UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

MARY K. JONES, Individually and on Behalf of All Others Similarly Situated, Plaintiff, v. PFIZER INC., et al., Defendants.	Civil Action No. 1:10-cv-03864-AKH Hon. Alvin K. Hellerstein ECF Case

MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION *IN LIMINE* NO. 2 TO EXCLUDE PLAINTIFFS' DESIGNATED EXPERTS MEREDITH ROSENTHAL AND CHRISTOPHER BAUM

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Plaintiffs' designated expert Meredith Rosenthal proposes to testify that Pfizer earned over $2 billion in profits caused by "off-label promotion" of Bextra, Geodon, Zyvox, and Lyrica.[1] Ms. Rosenthal, who is not a medical doctor and has no medical background, testified at her deposition that to develop this opinion, she relied on the medical expertise of Dr. Stan Finkelstein, a physician who works with Ms. Rosenthal's litigation consulting firm. As detailed during her deposition, Ms. Rosenthal "felt that [she] needed clinical expertise" to conduct her analysis and "deferred to [Dr. Finkelstein's] judgment" in making decisions that significantly affected her opinions.[2] Ultimately, she based a number of her conclusions in this case on Dr. Finkelstein's "clinical opinion."[3] However, Plaintiffs did not provide a Rule 26 expert report from Dr. Finkelstein. Indeed, they did not even disclose his existence or the fact that his "expertise" formed the bases of the opinions Ms. Rosenthal intends to offer at trial—until Ms. Rosenthal was asked at her deposition whether she consulted with any medical doctors.[4] Her expert report is devoid of any mention of Dr. Finkelstein, his purported "expertise," or the substance of his contributions in this case. There is nothing to indicate that his input was considered by Ms. Rosenthal, much less that it formed the "basis and reasons" for a number of her opinions, as required by Rule 26.

Plaintiffs' failure to provide an expert report from Dr. Finkelstein mandates the exclusion of Ms. Rosenthal—and her counterpart, Christopher Baum, who supplied the econometric models used by Ms. Rosenthal in forming her opinions—from trial. Rule 26 clearly states that an expert like Ms. Rosenthal, who is being offered pursuant to Rule 702, must prepare a written

[1] Dec. 10, 2014 Declaration of Amanda A. MacDonald ("Dec. 10, 2014 MacDonald Decl.") Ex. XX-2 (June 10, 2014 Expert Report of Dr. Meredith Rosenthal ("Rosenthal Rep.") 73, Table 8).

[2] Dec. 10, 2014 MacDonald Decl. Ex. OO-2 (Rosenthal (Sept. 11, 2014) Dep. 92:18–20, 121:7–15).

[3] Dec. 10, 2014 MacDonald Decl. Ex. OO-2 (Rosenthal (Sept. 11, 2014) Dep. 126:7–12).

[4] Dec. 10, 2014 MacDonald Decl. Ex. OO-2 (Rosenthal (Sept. 11, 2014) Dep. 23:23–24:11).

report that contains "a complete statement of all opinions the witness will express and the basis and reasons for them" and "the facts or data considered by the witness in forming them." Fed. R. Civ. P. 26(a)(2)(B)(i), (ii). The absence of such a disclosure requires her preclusion at trial. *See* Fed. R. Civ. P. 37(c)(1) (where party "fails to provide information or identify a witness as required by Rule 26(a) or (e), the party is not allowed to use that information or witness to supply evidence . . . at a trial"); *see also Giladi v. Strauch*, No. 94 CIV. 3976 RMBHBP, 2001 WL 388052, at *3 (S.D.N.Y. Apr. 16, 2001) ("The automatic sanction for a violation of Rule 26(a) is preclusion." (quotation marks omitted)). Here, Ms. Rosenthal did not disclose the "basis and reasons" for her most fundamental opinions, necessitating her exclusion from trial.

The opinions of Ms. Rosenthal (and Mr. Baum, who built his econometric models using Ms. Rosenthal's foundational assumptions) are further inadmissible because they rely in significant part on the conclusions of Dr. Finkelstein—conclusions that are beyond Ms. Rosenthal's expertise. Such reliance is improper. *Faulkner v. Arista Records LLC*, No. 07 CIV. 2318 LAP, 2014 WL 4547824, at *18 (S.D.N.Y. Sept. 15, 2014) (testimony of expert who "admittedly relied on another's expertise to produce his opinion" is "excludable as conduit testimony from an expert on a matter outside his field of expertise"); *see also Dura Auto. Sys. of Indiana, Inc. v. CTS Corp.*, 285 F.3d 609, 615 (7th Cir. 2002) (excluding expert whose own opinions were based on "discretionary choices" of undisclosed experts that were "beyond the scope of [the disclosed expert's] expertise"). Moreover, the unexplained, untested, and contradictory data supplied by Dr. Finkelstein and relied on by Ms. Rosenthal and Mr. Baum render their opinions unreliable and inadmissible under Federal Rule of Evidence 702. Finally, the opinions of these purported experts are irrelevant to Plaintiffs' securities claims and unfairly prejudicial.

