IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
CHARLESTON DIVISION

IN RE: LIPITOR (ATORVASTATIN CALCIUM) MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION	**MDL No. 2:14-mn-02502-RMG** **CASE MANAGEMENT ORDER NO. 67** **This Order relates to all cases.**

Plaintiff's Motion to Reconsider CMO 54 (Dkt. No. 1292)

In CMO 54, the Court excluded Dr. Jewell's analysis of the NDA data and ASCOT data, finding that "rather than conducting statistical analyses of the data and then drawing a conclusion from these various analyses, Dr. Jewell formed an opinion first, sought statistical evidence that would support his opinion, and ignored his own analyses and methods that produced contrary results." (CMO 54, Dkt. No. 1258 at 35). Plaintiffs have filed a motion for the Court to reconsider its rulings in CMO 54, (Dkt. No. 1292), and Defendant has filed a response. (Dkt. No. 1333).

A. Legal Standard

Under Rule 54(b), "[a]n interlocutory order is subject to reconsideration at any time prior to the entry of a final judgment." *Fayetteville Investors v. Commercial Builders, Inc.*, 936 F.2d 1462, 1469-70 (4th Cir. 1991). District courts in the Fourth Circuit look to the standards governing Rule 59 motions for guidance in analyzing an motion to reconsider an interlocutory order, though courts are not necessarily bound by the strictures of Rule 59(e). *See, e.g., Superior Bank, F.S.B. v. Tandem Nat'l Mortg., Inc.*, 197 F. Supp. 2d 298, 332 (D.Md. 2000); *R.E.*

Goodson Constr. Co., Inc. v. Int'l Paper Co., No. 4:02-cv-4184, 2006 WL 1677136 at *1 (D.S.C. June 14, 2006). A district court has the discretion to grant a Rule 59(e) motion in narrow circumstances: "(1) to accommodate an intervening change in controlling law; (2) to account for new evidence not available at trial; or (3) to correct a clear error of law or prevent manifest injustice." *Hill v. Braxton*, 277 F.3d 701, 708 (4th Cir. 2002) (internal quotations omitted). Motions to reconsider may not be used to make arguments that could have been made before the court issued its ruling. *Hill v. Braxton*, 277 F.3d 701, 708 (4th Cir. 2002). Nor are such motions opportunities to rehash issues already ruled upon because a litigant is displeased with the result. *Tran v. Tran*, 166 F. Supp. 2d 793, 798 (S.D.N.Y. 2001); *see also United States ex rel. Becker v. Westinghouse Savannah River Co.*, 305 F.3d 284, 290 (4th Cir. 2002) ("Mere disagreement does not support a Rule 59(e) motion."). Here, Plaintiffs argue that CMO 54 was "clearly erroneous and manifestly unjust." (Dkt. No. 1292 at 1).

B. Discussion

1. NDA Analysis in Dr. Jewell's Initial Report

The Court excluded Dr. Jewell's initial NDA analysis because it was apparent to the Court that Dr. Jewell came to a firm conclusion first and then sought statistical evidence to support this conclusion while ignoring any statistical evidence he found to the contrary. (Dkt. No. 1258 at 17). The Court's determination that Dr. Jewell's NDA analysis was improperly results driven was based on multiple considerations, including the misleading nature of some of the calculations, the inconsistency in the methodologies used by Dr. Jewell, Dr. Jewell's own testimony that he only considers evidence that will "support a strong opinion," the fact that some of his calculations were based on an obviously false assumption, and the fact that Dr. Jewell excluded from his report, and apparently ignored, his own analyses that did not support his

ultimate opinions. The Court finds that this decision was not clearly erroneous or manifestly unjust. Plaintiffs attack specific statements by the Court in their motion to reconsider, and the Court addresses each in turn.

As an initial matter, the Court found that regardless of Dr. Jewell's methodological flaws, Dr. Jewell's opinion that the NDA data "should have alerted Parke-Davis and Defendant to the possibility of increased risk of new-onset diabetes associated with atorvastatin treatment" should be excluded. (*Id.* at 7-9). Dr. Jewell's analysis only concerned single elevated glucose measurements, which Plaintiffs argued in other contexts were not diagnostic of diabetes. Dr. Jewell himself readily admitted that he had no expertise in diabetes, did not "quite know" what new-onset diabetes meant, and was unwilling to testify about the role or use of blood glucose as a surrogate marker for diabetes because he was not a clinician. (Dkt. No. 972-7 at 18-19, 65, 128; Dkt. No. 1247-14 at 251). Thus, by his own testimony, he lacked the expertise to opine about any implications that single glucose readings might have about the possibility of new-onset diabetes.

