

Corp., 561 F.3d 698, 705 (7th Cir. 2009). The *Daubert* standard applies to all expert testimony, whether based on scientific competence or other specialized or technical expertise. *Smith v. Ford Motor Co.*, 215 F.3d 713, 719 (7th Cir. 2000) (citing *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S.137, 141 (1999)).

Federal Rule of Evidence 702 provides:

If scientific, technical or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, or training or education may testify thereto in the form of an opinion or otherwise.

“In short, the rule requires that the trial judge ensure that any and all expert testimony or evidence admitted ‘is not only relevant, but reliable.’” *Manpower, Inc. v. Ins. Co. of Pa.*, 732 F.3d 796, 806 (7th Cir. 2013) (quoting *Daubert*, 509 U.S. at 589). In determining whether expert testimony is both relevant and reliable, courts in the Seventh Circuit perform a three-step analysis: “the witness must be qualified ‘as an expert by knowledge, skill, experience, training, or education,’ Fed. R. Evid. 702; the expert’s reasoning or methodology underlying the testimony must be scientifically reliable, *Daubert*, 509 U.S. at 592–93, 113 S.Ct. 2786; and the testimony must assist the trier of fact to understand the evidence or to determine a fact in issue.” *Ervin v. Johnson & Johnson, Inc.*, 492 F.3d 901, 904 (7th Cir. 2007) (citing FED. R. EVID. 702).

“[W]here such testimony’s factual basis, data, principles, methods, or their application are called sufficiently into question . . . the trial judge must determine whether the testimony has ‘a reliable basis in the knowledge and experience of [the relevant] discipline.’” *Kumho*, 526 U.S. at 149 (quoting *Daubert*, 509 U.S. at 592). “A *Daubert* inquiry is not designed to have the district judge take the place of the jury to decide ultimate issues of credibility and accuracy.” *Lapsley v. Xtek, Inc.*, 689 F.3d 802, 805 (7th Cir. 2012). “If the

proposed expert testimony meets the *Daubert* threshold of relevance and reliability, the accuracy of the actual evidence is to be tested before the jury with the familiar tools of ‘vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.’” *Id.* (quoting *Daubert*, 509 U.S. at 596). The district court possesses “great latitude in determining not only *how* to measure the reliability of the proposed expert testimony but also whether the testimony is, in fact, reliable.” *United States v. Pansier*, 576 F.3d 726, 737 (7th Cir. 2009) (citing *Jenkins v. Bartlett*, 487 F.3d 482, 489 (7th Cir. 2007)).

DISCUSSION

I. Kmart’s Motion to Exclude Relator’s Expert Dr. Joel Hay

Dr. Hay submitted his expert report on July 14, 2014, and issued revised reports on November 30, 2014 and July 11, 2017 (Docs. 324-1, 324-3, 422). Kmart argues Dr. Hay’s opinions are inadmissible because his damages calculation methodology is unreliable and irrelevant, and thus it will not help the trier of fact in reaching a verdict on the issues in this case. Kmart also asserts Dr. Hay’s methodology is fatally flawed because it is based on an incorrect understanding of Medicare Part D’s payment structure. Kmart claims this mistake is indicative of Dr. Hay’s lack of expertise regarding Medicare Part D, which renders him unqualified to serve as an expert.

A. Dr. Hay’s Qualifications

Under *Daubert* and the Federal Rules of Evidence, the Court must determine whether Dr. Hay is qualified as an expert by his knowledge, skill, education, or training. *Daubert*, 509 U.S. at 596; Fed. R. Evid. 702. “Whether a witness is qualified as an expert can only be determined by comparing the area in which the witness has superior knowledge, skill, experience, or education with the subject matter of the witness’s testimony.” *Gayton v. McCoy*, 593 F.3d 610, 616 (7th Cir. 2010) (quoting *Carroll v. Otis Elevator Co.*, 896 F.2d 210, 212

(7th Cir. 1990)). “The question we must ask is not whether an expert witness is qualified in general, but whether his ‘qualifications provide a foundation for [him] to answer a specific question.’” *Id.* at 617 (quoting *Berry v. City of Detroit*, 25 F.3d 1342, 1351 (6th Cir. 1994)).

