IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

Civil Action No. 3:17-01362

THE CITY OF HUNTINGTON,

Plaintiff,

v.

AMERISOURCEBERGEN DRUG CORPORATION, et al.,

Defendants.

v. Civil Action No. 3:17-01665

CABELL COUNTY COMMISSION,

Plaintiff,

v.

AMERISOURCEBERGEN DRUG CORPORATION, et al.,

Defendants.

MEMORANDUM OPINION AND ORDER

Pending before the court are defendants' motion to exclude the opinions of James E. Rafalski (ECF No. 1052) and defendants' motion to strike the errata sheet of James Rafalski (ECF No. 1140). For the reasons that follow, the motions are **DENIED**.

I. Background

James Rafalski ("Rafalski") worked as an investigator for the Drug Enforcement Agency ("DEA") for thirteen years. When he joined the DEA, he brought with him twenty-six years of law

enforcement experience. Judge Polster has described Rafalski's role at the DEA as follows:

Diversion Investigators are responsible for conducting regulatory, state, civil, administrative, and criminal investigations. From 2011 to 2017, Rafalski was primarily responsible for conducting administrative, civil, and regulatory investigations of DEA registrants. In this capacity, he investigated the criminal conduct of individual physicians regarding improper opioid prescriptions and conducted regulatory investigations involving, inter alia, Distributors' compliance with DEA requirements regarding suspicious order monitoring systems ("SOMS").

For example, in 2006, Rafalski conducted an accountability audit, record-keeping review, and security investigation of a Walgreens in Ohio to ensure compliance with controlled substances regulations and record keeping. This investigation resulted in the DEA issuing a letter of admonition for the maintenance of an inadequate SOMS.

From 2010 to 2013, Rafalski conducted an administrative investigation of The Harvard Drug Group to identify unusual patterns of distribution of oxycodone to Florida pain clinics. His work included the review of company records and policies, as well as the DEA's ARCOS data. This investigation resulted in the DEA issuing an order to show cause for, inter alia, developing a work-around to avoid triggering the company's SOMS.

Also, from 2010 to 2013, Rafalski conducted an administrative investigation of Masters Pharmaceutical, reviewing company files regarding customer due diligence, including questionnaires, onsite investigation reports, and SOMS information. This investigation resulted in the DEA revoking the company's registration to manufacture and/or distribute controlled substances.

From 2010 to 2017, Rafalski conducted an administrative investigation of Mallinckrodt in which he reviewed chargeback data that revealed some pharmacies and/or practitioners were utilizing

multiple Distributors to purchase the same product in large quantities. As a result of this investigation, the DEA and Mallinckrodt entered into a three-year Memorandum of Agreement.

In re Nat'l Prescription Opiate Litig., No. 1:17-MD-2804, 2019 WL 3934490, at *1-2 (N.D. Ohio Aug. 20, 2019) (citations omitted).

II. Legal Standards

a. Rule 702

The court incorporates by reference the legal standard set forth in its memorandum opinion of April 22, 2021 (ECF No. 1282).

b. Errata Sheet

On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

- (A) to review the transcript or recording; and
- (B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

Fed. R. Civ. P. 30(e)(1).

III. Discussion

a. Rule 702

While a bench trial does not eliminate the need to decide whether proffered expert opinions meet the requirements of Rule 702, it does allow the court to defer such a determination until after presentation of the opinions. The court has already

determined that it will exercise its discretion to allow other challenged experts to testify and to admit their testimony conditionally. See ECF No. 1282. The court incorporates its previous order here and determines that Rafalski should be allowed to present his opinions subject to the court's ability to exclude them, should it turn out that they do not pass muster under Rule 702.

b. Errata Sheet

Rafalski submitted an errata sheet that makes several corrections to his deposition testimony. Defendants argue that Federal Rule of Civil Procedure 30(e) does not allow these changes, characterize the changes (particularly two of them) as "gamesmanship" (ECF No. 1142, at 9), and ask the court to strike the errata sheet.

The parties acknowledge that there is no binding precedent on whether substantive changes are permitted in an errata sheet. In the context of summary judgment, the Third Circuit has adopted a case-by-case approach to this question. See EBC, Inc. v. Clark Bldg. Sys., Inc., 618 F.3d 253, 268 (3d Cir. 2010). Until the Fourth Circuit holds differently, this approach is a sound one. See Preston v. Grimes, No. 7:19-CV-00243, 2021 WL 150168, at *2 (W.D. Va. Jan. 15, 2021) ("The court is still persuaded that the case-by-case approach is best."). "Although some authority questions the scope of substantive changes

permitted under Rule 30(e), the rule itself clearly recognizes that a deponent may make any 'changes in form or substance' which the witness desires." Holland v. Cedar Creek Mining, Inc., 198 F.R.D. 651, 653 (S.D.W. Va. 2001). In other words, substantive changes are generally allowed, but the court may reject them when appropriate.

Rejection of the errata sheet is not called for here. This is not a case where "[p]reservation of the original testimony for impeachment at trial [would] serve[] as cold comfort" to defendants. See EBC, 618 F.3d at 268. The court disagrees that defendants face the kind of prejudice that would warrant striking the errata sheet. Defendants assert that allowing the errata sheet will "undermine[] [their] ability to examine Mr. Rafalski" on inconsistencies in his analysis. (ECF No. 1173, at 9.) It is not clear how this is so, as "[t]he witness who changes his testimony on a material matter between the giving of his deposition and his appearance at trial may be impeached by his former answers." Holland, 198 F.R.D. at 653. Defendants can point out the changes, and the trier of fact is free to accept or reject them.

¹ <u>See Creech v. Nguyen</u>, 153 F.3d 719 (4th Cir. 1998) ("The jury also had before it an *errata* sheet to Dr. Nguyen's deposition, which in substance changed his deposition testimony regarding the presence of the elastic bands on January 11, 1991 from "still on" to "no" longer still on. Dr. Nguyen told the jury that he changed his testimony because, upon his subsequent

Defendants also assert that allowing the errata is prejudicial to their <u>Daubert</u> motion seeking to exclude Rafalski from testifying at trial. Again, if both versions of his answers are available, Rafalski's alleged misunderstanding should be apparent. If Rafalski's methods are in fact reliable, his opinions should be admitted regardless of whether he misspoke in his deposition.

IV. Conclusion

Defendants find fault with the reliability of Rafalski's opinions. For the reasons expressed above, defendants' motion to exclude his opinions (ECF No. 1052) is **DENIED** without prejudice.

Defendants also find fault in Rafalski's errata sheet. But if Rafalski had not submitted an errata sheet, and had attempted to clarify his answers at trial, defendants likely would have faulted him on that basis. (See ECF No. 1005-1, at 12 (stating that another witness had an opportunity to change her testimony through an errata sheet).) Certainly, there are cases where deponents may abuse Rule 30(e). But because the court is

review of Creech's medical chart and "certain documents prepared by Mr. Creech in November of 1990," he believed his deposition testimony that the elastic bands were still on as of January 11, 1991 to be inaccurate. Once again, the jury, in weighing the credibility of the evidence, was entitled to accept or reject Dr. Nguyen's explanation for changing his deposition testimony.") (citations to record omitted).

unconvinced that this is one of them, defendants' motion to strike the errata sheet (ECF No. 1140) is **DENIED**.

The Clerk is directed to send a copy of this Memorandum Opinion and Order to those counsel of record who have registered to receive an electronic NEF.

IT IS SO ORDERED this 23rd day of April, 2021.

ENTER:

David A. Faber

Senior United States District Judge