In their motion to reconsider, Plaintiffs argue that "[g]iven that diabetes is, as noted by other experts in this case on both sides, a disease defined by glucose dysregulation, this [NDA] evidence should have alerted Pfizer to the *potential* that longer-term exposure to its drug *might* increase the risk of new-onset diabetes among patients without prediabetes or normal baseline glucose levels." (Dkt. No. 1292 at 5 (emphasis in original)). While this may (or may not) be true, the Court's holding was simply that Dr. Jewell lacked the clinical expertise to so opine. This holding was not clearly erroneous or manifestly unjust.

Next, the Court found that Dr. Jewell's decision to include participants with elevated glucose at baseline created the potential for confounding, did not test for "new-onset" diabetes,

and was contrary to his methodologies in all of his other analyses. (Dkt. No. 1258 at 9-14). On reconsideration, Plaintiffs argue that with all of Dr. Jewell's other analyses, he was studying the endpoint of "new onset diabetes," but that with regard to the NDA data, Dr. Jewell was studying the endpoint of "clinically meaningful elevations in glucose." (Dkt. No. 1292 at 12-13). Thus, Plaintiffs argue, his other analyses are not inconsistent with his NDA analysis, just different.

The Court addressed this argument in CMO 54: "These claims are belied by Dr. Jewell's use of this data to support opinions about 'the possibility of increased risk of new-onset diabetes,' . . . and Plaintiffs' argument that this NDA data supports the opinion that 10 mg of Lipitor causes new onset diabetes." (Dkt. No. 1258 at 11). Plaintiffs only make the Court's point in paraphrasing Dr. Jewell's opinion:

> In other words, the evidence of an increased incidence of clinically meaningful glucose elevation in the NDA should have alerted Defendants to the possibility that longer-term exposure to atorvastatin might increase the risk of new-onset diabetes in patients with normal or pre-diabetic baseline glucose levels given longer-term exposure.

(Dkt. No. 1292 at 13). To the extent that Dr. Jewell is attempting opine that a change in glucose levels based on a single glucose reading have implications for new-onset diabetes, he lacks the clinical expertise to so opine. To the extent that Dr. Jewell is attempting to use a well-established definition of diabetes to analyze data about diabetes, his methods are inconsistent with ***all*** of his other analyses and fail to actually use such a definition. Either way, his opinion is problematic.

The Court went on to state that "even assuming that [Dr. Jewell] did want to assess significant changes in glucose levels, regardless of baseline characteristics, this is not what he assessed." (Dkt. No. 1258 at 11). The Court explained that Dr. Jewell "included 100% of the participants that had an elevated glucose measurement during a trial, regardless of whether they

actually experienced any significant increase in glucose from baseline." (*Id.* at 11-12). For example, the Court noted that Patient #1 had a baseline glucose measurement of 131 mg/dL and an on-treatment glucose measurement of 133 mg/dL, a change that Plaintiffs' clinical expert, testified was "minor." (*Id.* at 12).

In their motion to reconsider, Plaintiffs do not address the fact that Patient #1 did not, according to their own experts, have a significant change in glucose levels, proving Dr. Jewell's assumption that all participants in Table 42 had "clinically meaningful elevations in glucose" false. Rather, Plaintiffs seized on a footnote in the Court's order regarding the ISS's definition of this term, submitted additional documents not considered by Dr. Jewell or presented to the Court in original briefing regarding this definition, and then reargued its position that Dr. Jewell should be allowed to assume that these participants had "clinically meaningful elevations in glucose." (Dkt. No. 1292 at 7-15).

Given the obvious dispute about how to interpret Section 5.2 of the ISS, the Court will reconsider footnote 13 of CMO 54, and amends the order to delete the last two sentences of footnote 13. However, this does nothing to change the Court's analysis. Dr. Jewell's analysis was based on the obviously false assumption that every participant counted in Table 42 had a "clinically meaningful elevation in glucose." Allowing testimony based on an obviously false assumption, as conceded by Plaintiffs' clinical expert, would be abdicating this Court's role as a gatekeeper under *Daubert*.[1]

In making its ruling under Rule 702, the Court also considered the results-driven decision to use the mid-p test when the Fisher exact test did not return a statistically significant p-value.

