Court finds that there are insufficient undisputed facts on which the Court can make a summary judgment determination and reserves this question for the jury.

2. Falsity

Lilly also argues that the Relator fails to meet the falsity element of the False Claims Act. A statement may be deemed 'false' for purposes of the False Claims Act if the statement represents "an objective falsehood,'" *U.S. ex rel. Yannacopoulos v. Gen. Dynamics*, 652 F.3d 818, 836 (7th Cir. 2011), or "if it is made in contravention of a statute, regulation, or contract." *Thulin v. Shopko Stores Operating Co., LLC*, 771 F.3d 994, 998 (7th Cir. 2014). There are several types of false statements, including "a claim for payment which is itself literally false

and fraudulent," "fraud in the inducement," and "implied false certification." *Prose*, 17 F.4th at 740.

Similar to its scienter argument, Lilly states there is no statute or final regulation that contained the words "price increase value" or "price appreciation credit" until 2016. As a result, Lilly argues no jury could find a "clear obligation" of duty to include this part of the price in the Average Manufacturer's Price. *U.S. ex rel. Quinn v. Omnicare Inc.*, 382 F.3d 432 (3d Cir. 2004). Without this obligation, Lilly argues the statute is ambiguous.

To demonstrate the ambiguous nature of the statute, Lilly offers the following alternative interpretation of its obligations under the 1991 National Rebate Agreement: "Congress did not include any temporal limitations on 'price' in the AMP statute, and so one reasonable interpretation is that the undefined term refers to the "initial price" charged to the wholesalers (*i.e.*, excluding PIV)." (Mem. at 33, Dkt. No. 315.) This interpretation is foreclosed by the AMP's definition, which explicitly states that the AMP "must be adjusted by the Manufacturer if cumulative discounts or other arrangements subsequently adjust the prices actually realized." The Court finds the requirement for the "price actually realized" forecloses Lilly's theory that it is a reasonable interpretation

of the guidelines to submit an "initial price" for the ultimate AMP calculations. The definition of the word "price," states, "the amount of money given or set as consideration for the sale of a specified thing." *Price, Merriam-Webster Dictionary* (2022) (https://www.merriam-webster.com/dictionary/price). The fact that Lilly tries to define "price" to mean "initial price" is a contortion of the regular meaning of the word and an internally inconsistent with itself.

Finally, Lilly argues that the "the FCA is not an appropriate vehicle for policing technical compliance with administrative regulations." *U.S. ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1020 (7th Cir. 1999). Lilly argues that, when there is a disputed legal issue as to the falsity of a statement, the Court should avoid punitive payments of the FCA. Because the Court finds, as a matter of law, that alternative readings of the statute as proposed by Lilly are objectively unreasonable, this argument also fails.

Relator's motion for summary judgment asks the Court to find that the record conclusively demonstrates that the statements were false in two respects. First, Relator argues that they were factually false because the AMP and related calculations were factually incorrect. Second, Relator ask the Court to find that the AMP certifications were legally false,

because Lilly certified that its AMPs were calculated in compliance with the law, and they were not.

In response, Lilly presents the same arguments discussed, and rejected, above. Lilly believes that the law was ambiguous, and thus the statements could not be false. As pointed out by the Relator, Lilly has essentially admitted through its actions that the claims were false. Since 2017, Lilly has included "price increase value" in its Average Manufacturer's Price submissions. Lilly does not intend to argue that these new submissions are false, making it impossible to argue the prior ones were not false, particular as the Court has determined as a matter of law that Lilly's interpretation of statute was objectively unreasonable. For these reasons, the Court grants Relator's motion for summary judgment on falsity and holds that Lilly's AMP calculations and related certifications were factually and legally false.

3. Materiality and Causation

Under the False Claims Act, a false statement is material is "a reasonable person would view the condition as important to a choice of action in the transaction" or "the defendant knew or had reason to know that the recipient of the representation attaches importance to that condition." *Prose*, 17 F.4th at 743.

Relator does not seek to apply either of these materiality standards in its briefing. Relator argues that, because Lilly's falsely lowered its Average Manufacturer's Price, it paid less money under the regulatory scheme, and thus materiality is established as a matter of law. This is incorrect. "[S]tatutory, regulatory, and contractual requirements are not automatically material, even if they are labeled conditions of payment." *Universal Health Servs., Inc. v. United States ex. rel. Escobar*, 579 U.S. 176, 191 (2016). Relator must prove more than a difference in payment to show materiality under the False Claims Act.

In seeking summary judgment on causation, Relator does not even articulate the correct standard for causation in his briefing. The Court does not consider this to be a serious argument. The Motion for Summary Judgment as to both materiality and causation is denied.

IV. CONCLUSION

For the reasons stated herein, the Court rules as follows:

1. Denies Defendant Eli Lilly's Motion for Summary Judgment (Dkt. No. 314);

2. Denies in part and grants in part Relator's Motion for Summary Judgement (Dkt. No. 311); and

3. Grants in part and denies in part the Motions to Exclude Expert Opinions and Testimony. (Dkt. Nos. 293, 295, 297, 299, 301.)

IT IS SO ORDERED.

Harry D. Leinenweber, Judge
United States District Court

Dated: 2/28/2022