

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

**In re Injectafer Products Liability
Litigation**

CIVIL ACTION

ALL CASES

NO. 19-276

MEMORANDUM OPINION

Before the Court is Plaintiffs' Motion to Strike errata sheets prepared by Defendants¹ proposing changes to the depositions of eight corporate witnesses. Plaintiffs argue that the errata sheets are procedurally and substantively improper under Rule 30(e) of the Federal Rules of Civil Procedure. The only procedural argument made by Plaintiffs is that the one-word or similarly short reasons justifying the deposition changes are insufficient.² As to substance, Plaintiffs argue that the deposition changes materially alter and contradict the original testimony. For the reasons that follow, Plaintiffs' Motion to Strike Improper Errata Modifications is granted in part and denied in part.

I. LEGAL STANDARDS

Rule 30(e) of the Federal Rules of Civil Procedure provides that “[o]n 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” to “review the transcript or recording” and “if there are changes in form or substance, to sign a statement listing

¹ Only Defendants Luitpold Pharmaceuticals, Inc., American Regent, Inc., Daiichi Sankyo, Inc., and Daiichi Sankyo US Holdings, Inc. do.

² While Plaintiffs also take issue with the fact that errata sheets submitted by Defendants were “unsworn” inasmuch as they were not notarized, there is no procedural requirement that errata sheets be notarized under Rule 30(e)—nor do Plaintiffs point to any such requirement. *See EBC, Inc. v. Clark Bldg. Sys., Inc.*, 618 F.3d 253, 266 (3d Cir. 2010) (describing the rule’s procedural requirements).

the changes and the reasons for making them.” Fed. R. Civ. P. 30(e).

The Third Circuit has set forth the procedural and substantive requirements under Rule 30(e) to evaluate proposed errata changes to deposition transcripts. *EBC, Inc. v. Clark Bldg. Sys., Inc.*, 618 F.3d 253, 265 (3d Cir. 2010). Procedurally, while the party seeking Rule 30(e) changes must “include with the proposed changes a statement of reasons for making them,” a party or deponent “need only provide some reason” to clear this “procedural hurdle.” *Id.* at 266 & n.13.

With respect to substantive changes, the Third Circuit has adopted a “flexible approach.” The determination of what is a permissible substantive change to a deposition under Rule 30(e) is “fact-sensitive” and is made on a case-by-case basis. *EBC*, 618 F.3d at 270. Under this approach, there is no need to “consider proposed substantive changes that materially contradict prior deposition testimony, if the party proffering the changes fails to provide sufficient justification.” *Id.* at 268. Yet even contradictory changes may be permissible “if sufficiently persuasive reasons are given, if the proposed amendments truly reflect the deponent’s original testimony, or if other circumstances satisfy the court that amendment should be permitted.” *Id.* at 270. That said, review of substantive changes under Rule 30(e) must guard against potential abuse, and must limit changes that are made for “tactical reasons.” *Bartos v. Pennsylvania*, 2010 WL 1657284, at *6 (M.D. Pa. Apr. 23, 2010).

One such tactical reason to which a Court must be sensitive is where a proposed change appears designed to create, for the purposes of a summary judgment motion, “a genuine issue of material fact (or eliminate the same) simply by re-tailoring sworn deposition testimony to [a party’s] satisfaction.” *Id.* at 267-68. At summary judgment, the reviewing court may refuse to consider substantive changes that materially contradict the original deposition testimony if

sufficient justifications are not provided—akin to the treatment of “sham affidavits.” *See id.* at 268-70 (“We see no principled reason to distinguish between affidavits and errata sheets in this context, and we conclude that the proper analysis for each is the same.”).

Two safeguards protect against such potential abuse. First, the original testimony is not expunged from the record, allowing the opposing party to revisit the issue at summary judgment as well as to use the original testimony for cross-examination and impeachment purposes at trial. *See id.* at 267. Second, courts may permit the deposing party to reopen the deposition in order to question the deponent on the alterations, with costs borne by the amending party. *Id.* It remains in the discretion of the reviewing court to reopen the depositions. *See id.* To determine whether reopening a deposition is warranted, consideration of the number and type of changes made by the party/deponent is appropriate. *See Reilly v. TXU Corp.*, 230 F.R.D. 486, 490 (N.D. Tex. 2005); *Allen & Co. v. Occidental Petroleum Corp.*, 49 F.R.D. 337, 341 (S.D.N.Y. 1970) (“We come next to the question of whether the changes made in the testimony were so substantial as to cause the deposition to become incomplete or useless without further testimony.”).