Accordingly, pursuant to Federal Rules of Civil Procedure 26 and 37 as well as Federal Rules of Evidence 401, 402, 403, and 702, Defendants respectfully submit this motion *in limine* to exclude opinions and testimony of Ms. Rosenthal and Mr. Baum.

BACKGROUND

Ms. Rosenthal, a professor of health care economics, purports to determine the amount of revenue attributable to Defendants' alleged "fraudulent" behavior by imagining an "economic picture of what would have happened" if Pfizer had not promoted Bextra, Geodon, Lyrica, and Zyvox off-label.[5] To create that "picture" for Bextra, Geodon, and Lyrica,[6] Ms. Rosenthal "assumed" that in a world without off-label marketing, "Pfizer's sales force would have marketed [the drugs] solely to physicians who treat the conditions indicated" on their labels.[7] To determine the "physicians who treat the conditions indicated," Ms. Rosenthal divided dozens of medical specialties into two groups: those specialties she believes "typically" treat the on-label conditions and those she believes do not.[8] Next, she added up all of the money Pfizer spent on marketing the products to the specialties she feels do not treat the indicated conditions (which she refers to as "challenged" specialties) to calculate Pfizer's "off-label detailing" and fed that

[5] Dec. 10, 2014 MacDonald Decl. Ex. XX-2 (Rosenthal Rep.) ¶¶ 37, 55, 72, 85, 103.

[6] Ms. Rosenthal did not use econometric analysis or input from Mr. Baum to estimate Pfizer's alleged profit from off-label marketing of Zyvox. Rather, she purports to "adapt the damage methodology" used by Pfizer's government investigations attorneys in an earlier case to calculate these purported profits. Dec. 10, 2014 MacDonald Decl. Ex. XX-2 (Rosenthal Rep.) ¶ 103.

[7] Dec. 10, 2014 MacDonald Decl. Ex. XX-2 (Rosenthal Rep.) ¶¶ 55, 72, 85.

[8] Dec. 10, 2014 MacDonald Decl. Ex. XX-2 (Rosenthal Rep.) ¶¶ 55, 72, 85; Dec. 10, 2014 MacDonald Decl. Ex. OO-2 (Rosenthal (Sept. 11, 2014) Dep. 41:3–7 ("You divided the world into two different types of medical specialties, challenged and nonchallenged, for each of these three medications, correct? A. Yes, I did.")).

number to Mr. Baum.[9] She also assumes that in a world without off-label promotion, Pfizer would not have distributed any free 20-mg samples of Bextra, even to non-challenged specialties, and provided that assumption to Mr. Baum, as well.[10] Finally, using IMS National Disease and Therapeutic Index (NDTI) data, she created a list of "competitor" drugs for Bextra, Geodon, and Lyrica for use by Mr. Baum in developing his models.[11]

Mr. Baum, relying on the assumptions and information given to him by Ms. Rosenthal,[12] created econometric models purportedly showing the effect of promotional spending, including the provision of free 20-mg samples, on the sales of the products.[13] He then plugged the amount of Pfizer's "off-label" promotional spending (as calculated by Ms. Rosenthal) into his models to determine how many pills ("inflated units") Pfizer sold as a result of that spending and the provision of 20-mg samples.[14] Ms. Rosenthal then does "very simple accounting" using the number of "inflated units" and Pfizer's financial data[15] to calculate the "profit earned from sales caused by off-label promotion"—over $1.5 billion for Bextra, Lyrica, and Geodon.[16]

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[9] Dec. 10, 2014 MacDonald Decl. Ex. XX-2 (Rosenthal Rep.) ¶¶ 37; Dec. 10, 2014 MacDonald Decl. Ex. OO-2 (Rosenthal (Sept. 11, 2014) Dep. 44:4–19 ("Q: And then once you make that estimate, then you provide those numbers to Dr. Baum, in this case, to run his econometric model? A. That's correct.")).

[10] Dec. 10, 2014 MacDonald Decl. Ex. XX-2 (Rosenthal Rep.) ¶¶ 57–58.

[11] Dec. 10, 2014 MacDonald Decl. Ex. XX-2 (Rosenthal Rep.) ¶ 38.

[12] Dec. 10, 2014 MacDonald Decl. Ex. TT-2 (June 10, 2014 Expert Report of Dr. Christopher F. Baum ("Baum Rep.") at 1 ("In preparing these econometric estimates, I have relied on Dr. Meredith Rosenthal's description of the pharmaceutical market, the history of each drug as well as the determination of the but-for assumptions appropriate for this case and the drugs at issue.").