Kmart acknowledges Dr. Hay holds a Ph.D. in Economics from Yale University and is a tenured Full Professor and Founding Chair of Pharmaceutical Economics and Policy in the School of Pharmacy at the University of Southern California. Yet, Kmart contends, Dr. Hay’s experience in the field of pharmaceutical economics does not extend to data analysis and submission of Medicare Part D claims. For example, he has not published any articles on Medicare Part D and has done no research regarding the program. While he once served as a consultant for CMS, this experience was not related to Medicare Part D. Furthermore, during his deposition, Dr. Hay demonstrated only a cursory familiarity with the Medicare Part D payment structure and appeared unfamiliar with basic Medicare Part D concepts and terminology. According to Kmart, this lack of specialized knowledge disqualifies Dr. Hay from offering an opinion regarding damages to the Medicare Part D program.

In response, Relator notes that Dr. Hay was a founding Executive Board member of the American Society for Health Economics as well as the International Society of Pharmacoeconomics and Outcomes Research, that he has authored hundreds of articles and conducted hundreds of studies within his field, and that he has served as an expert in dozens of other cases.

A review of Dr. Hay’s report and attached curriculum vitae indicates he is well qualified to opine on the damages allegedly sustained by the Government in this case. According to his report, Dr. Hay has authored or coauthored more than 500 scientific abstracts, reports, and presentations, including more than 200 peer-reviewed scientific

articles and commentaries in the fields of pharmaceutical markets, pharmaceutical economics, and health economics, among others. He also has published peer-reviewed scientific articles and abstracts on the structure and organization of the market for U.S. pharmaceuticals. Relator hired Dr. Hay to “do the math”; his expertise and experience in economics, specifically pharmaceutical economics, renders him more than competent to do so. Dr. Hay will not be excluded on the basis of his qualifications.

B. Reliability of Dr. Hay’s Opinions

Kmart also argues Dr. Hay’s opinions and calculations are unreliable for two reasons. First, Kmart avers Dr. Hay failed to incorporate the structure of the Medicare Part D program into his methodology, making his damages calculations – attributing \$85 million to the Medicare Part D program – inaccurate. Second, Kmart argues that Dr. Hay’s opinions regarding damages beyond Medicare Part D also are inadmissible because his U&C calculations do not accurately reflect the varying pricing structures and limitations between Kmart’s various discount programs.

1. Dr. Hay’s Medicare Part D Calculations

Kmart argues Dr. Hay calculated damages as if Medicare Part D were a “fee-for-service” program with a dollar-for-dollar financial impact on the Government, which it is not. Rather, CMS pays Plan Sponsors a fixed monthly amount for each enrolled beneficiary. CMS then conducts an annual “reconciliation” with Pharmacy Benefit Managers (“PBMs”) and Plan Sponsors to determine whether an individual PBM/Plan Sponsor should receive additional funds. Kmart states that the only possible way the alleged overcharges would have resulted in the Government paying more is if the overcharges had a financial impact on the annual reconciliation process. While an overcharge may affect the PBM/Plan

Sponsor and its bottom line, PBMs/Plan Sponsors are only reimbursed a percentage of any excess claims costs exceeding a threshold amount called a “risk corridor.” Kmart argues that neither Relator nor Dr. Hay presented any evidence that Kmart’s higher U&C prices would push a PBM/Plan Sponsor outside its risk corridor and trigger an annual reconciliation payment. Even if they had, the reconciliation adjustment would not result in a dollar-for-dollar reimbursement to a Plan Sponsor. Kmart contends that only by determining whether CMS provided any additional payments to PBMs/Plan Sponsors could Dr. Hay calculate the actual damages the Government may have sustained as a result of Kmart’s receipt of alleged overpayments from Medicare Part D PBMs and Plan Sponsors.