[1] Plaintiffs' claim that the Court's conclusion here is inconsistent with its finding regarding the ASCOT analysis is meritless. Here, the underlying data clearly show that Dr. Jewell's assumption is false. As explained below, Dr. Jewell does not claim that the determinations of the blinded Endpoint Committee in ASCOT were incorrect.

Plaintiffs do not dispute that when Dr. Jewell calculated the estimated Relative Risk from the data to be 3.0, he initially used the Fisher exact test to obtain a p-value of 0.0654, that Dr. Jewell failed to mention or include this result in his report (and thus, did not state that it was given any consideration in his opinion), and that he then used the mid-p test that he knew would "[a]lmost surely" produce a lower p-value than the Fisher exact test, despite the fact that he used the Fisher exact test for *all* of his other analyses. (*See* Dkt. No. 1258 at 16-17 (citing 21 other instances where Dr. Jewell used a p-value, rather than a mid-p value)). Dr. Jewell used the mid-p test only where he needed it for statistical significance in relation to his estimated Relative Risk of 3.0.[2]

In their motion to reconsider, Plaintiffs argue that Dr. Jewell's opinion was based on multiple epidemiological measurements, including the Odds Ratio and the absolute Risk Difference, both of which were statistically significant. (Dkt. No. 1292 at 16-18). Thus, Plaintiffs argue, Dr. Jewell did not exclusively rely on the mid-p test for this opinion. However, the only epidemiological measurement mentioned in Dr. Jewell's summary NDA opinion is the 3.0 ("three-fold") Relative Risk ratio:

> The placebo-controlled data showed a ***statistically significant three-fold*** higher incidence of clinically meaningful abnormal increases in blood glucose measurement greater than 1.25 times the upper limit of normal, a level that, if persistent, is diagnostic for diabetes, with some evidence of a dose response. The NDA data thus provides reasonable, and statistically significant, evidence of atorvastatin's adverse effect on glucose metabolism, and thus, should have alerted Parke-Davis and Pfizer to the possibility of increased risk of new-onset diabetes associated with atorvastatin treatment.

(Dkt. No. 1247-9 at 7). Dr. Jewell did not state the estimated Odds Ratio or mention the relatively small 2.2% absolute Risk Difference. (Dkt. No. 1247-9 at 7). The only basis for his

[2] Plaintiffs as much as admit this. They argue that Dr. Jewell used the mid-p test "in this instance because of its increased power." (Dkt. No. 1292 at 17). A statistical test with "increased power" is definitionaly a test that is less conservative, and as Dr. Jewell testified, will "[a]lmost surely" return a lower p-value.

opinion that there is a "statistically significant three-fold higher incidence of clinically meaningful abnormal increases in blood glucose" is Dr. Jewell's anomalous use of the mid-p test after the Fisher exact test did not return a statistically significant result. As explained in CMO 55, having a Relative Risk ratio above 2.0 has incredibly important implications for Plaintiffs' case and no other clinical trial data support a relative risk ratio anywhere close to 3.0. Dr. Jewell changed the methodology he employed to obtain a particular result, a statistically significant Relative Risk ratio of 3.0. This is the epitome of results-driven, litigation-driven expert testimony.

Next the Court found Dr. Jewell's opinion regarding the average increase in blood glucose in the NDA trials misleading. (Dkt. No. 1258 at 17-22). Dr. Jewell calculated the average increase in glucose levels, for those that experienced "clinically meaningful increases" in glucose levels, to be 30.8 mg/dL and opined that "on average, these 40 individuals, almost all of them on atorvastatin, experienced a very significant increase in blood glucose levels following initiation treatment." (Dkt. No. 1247-9 at 15-16). Dr. Jewell follows the calculation, in the very next paragraph, with the opinion that "the available glucose data support the findings noted above about the adverse effect of atorvastatin on blood glucose in that glucose tends to increase more on average for atorvastatin patients than for placebo subjects." (Dkt. No. 1247-9 at 16). However, Dr. Jewell's average was based on the placebo and experimental groups, ***combined***. The Court found this statistic, so used, highly misleading and stated that if allowed under Rule 702, the Court would exclude it under Rule 403. (Dkt No. 1258 at 22 n.26).