II. DISCUSSION

Plaintiffs argue that the proffered deposition changes are procedurally and substantively impermissible under Rule 30(e).

A. Procedural Sufficiency under Rule 30(e)

With respect to procedural sufficiency, Plaintiffs argue that Defendants’ one-word or similarly short explanations for their proposed alterations do not fulfill the requirements of Rule 30(e). But the Third Circuit has clarified that a deponent “need only provide some reason” to clear this “procedural hurdle.” *EBC*, 618 F.3d at 266 n.13. Here, the errata are all accompanied by reasons—albeit reasons characterized by their brevity—so there is no procedural deficiency.

B. Substantive Sufficiency under Rule 30(e)

Defendants seek to justify their proposed substantive changes on the grounds that they are clarifications, that the witness forgot something in the deposition only to remember it later, that they correct misspoken or incorrect answers, that they complete a thought or cut-off answer, and that they remove statements allegedly made as a joke (a “tongue-in-cheek” response). As set forth below, while some of the justifications for these errata are unpersuasive and insufficient to justify the scope of changes to the original testimony, others are permissible.

i. *Substantively Impermissible Errata*

a. “Clarifications”

In response to questions concerning a discussion about the description of hypophosphatemia in company protocols during a publications committee meeting, Shivani Kapadia initially testified as to her limited knowledge. Defendants offer the following changes (set forth in bold and italicized) to purportedly clarify the original testimony:

Q. Okay. And so the concern here is that how do we describe hypophosphatemia, and it is not clear in the protocol, that’s one of the concerns raised here, right?

A. I don’t remember the protocol word-for-word, and that’s (sic) looks like it’s coming from there, so... ***this discussion involved whether the true incidence of treatment for HPP was being reported not the description of HPP.***

...
Q. Okay. But it is clear that there is concern that the protocols are not clear regarding hypophosphatemia, and their concern is that when protocols aren’t clear about hypophosphatemia you’re going to have an underreporting, right?

...
A. Yeah, I personally did not review these case report forms, so I can’t comment on what was in these case report forms. I was a minute note-taker here, recording meeting minutes. ***[B]ut this discussion involved whether there was a potential for the treatment of HPP being underreported not whether HPP was being underreported.***

These changes go beyond clarification to add material well beyond the scope of the deponent’s original replies. The justifications of “Answer was cut-off and clarification” and “Clarification”

are unpersuasive and insufficient to explain the substance of the changes in light of the nature of her initial responses, which focus on her limited knowledge of the matters that are the subject of the questions. *See Patroni v. Harrah's Atl. City Operating Co., LLC*, 2022 WL 2375721, at *3-*5 (D.N.J. June 30, 2022) (striking amendments where changes were beyond the scope of the question and original response).

In response to a question about training materials provided to clinical nurse educators, Lynell D'Sylva initially offered a simple affirmative answer, which Defendants seek to augment as follows:

Q. And you had testified that that wasn't on the training materials, but you recall having conversations and interactions with CMPs and CNEs explaining what the 27 percent number meant, correct?

A. Yes, that's correct.³ ***The 27% is not included in the field decks but the prescribing information was available.***

This addition is insufficiently justified because the alteration goes beyond the scope of the question and initial response. *See id.* at *5.

Defendants also seek to change a response by D'Sylva to a question about whether Defendants have conducted a Phase 4 clinical trial for hypophosphatemia, replacing "We have not conducted a Phase 4 specific hypophosphatemia trial" with "***We have not yet completed our Phase 4 hypophosphatemia substudy.***" This alteration presents a clear change in meaning—even if not a strict contradiction—and is inconsistent with the original testimony. *See id.* at *3 (finding alterations making answers more complete or accurate unjustified where inconsistent with original deposition testimony).