Kmart also argues that Dr. Hay’s report improperly treats alleged overcharges paid by Part D PBMs or Plan Sponsors as damages to the Government. Kmart notes that Dr. Hay’s presumption that PBMs and Plan Sponsors “stand in the shoes of the government” has been rejected by the Seventh Circuit, which held they are not officers or employees of the United States. Because Dr. Hay’s methodology calculates overcharges to the private PBMs or Plan Sponsors and not actual damages to the Government, his conclusions are unreliable, irrelevant, and would not be helpful to the trier of fact.

In response, Relator first suggests that Dr. Hay’s testimony is relevant not only to damages, but also to the elements of materiality and falsity under the False Claims Act.¹ Relator asserts that under the False Claims Act, a defendant who submits a false claim is liable for civil penalties regardless of whether the Government suffered damages. As a result, Relator need not even prove the amount of damages suffered by the Government. *See*

¹ At oral argument, counsel for Relator indicated Dr. Hay was hired only to “do the math,” and would not, himself, offer any opinions on the elements of materiality or falsity.

Garbe, 824 F.3d at 639 (“*Garbe* is required to show only that Kmart’s allegedly false claims were material to Kmart’s receipt of more money than it should have gotten.”).

Nevertheless, Relator argues, Dr. Hay’s report is also admissible on the issue of damages “or the appropriate outer bound of permissible penalties.” In every instance where Kmart submitted a claim for reimbursement in an amount higher than its everyday discount prices, the Government overpaid Kmart. By fraudulently diverting Part D funds to itself, Relator argues, Kmart harmed the Part D program penny-for penny, dollar-for-dollar, in the exact amount of the overcharges. The fact that the Government pays PBMs or Plan Sponsors a “fixed” amount does not reduce the harm to the Government. Relator asserts that Kmart’s proposed methodology is but one way to measure damages in this matter—not the only way.

In determining whether Dr. Hay’s analysis is reliable, the Court must focus on Dr. Hay’s methodology, “not the factual underpinnings or the substance of the expert’s conclusions.” *Klaczak v. Consol. Med. Transp.*, 458 F. Supp. 2d 622, 665 (N.D. Ill. 2006) (citing *Smith v. Ford Motor Co.*, 215 F.3d 713, 718, 719 (7th Cir. 2000) (“It is not the trial court’s role to decide whether an expert’s opinion is correct. 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.”)).

Dr. Hay examined the prices that Kmart charged to customers who purchased drugs without using any insurance benefits and calculated various averages of those prices (Doc. 367-1). He then identified instances in which Kmart reported a U&C price that exceeded those averages or the amount charged under Kmart’s generic drug program in effect at the time of the sale, and he calculated the difference between the amount paid by those without

insurance and the amount received in reimbursements for the same drugs from Government programs, as well as California and Illinois private payors (*Id.*).

The Court finds Dr. Hay's analysis relevant and reliable. The issue of damages is certainly pertinent to the case, and Dr. Hay's methodology for calculating damages is sound. That is not to say it is correct, only that it is admissible and, of course, subject to "the familiar tools of 'vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.'" *Lapsley*, 689 F.3d at 805 (quoting *Daubert*, 509 U.S. at 596). As the Seventh Circuit stated in *Schultz v. Akzo Nobel Paints, LLC*:

. . . the key to the gate is not the ultimate correctness of the expert's conclusions. Instead, it is the soundness and care with which the expert arrived at her opinion; the inquiry must 'focus . . . solely on principles and methodology, not on the conclusions they generate.'

Schultz v. Akzo Nobel Paints, LLC, 721 F.3d 426, 431 (7th Cir. 2013) (citing *Daubert*, 509 U.S. at 595).

Kmart is entitled to test Dr. Hay's conclusions and question the reasoning behind his methodology (*i.e.*, why he did not evaluate the annual reconciliation process) at trial. Clearly, Kmart disagrees with Relator's chosen method of proving damages. But that does not make the method unreliable. Dr. Hay's testimony regarding Medicare Part D damages will be permitted at trial.