On reconsideration, Plaintiffs argue that Dr. Jewell was only attempting "to quantify the qualitative statement that these lab abnormalities represented clinically meaningful deviations from baseline, *irrespective of intervention*." (Dkt. No. 1291 at 21 (emphasis in original)).

However, Plaintiffs' argument in initial briefing was to the contrary; they argued that "[w]hat [these averages] show is that, among those whom it affects, Lipitor can raise blood glucose sufficiently to take an individual with no prior glucose abnormalities—that, with a baseline glucose level less than 100 mg/dL—and elevate that individual's glucose beyond the threshold for new onset diabetes, at 125 mg/dL." (Dkt. No. 1053 at 34). Regardless of Dr. Jewell's intentions, the Court's exclusion of this opinion under Rule 403 is not clearly erroneous or manifestly unjust.

Furthermore, the role of this particular calculation in the Court's conclusion that Dr. Jewell's analysis was inappropriately results driven is described in detail in CMO 54, (Dkt. No. 1258 at 17-22), not discussed in Plaintiffs' motion to reconsider, and well founded. Dr. Jewell opines that "the available glucose data support the findings noted above about the adverse effect of atorvastatin on blood glucose in that glucose tends to increase more on average for atorvastatin patients than for placebo subjects, and that such changes tend to be higher for those participants exposed to higher doses of atorvastatin." (Dkt. No. 1247-9 at 16). However, Dr. Jewell excluded from his report and ignored his own analyses that did not support this opinion. As explained in CMO 54, he compared the increase in glucose among all participants in the Lipitor and placebo groups, and found the differences to be very small. (Dkt. No. 1258 at 19-20). However, he failed to mention this in his report because he "didn't believe the data . . . supported that being the basis of the kinds of opinions [he] wanted to put in [his] summary, so [he] did not include it." (Dkt. No. 1247-8 at 231).

The Court finds that its decision to exclude Dr. Jewell's initial NDA analysis under Rule 702 was not clearly erroneous or manifestly unjust. The Court appropriately considered a number of factors, listed above and in CMO 54. These factors are all indicia of results-oriented,

litigation-driven expert testimony, and the Court did not clearly err in finding the testimony unreliable. The Court also finds that the testimony's probative value is substantially outweighed by its danger to confuse and mislead the jury and excludes the testimony under Rule 403.

2. Dr. Jewell's Supplemental NDA Analyses

As Plaintiffs state, Dr. Jewell's supplemental analyses "were performed to demonstrate Pfizer's criticisms lacked merit." (Dkt. No. 1292 at 24). Because the Court has determined that it appropriately excluded Dr. Jewell's initial NDA analysis, Pfizer's criticisms of that analysis and Dr. Jewell's rebuttal report to those criticisms are now irrelevant and moot. Thus, the motion with regard to the Court's exclusion of Dr. Jewell's supplemental/rebuttal analysis is also moot. Nevertheless, to ensure a complete record, the Court will address Plaintiffs' arguments specifically pertaining to the supplemental/rebuttal report.

Plaintiffs first take issue with footnote 28 of CMO 54, which notes that the data set in Dr. Jewell's supplemental report appeared to differ from that in his original report. (Dkt. No. 1258 at 24 n.28). Plaintiffs have pointed to Dr. Jewell's explanation for this apparent difference. (Dkt. No. 1292 at 25-27). Thus, the Court reconsiders this statement and amends CMO 54 to delete footnote 28. However, this footnote did not bear on the Court's analysis but only served to explain why the Order used the phrase "***new*** data set." (*See* Dkt. No. 1258 at 24 (emphasis added)).

Plaintiffs next argue that the Court mistook Dr. Jewell's sensitivity analyses for trying multiple models and then picking the one that he wanted. (Dkt. no. 1292 at 27-29). This argument is well taken. The Court misapprehended Dr. Jewell's actions due to Dr. Jewell's testimony that he "played around" with these models, "making sure [he] was getting the right

result." Therefore, the Court amends CMO 54 by deleting the first 5.5 lines of the first full paragraph on page 23, such that it now reads:

> However, the model was not a good fit for the data and had extremely high standard errors such as 3.4 X 10^29 and 1.58 X 10^14. (Dkt. No. 1247-13 at ¶ 28; *see also id.* ("it is surprising that Dr. Jewell still proceeded to report the treatment difference estimate even though his computer output clearly indicated there is a serious data fitting problem.")).