³ Plaintiffs' Motion records this statement as "Yes, that is correct," but the transcript provided reads, "Yes, that's correct."

b. “Forgot” or “Remembered”

David Bregman initially testified “Yes” he recalled there was some instruction in the VIT-9031 protocol about how to manage hypophosphatemia, but Defendants seek to change the answer to “*No*” because Bregman “forgot it was not in 9031 protocol.” Bregman testified as to his then-present recollection: changing his answer based on later review or remembrance renders the answer unresponsive to the original question. *See id.* at *4 (striking amendment where deponent originally provided a responsive answer and proposed change was not “fully responsive” to the question posed).

c. “Misspoke” or “Correcting Answer”

Defendants propose changes to a response by Bregman to a question about whether a company would make a health condition or injury a primary or secondary endpoint of a clinical study, replacing the answer, “Yes. I think that if that’s something that the company wants to show, that it would probably be a primary or secondary endpoint,” with “*No, typically adverse events are not primary or secondary endpoints of studies, but instead are safety endpoints.*” The alteration is contradictory and inconsistent with the original testimony provided and will not be permitted. *See id.* at *3 (striking inconsistent changes purporting to make answers more complete or accurate).

d. “Tongue-in-Cheek Response”

Bregman made the following comment in response to a question about whether, in hindsight, he thought it was a mistake not to include certain information on hypophosphatemia in clinical trial materials: “With the benefit of hindsight, I mean, knowing I was going to be speaking to you in a deposition, for sure.” Defendants propose to remove this statement entirely, justifying the change on the basis that the statement was “tongue-in-cheek” and the deponent does not “want it taken out of context.” The mere fact a deponent may regret saying something

at deposition, even if the statement was made in jest, is not sufficient reason to alter or remove testimony with the potential result of creating (or eliminating) a dispute of fact. The amendment is wholly inconsistent with the original testimony and will not be allowed.

ii. Substantively Permissible Errata

Numerous errata specifically discussed in Plaintiffs' Motion, however, are permissible because they are sufficiently justified. Nevertheless, in that it is too early to tell whether they may create genuine factual disputes at summary judgment, the original testimony will be preserved alongside the modified testimony to allow for any necessary evaluation at summary judgment. At summary judgment review, if any errata changes create genuine disputes of material fact they will be ignored in favor of the original testimony. *See EBC*, 618 F.3d at 267-68. If the matter proceeds to trial, the original testimony may also be used for cross-examination or impeachment purposes at trial. *See id.* at 267.

a. “Clarifications”

Defendants propose additions to a response by Bregman to a question about whether it is possible that a clinical investigator treated a patient for severe hypophosphatemia and Defendant American Regent, Inc. was not aware of that fact: “I mean, it is possible – ***only if the clinical investigator does not record the information to us which was done here.***” This change is not necessarily contradictory and appears to be sufficiently justified on the basis that the proposed change makes the answer clearer. *See Patroni*, 2022 WL 2375721, at *3 (permitting changes that were “not necessarily contradictory” where justified as making answers more accurate).

Defendants propose adding the following to a response by Todd Koch to a question regarding the appropriate schedule of events for serum phosphorus testing:

I mean, that certainly was a common – a common timeframe that we measured phosphorus. But the changes that we saw were over time, not immediate. So I’m

going to say that it certainly was a common schedule that we followed ***but varied depending on the study.***

This change is consistent with the original testimony and appears to be warranted as making the answer more complete or accurate. *See id.*

Defendants propose adding the following to a response by Angelia Butcher to a question about which clinical trials were submitted to the FDA for approval:

Q. But specifically in regards to approval, it was just 30 and 31, correct?

A. Yes ***these were the pivotal ones for approval.***

This change appears to be consistent with the original testimony and sufficiently justified as making the answer more accurate or complete. *See id.*

Defendants propose to change a response by Syed Quadri to a question about whether a reported case of severe hypophosphatemia lasted for over two months from “Correct” to “***Incorrect. Just over a month based on her measurement on April 23.***” While contradictory, the change appears to be sufficiently justified as a clarification upon further review of an exhibit used at deposition. *See id.*

b. **“Forgot” or “Remembered”**

Defendants propose multiple changes to responses by Linda Mundy to questions regarding the schedule of evaluation during certain clinical trials, replacing the initial figures with alterations in order, as the errata sheet states, to accurately reflect the schedule of evaluation. The alterations are inconsistent to the extent they provide different values but appear to be appropriate as making the answers more accurate or complete. *See id.* If Mundy’s later recollection is of any material significance in later proceedings in this matter Plaintiffs will have recourse to the original testimony. *See EBC, 618 F.3d at 267.*