2. *Dr. Hay's Methodology for Calculating the Usual & Customary Price*

Kmart also argues that Dr. Hay's opinions regarding damages beyond Medicare Part D are inadmissible because his U&C calculations do not accurately reflect the varying pricing structures and limitations between Kmart's various discount programs. Kmart asserts it is not possible to accurately and reliably calculate the amount overcharged without using the actual discount program prices and terms in effect at the time of each claim. For

example, for all claims prior to June 23, 2008, Dr. Hay uses \$15 as the U&C price, despite the fact that Kmart's discount program price for some prescriptions at that time was \$25, \$35, or \$45. Kmart further contends that Dr. Hay's calculations do not reflect the fact that Kmart's discount program pricing was limited to certain quantities (or days supply) for drugs on the formulary and whether the quantity (or days supply) would have been eligible for discount pricing under the terms of that discount program.

Kmart further argues Dr. Hay incorrectly applied the same U&C definition to all claims, regardless of the actual U&C definition of each specific payer. While commercial payers and Government programs such as Medicaid and Medicare may define U&C differently, Dr. Hay relies upon a general industry definition of U&C as "the cash price" of a drug. Kmart asserts it was feasible for Dr. Hay to collect and apply such varying definitions, such as the individual state Medicaid U&C definitions, yet he failed to do so. As a result, Kmart claims, Dr. Hay's methodology is not reliable, relevant, or helpful.

In response, Relator argues that Dr. Hay analyzed the transaction data by year and compared the sale price and reported price on the basis of drug, dosage, quantity, and administration on a transaction-by-transaction basis. Dr. Hay then calculated the U&C price in nine different ways: the program price; the minimum, maximum, mean, and median prices; and the 1%, 25%, 75%, and 99% quartiles. Relator also asserts that Kmart is merely rehashing one of its summary judgment arguments, that Kmart is faulting Dr. Hay for not offering a legal opinion on the meaning of the various statutes, regulations, and contracts at issue, and that all of Kmart's criticisms go to the weight of his testimony, not his admissibility.

The Court again agrees with Relator that Dr. Hay's methodology for calculating U&C is relevant and reliable. Dr. Hay "thoroughly analyzed Kmart's sales data, examining it on a drug-by-drug, quantity-by-quantity, store-by-store, and day-by-day basis" (Doc. 367-1). He also reviewed and summarized contracts entered with 1,000 third-party payers, analyzing whether the contract listed U&C in the reimbursement methodology and how each contract defined U&C (if the contract provided such a definition). He then calculated Kmart's U&C prices in the nine different ways discussed above in order to avoid offering a legal opinion on the meaning of each independent statute, regulation, or contract (*Id.*). The Court finds Dr. Hay's methodology for computing Kmart's U&C prices reliable and of assistance to the jury in understanding the evidence. Accordingly, Dr. Hay's testimony is admissible.

II. Relator's Motion to Exclude Kmart's Expert Dorothy DeAngelis

Relator has moved to exclude the report and testimony of Kmart's expert witness Dorothy DeAngelis (Doc. 322). DeAngelis has more than 24 years of consulting experience in the healthcare field, providing consulting advice to health care and pharmaceutical companies on regulatory compliance, managed care and pharmaceutical operations, and reimbursement and claims processing (Doc. 322-1, p. 5). Among many other qualifications, DeAngelis has worked in Medicare Part D since its inception and spent years working in pricing and underwriting for an HMO, calculating drug costs and determining how prescription drug benefits would be priced. She also served as a Medicare Compliance Officer, where she was responsible for ensuring that health plans offered prescription drug benefits in accordance with Medicare regulatory requirements (*Id.*). Kmart retained DeAngelis to rebut the damages theory proffered by Relator in his pleadings, as well as to rebut the testimony of Relator's experts. DeAngelis purports to offer testimony about the

structure and operation of the Medicare Part D program and whether Relator's experts account for distinctions in the Part D plan payment mechanisms when calculating damages.

Relator does not challenge DeAngelis's qualifications, but instead claims DeAngelis's rebuttal opinions are irrelevant and must be excluded because they would not help a jury determine a fact in issue. Specifically, Relator claims DeAngelis's testimony discusses whether Kmart's alleged overbillings caused the Government to pay more money than it otherwise would have. According to Relator, however, that is not the claim before the Court. Rather, Relator is claiming that Kmart's overbillings wrongfully diverted Medicare Trust Fund monies to Kmart that Congress intended to put to other uses, namely, the payment of Medicare Part D beneficiaries' pharmacy claims and the administration of the Medicare Part D program. Relator also contends it is the law of the case that tracing the flow of funds through Medicare Part D is unnecessary. Thus, DeAngelis's testimony is irrelevant to the claims in this case.