[13] Dec. 10, 2014 MacDonald Decl. Ex. TT-2 (Baum Rep.) ¶¶ 17–24.

[14] Dec. 10, 2014 MacDonald Decl. Ex. TT-2 (Baum Rep.) ¶¶ 25–26 (computing "the change in sales" using the "but-for values of promotion for each of the drugs that were provided to [him] by Dr. Rosenthal").

[15] Dec. 10, 2014 MacDonald Decl. Ex. OO-2 (Rosenthal (Sept. 11, 2014) Dep. 45:2–20).

[16] Dec. 10, 2014 MacDonald Decl. Ex. XX-2 (Rosenthal Rep.) 73, Table 8.

In sum, the hundreds of pages of opinions, charts, tables, data, and models in these two experts' reports all boil down to the amounts of assumed "off-label" spending by Pfizer that Ms. Rosenthal told Mr. Baum to plug into his models. If these amounts change (i.e., if Ms. Rosenthal categorizes the medical specialties differently), the number of "inflated" units changes, as does the "profit" allegedly earned by Pfizer. The significance of this number makes the grouping of medical specialties as on- or off-label the "most important" part of Ms. Rosenthal's analysis—which she herself conceded.[17] And as Ms. Rosenthal detailed at her deposition, she lacks the requisite expertise to make those medical specialty classifications. Rather, she thought it "important" to have "clinical expertise" to "review [her] categorization of th[o]se specialties" that allowed her to determine the amounts of "off-label detailing."[18] She also required medical expertise to interpret NDTI codes in developing the list of "competitor" drugs of Bextra, Geodon, and Lyrica that Mr. Baum relied on in creating his models.[19] For that expertise, Ms. Rosenthal relied on Dr. Stan Finkelstein.

Dr. Finkelstein, who is not referenced in Ms. Rosenthal's or Mr. Baum's reports and whose existence was not revealed to Defendants until Ms. Rosenthal's deposition on September

[17] Dec. 10, 2014 MacDonald Decl. Ex. OO-2 (Rosenthal (Sept. 11, 2014) Dep. 94:12-19 (" Q: . . . [T]his choice about what you include as challenged or nonchallenged is the most important decision you had to make in your model because that dictates what amount of detailing dollars are going to be included in the off-label category, correct? . . . A: It was certainly an important decision."); *id.* at 95:11–16 ("A: In general, I would say quantifying the level of off-label marketing effort was the first step in what I did, that was – without that, I could not have calculated damages. So in that sense, it was the most important.")).

[18] Dec. 10, 2014 MacDonald Decl. Ex. OO-2 (Rosenthal (Sept. 11, 2014) Dep. 92:18–20, 133:2–6).

[19] Dec. 10, 2014 MacDonald Decl. Ex. OO-2 (Rosenthal (Sept. 11, 2014) Dep. 25:8–19 ("Dr. Finkelstein helped me in two particular sets of decisions that I made. He provided clinical input when I was reviewing the diagnosis codes and alternative therapies in constructing the list of competitor drugs for each of the drugs that Dr. Baum used regression models to estimate impact. He also helped me review the specialties in the promotional data with regard to the appropriateness of including or excluding those specialists in my measure of off-label detailing.").

11, 2014—despite having billed 47 hours on the case prior to August 31, 2014[20]—is a "general internist."[21] Ms. Rosenthal testified that he was "qualified to opine on pharmaceutical treatment broadly,"[22] but she was unable to provide support for this assertion or answer basic questions about his clinical experience:

> Q: Is he an expert in the treatment of the diseases for which these four medications are indicated? . . .
>
> A: I don't know if he would call himself an expert, no.[23]
>
> ***
>
> Q: How often has Dr. Finkelstein interacted with anesthesiologists?
>
> A: I don't know.[24]
>
> ***
>
> Q: And does he understand—"he" meaning Dr. Finkelstein—the clinical norms of coding practices for orthopedists and rheumatologists?
>
> A: I think you would have to ask Dr. Finkelstein.[25]
>
> ***
>
> Q: What experience does Dr. Finkelstein have in treating psychiatric disorders?
>
> A: I can't speak to his experience.[26]
>
> ***
>
> Q: Has he ever treated patients for psychiatric disorders?

[20] Dec. 10, 2014 MacDonald Decl. Ex. OO-2 (Rosenthal (Sept. 11, 2014) Dep. 35: 9-14).

[21] Dec. 10, 2014 MacDonald Decl. Ex. OO-2 (Rosenthal (Sept. 11, 2014) Dep. 24:9–11).