Defendants propose changes to a response by Marsha Simon to a question about whether

Defendant American Regent, Inc. responded to a recommendation from the FDA, changing “No, we did not. We accepted the proposal from the FDA,” to “***Yes, we did, in a letter to FDA on July 15, 2013.***” While contradictory, it is possible that the answer makes the response more accurate, and the change appears to be sufficiently justified as a recollection after the deponent was shown an exhibit later in deposition.

c. “Misspoke” or “Correcting Answer”

Defendants propose the same change for two responses by Bregman: (1) his response to a question about particular circumstances constituting an adverse event, “So it would be called an adverse event if it was below the lower limit of normal”; and (2) his response to a question about whether it would still be an adverse event simply from the blood measurement, “Right. Correct.” The proposed change for each is “***No, it would only be an adverse event if the clinical investigator determined the drop in blood phosphorous was a clinically significant worsening.***” This change, while contradictory at least to the second response, appears to be sufficiently justified as correcting misspoken testimony. It is possible that the proposed change makes the responses more accurate and that the deponent misspoke. *See Patroni*, 2022 WL 2375721, at *3-*4.

Defendants propose to change responses by Bregman to questions about the potential clinical significance of a decrease in phosphorous levels from “going down to 2” to “***going down to less than 2.***” This change is not necessarily contradictory and appears to be sufficiently justified as correcting a misspoken statement. *See id.*

Defendants propose adding to a response by Bregman to a question about whether two 750 milligram doses of Injectafer would lead to a greater decrease in serum phosphorus than one

1000 milligram dose⁴: “Yes, I think that is possible, that receiving 1.5 milligrams would lead to a higher—sorry, 1,500 milligrams would lead to a higher than 1,000, yes *if received all at once as separating the two 750 mg doses over 7 days would make the patient less susceptible to serum phosphorous decreases than one shot of 1000 mg.*” This qualification is not necessarily contradictory, and it is appropriate in that the proposed change makes the response more accurate or complete. *See id.*

But, once again, in each of these instances if that turns out not to be the case then the original remains for use, as warranted at summary judgment and, if necessary, at trial.

d. “Finish Thought / Cut-Off on Answer”

Defendants propose adding to a response by Simon to a question about whether a drug’s label is the main vehicle for communicating the drug’s efficacy and risks, changing “It would be one of the—yes” to “*It would be one of the sources of information. Yes.*” This change is not necessarily inconsistent with the original testimony because it appears that the deponent was cut off or otherwise stopped speaking in the middle of the sentence and is justified as making the answer more complete. *See id.* While finishing a thought is not necessarily a proper justification for an errata modification, here it appears to be justified and within the flexible scope of the Third Circuit’s approach to Rule 30(e).

C. Remaining Errata

There are other changes to deposition testimony proposed by the Defendants in the errata sheets, which Plaintiffs do not specifically address. Most of them are transcription errors, which are easily encompassed within Rule 30(e)’s scope such that the changes should be made—nor do

⁴ The question is cut off in the excerpts provided by Plaintiffs, so the Court adopts the characterization of the question that both Plaintiffs and Defendants use.

Plaintiffs argue to the contrary. As to the remaining errata that are more substantive in nature, since the parties provide nothing to the Court whereby it would be possible to determine one way or the other whether they would create a genuine dispute of fact, they will be evaluated at summary judgment to the extent that they are raised by the parties in their briefs.

D. Request for Reopening Depositions

Plaintiffs ask to re-open depositions in which the Court has approved Defendant's proposed errata changes. While reopening depositions in light of Rule 30(e) alterations may be warranted, *EBC*, 618 F.3d at 267-68, here it is not. Judging by the examples offered by Plaintiffs, the unstricken errata are not of a degree or quality to justify the expense and delay of reopening depositions. This is not an instance where the changes made are "so substantial as to cause the deposition(s) to become incomplete or useless without further testimony." *Allen & Co.*, 49 F.R.D. at 341.

An appropriate order follows.

BY THE COURT:

/s/Wendy Beetlestone, J.

WENDY BEETLESTONE, J.