In response, Kmart argues that DeAngelis's testimony is directly relevant to a key factual issue: whether and to what extent the Government suffered any damages. Kmart contends that DeAngelis's report explains how Dr. Hay completely failed to take into consideration the complex nature of the Medicare Part D program and therefore incorrectly equated the "excess reimbursement" amount allegedly received by Kmart with financial loss to the Government. To that end, DeAngelis's testimony is directly relevant to the question of whether Kmart's alleged false statements caused the Centers for Medicare and Medicaid Service ("CMS") to pay out additional funds to Plan Sponsors.

Kmart further argues that even though Relator says he is no longer going to prove CMS paid out additional funds in order to establish damages, Dr. Hay's report and his

testimony both assess the alleged dollar-for-dollar impact on the Government. Accordingly, unless Dr. Hay's report is stricken, DeAngelis's testimony is relevant and necessary to rebut Dr. Hay's assertions and to show there is no financial impact on the Government as a result of Kmart's alleged conduct. Furthermore, DeAngelis's report is directly relevant to rebut Relator's assertion that by diverting funds from PBMs and Plan Sponsors, Kmart caused Part D beneficiaries' claims or Plan Sponsors' administration costs to go unpaid. In her report, DeAngelis explains how this scenario would not occur in the Medicare Part D program due to the annual reconciliation process, under which a Plan Sponsor is later reimbursed for a portion of any additional funds expended. In other words, all claims would have been paid regardless of Kmart's alleged conduct.

The Court agrees with Kmart that DeAngelis's opinions are relevant to the facts in this case. A review of her opinions and conclusions demonstrates her report clearly rebuts the conclusions of Relator's experts. DeAngelis's report discusses the structure of the Medicare Part D program, how CMS reimburses Plan Sponsors, and how Medicare differs from Government funded fee-for-service programs such as Medicaid or Tricare. She then explains how Relator's experts failed to distinguish the unique structure of the Part D program when analyzing Relator's claims against Kmart. Specifically, DeAngelis finds that Dr. Hay failed to consider significant facts including the competitive bidding and risk adjustment processes, the reconciliation process and how it is conducted, and the type of data needed to accurately perform Dr. Hay's analyses (data that apparently is not in the record). DeAngelis concludes that Dr. Hay's report is missing a true assessment of what impact, if any, can be specifically allocated to the Government through the Part D program. The Court believes DeAngelis's report is highly relevant to the issues at hand and, in

particular, to rebutting the opinions of Relator's experts. To the extent Relator seeks to question DeAngelis's conclusions, he can do so on cross-examination.

Relator also argues that, to the extent DeAngelis's opinions are relevant, they are relevant to a *legal* question: whether Kmart's inflated billings to Medicare Part D constitute compensable injury to the Government for which the Government can recover damages. DeAngelis states that Dr. Hay "inappropriately equates the alleged 'excess reimbursement' amount allegedly received by Kmart with damage to the government as it relates to the Medicare Part D program." According to Relator, DeAngelis's assertion that there is only one way Medicare Part D can sustain a compensable loss constitutes an inadmissible legal conclusion.

The Court disagrees with Relator that DeAngelis's opinions are relevant only to a legal question. Dr. Hay has presented one way of calculating damages in this case; DeAngelis has presented another. That DeAngelis believes her way is the right way does not transform her expert opinion into a legal conclusion.

CONCLUSION

For these reasons, Defendant Kmart Corporation's Motion to Exclude the Proffered Expert Testimony of Joel W. Hay Under *Daubert* (Doc. 323) is **DENIED**. Relator James Garbe's Motion to Exclude the Testimony is Kmart's Expert Dorothy DeAngelis (Doc. 322) is also **DENIED**.

IT IS SO ORDERED.

DATED: July 21, 2017



NANCY J. ROSENSTENGEL
United States District Judge