While the Court's impression that Dr. Jewell tried multiple models in his supplemental report contributed to the Court's conclusion that the testimony was unreliable, this was only one of the bases for the Court's ruling. Plaintiffs have not attacked the other bases for the Court's rulings, which include astoundingly high error rates in the range of quadrillions or septillions, Dr. Jewell's own testimony that the data was "tricky to fit" to the model due to its unusual characteristics, and the dramatically wide confidence intervals, which both Dr. Jewell himself and the Reference Manual on Scientific Evidence warn against. (Dkt. No. 1258 at 23-24). The Court finds that in consideration of these factors and of the other indicia of unreliability with regard to Dr. Jewell's original NDA analysis, its exclusion of this testimony under Rule 702 was not manifestly unjust or clearly erroneous.

3. ASCOT Analysis

Finally, the Court excluded Dr. Jewell's "reanalysis" of the ASCOT data. In his reanalysis, Dr. Jewell reached a conclusion contrary to that of the peer-reviewed, published article on ASCOT. The primary difference between Dr. Jewell's analysis and those of the ASCOT researchers was that the ASCOT researchers used adjudicated data for the determination of the endpoint "new onset diabetes," where has Dr. Jewell used unadjudicated lab data.

As an initial matter, the Court did not, as Plaintiffs claim on reconsideration, hold that a reanalysis of data from a published study is always, or even often, improper or excludable if not

also published in a peer-reviewed journal. The Court recognizes such testimony can be reliable and important. Rather, the Court held that, "an expert cannot simply, ***without any explanation*** for rejecting a published, peer-reviewed analysis, conduct his own 'reanalysis' solely for the purposes of litigation and testify that the data support a conclusion opposite that of the studies' authors in a peer-reviewed publication." (CMO 54, Dkt. No. 1258 at 32 (emphasis added) (citing cases)).

"Peer review and publication weigh heavily in the calculus of the reliability of expert testimony because such peer review 'increases the likelihood that substantive flaws in methodology will be detected.'" *Hall v. Baxter Healthcare Corp.*, 947 F. Supp. 1387, 1406 (D. Or. 1996). Thus, courts are appropriately skeptical of *post-hoc*, reanalyses conducted solely for the purpose of litigation that reach conclusions contrary to peer-reviewed published studies. *See, e.g., Ealy v. Richardson-Merrell, Inc.*, 897 F.2d 1159, 1162-63 (D.C. Cir. 1990) (rejecting testimony of "the plaintiff's epidemiology expert . . . [who] tried to refute the validity of the published epidemiological data through her own unpublished reanalysis"); *Lynch v. Merrell-Nat'l Labs. Div. of Richardson-Merrell, Inc.*, 646 F. Supp. 856, 865 (D. Mass. 1986) ("Even if this Court were to find the methodology of Dr. Swan's re-analysis credible, this Court still could not accept result-oriented re-analysis of epidemiological studies . . . , such as that performed here by Dr. Swan, as reliable data upon which to base an opinion on causation."), *aff'd*, 830 F.2d 1190 (1st Cir. 1987).

However, as the Court stated in CMO 54, "[t]his is not to say that a reanalysis of published data is never admissible." (CMO 54, Dkt. No. 1258 at 32). Instead, the expert must provide an explanation for why a reanalysis is warranted, or in the words of the Ninth Circuit, she must "validate" her reanalysis in some way. (*Id.*); *Daubert v. Merrell Dow Pharm., Inc.*, 43

F.3d 1311, 1320 (9th Cir. 1995). As the *Zoloft* court explained, "results-oriented, post-hoc re-analyses of existing epidemiological studies are disfavored by scientists and often deemed unreliable by courts, unless the expert can validate the need for reanalysis in some way." *In re: Zoloft (Sertraline Hydrocloride) Products Liab. Litig.*, No. 12-MD-2342, 2015 WL 7776911, at *14 (E.D. Pa. Dec. 2, 2015).

This burden is not nearly as onerous as Plaintiffs suggest. The Court gave two examples in CMO 54: a expert can validate her reanalysis by publishing it in a peer-reviewed journal or by pointing to a methodological flaw in the published study and explaining how she corrected the flaw. (CMO 54, Dkt. No. 1258 at 32). There are other ways. For example, the Third Circuit found a reanalysis appropriate where the latency period for lung cancer was disputed and the expert's reanalysis assumed a different latency period than the published study. *In re TMI Litig.*, 193 F.3d 613, 713 (3d Cir. 1999), *amended on other grounds*, 199 F.3d 158 (3d Cir. 2000). The Ninth Circuit explained that "epidemiologists might validate their reanalyses by explaining why they chose only certain of the data that was available." *Daubert*, 43 F.3d at 1320. And, as Plaintiffs note in their briefing, Dr. Jewell's reanalysis was allowed in a case where he, appropriately, removed patients experiencing dizziness and sleepiness from the data set. (Dkt. No 1292 at 50-51).

However, reanalyses conducted solely for the purposes of litigation without sufficient explanation will be rejected. *See, e.g., Kelley v. Am. Heyer-Schulte Corp.*, 957 F. Supp. 873, 879 n.5 (W.D. Tex. 1997) (reanalysis using a larger p-value excluded); *In re: Zoloft*, 2015 WL 7776911 at *13 (rejecting one of Dr. Jewell's reanalyses for improperly rejecting author's conclusion regarding confounding); *id.* (rejecting another of Dr. Jewell's reanalyses because he

did not provide an explanation for "rejecting the assumption of the study authors and drawing his own assumption").

Turning to Dr. Jewell's reanalysis of ASCOT, the only reason given by Dr. Jewell for conducting a reanalysis with lab data, instead of using the adjudicated endpoint data, was that the blinded Endpoint Committee used a "non-standard" definition of "diabetes."[3] (Dkt. No. 1247-11 at 4, 7). Had the Endpoints Committee actually used a non-standard definition of diabetes, this may be an acceptable reason to conduct a reanalysis using a standard definition. However, Dr. Jewell testified at deposition that while he "presume[d] that an explicit definition was provided to [the Endpoint Committee]"; he simply did not "know exactly what the definition was." (Dkt. No. 1247-14 at 4; *accord* Dkt. No. 1247-14 at 24-25, 28). Because he did not know what definition the Endpoint Committee used, he did not know "if they got it right or wrong."[4] (Dkt. No. 1247-14 at 32).

The Endpoint Committee did, in fact, use a standard definition of diabetes as explained in CMO 54. Plaintiffs argue that which criteria were used by the Endpoint Committee is a "Contested Issue of Expert Judgment." (Dkt. No. 1292 at 37). This is incorrect. Which criteria were used by the Endpoint Committee is a simply question of fact, not of expert judgment, and the only testimony on this factual issue (and the only evidence of how the blinded Endpoint Committee operated) before the Court is the testimony of Dr. Hemingway.[5] Furthermore, even it were a matter of "expert judgment," the testimony of Plaintiff's expert Dr. Jewell is that he

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[3] To the extent that Plaintiffs' counsel raises any other explanations, they are not reasons Dr. Jewell gave for using unadjudicated lab data rather than adjudicated endpoint data.

[4] Given Dr. Jewell's confusion, Plaintiffs could have conducted discovery on what definition was, in fact, used by the Endpoint Committee.

[5] The Court must make preliminary factual determinations under Rule 104(a) in its gate keeping role. *See, e.g., Ruffin v. Shaw Indus., Inc.*, 149 F.3d 294, 296 (4th Cir. 1998).

simply did not know which definition was used by the Endpoint Committee. (Dkt. No. 1247-14 at 4, 24-25, 28). An expert's statement that he simply does not know what the Endpoint Committee did or whether "they got it right or wrong" is not enough to reject adjudicated data from a blinded Endpoint Committee of clinicians,[6] and the Court's exclusion of Dr. Jewell's reanalysis was neither clearly erroneous nor manifestly unjust.

C. Conclusion

Plaintiffs' motion for reconsideration (Dkt. No. 1292) is **GRANTED IN PART AND DENIED IN PART**. CMO 54 is amended to delete the last two sentences of footnote 13, to delete footnote 28, and to delete the first 5.5 lines of the first full paragraph on page 23, as explained above. The motion is otherwise **DENIED**.

AND IT IS SO ORDERED.

Richard Mark Gergel
United States District Court Judge

February 29, 2016
Charleston, South Carolina

[6] As explained in CMO 54, randomized controlled trials have pre-specified adjudication processes for determining whether certain events have taken place (i.e., whether certain endpoints have been reached) for the very purpose of ensuring reliable and valid results in those determinations and to safeguard against bias.