[22] Dec. 10, 2014 MacDonald Decl. Ex. OO-2 (Rosenthal (Sept. 11, 2014) Dep. 24:12–18).

[23] Dec. 10, 2014 MacDonald Decl. Ex. OO-2 (Rosenthal (Sept. 11, 2014) Dep. 24:19–25:4).

[24] Dec. 10, 2014 MacDonald Decl. Ex. OO-2 (Rosenthal (Sept. 11, 2014) Dep. 98:22–99:2).

[25] Dec. 10, 2014 MacDonald Decl. Ex. OO-2 (Rosenthal (Sept. 11, 2014) Dep. 124:6–14).

[26] Dec. 10, 2014 MacDonald Decl. Ex. OO-2 (Rosenthal (Sept. 11, 2014) Dep. 158:1–5).

A: I don't know.[27]

According to Ms. Rosenthal, she needed Dr. Finkelstein's "clinical expertise" to "ascertain which clinical specialties are involved in decision-making for particular conditions" and are therefore "non-challenged" specialties for that condition.[28] Ms. Rosenthal did not appear to know how Dr. Finkelstein developed his opinions as to on- and off-label specialties;[29] as Dr. Finkelstein did not submit a report in this case, Defendants have no way of knowing this information. As Ms. Rosenthal testified,

> Again, these specific decisions about which of these vaguer terms to include or exclude as on or off label were based on Dr. Finkelstein's clinical expertise. I cannot, as I sit here now, recall his rationale for each and every one of them.[30]

Nor could Ms. Rosenthal articulate an objective basis for the determinations she and Dr. Finkelstein made on these issues—indeed, for some of the specialties she and Dr. Finkelstein categorized as challenged, a majority of the prescriptions written were for *on-label* indications.[31]

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[27] Dec. 10, 2014 MacDonald Decl. Ex. OO-2 (Rosenthal (Sept. 11, 2014) Dep. 158:10–14).

[28] Dec. 10, 2014 MacDonald Decl. Ex. OO-2 (Rosenthal (Sept. 11, 2014) Dep. 88:1–4; *see also id.* 92:18–20 ("I felt that I needed clinical expertise to review my categorization of these specialties. I believed it was important.").

[29] *See, e.g.*, Dec. 10, 2014 MacDonald Decl. Ex. OO-2 (Rosenthal (Sept. 11, 2014) Dep. 118:8-21 ("Q: But generally, what input did you get from Dr. Finkelstein with respect to interpretation of the codes for Bextra? A: I can't tell you code by code, but he reviewed all of the codes."), 120:17-121:15 ("Q: In other words, there were certain codes, whereas you put it earlier, it was unclear as to whether it would be off-label or on-label use, and you consulted with Dr. Finkelstein about those and deferred to his judgment as to where to include it as off label or on label, correct? . . . A: Yes, that's correct.")); *see also id.* 24:19–25:4; 214:1–215:9.

[30] Dec. 10, 2014 MacDonald Decl. Ex. OO-2 (Rosenthal (Sept. 11, 2014) Dep. 123:1–6); *see also id.* at 214:12–215:9 ("Q: Looking at table five in the specialty of cardiology, do you know why cardiologists would prescribe Lyrica on label the majority of the time? A. I do not. Q. Did you have any discussion with Dr. Finkelstein about that? A. I don't recall.").

[31] *See* Dec. 10, 2014 MacDonald Decl. Ex. OO-2 (Rosenthal (Sept. 11, 2014) Dep. 89:11-94:2 (classification was not based on a fixed, bright-line percentage of off-label promotions written by a particular specialty)); Dec. 10, 2014 MacDonald Decl. Ex. XX-2 (Rosenthal Rep.) at 59, Table 5 (identifying cardiology and rheumatology as specialties detailed for off-label promotion despite off-label prescription rates, respectively, of 48.9% and 44%)).

Rather, their opinions about challenged specialties came down to judgment calls and deference on Ms. Rosenthal's part to Dr. Finkelstein's expertise:

> And so where I had questions about whether a specialty should be appropriately included or excluded, those are the ones that I spent most of the time talking over with Dr. Finkelstein and also reviewing the extent to which the evidence supporting the complaint was focused on marketing to those particular specialties.[32]

Ms. Rosenthal used these judgment calls by Dr. Finkelstein, together with the percentage of "off-label" prescriptions written by each specialty (for which she also required Dr. Finkelstein's assistance to determine which NDTI codes were on- and off-label),[33] and Plaintiffs' allegations in the case (which she assumed would be proven at trial)[34] to determine which specialties were "challenged."

The undisclosed conclusions reached by Dr. Finkelstein had an enormous impact on Ms. Rosenthal's ultimate conclusion that Pfizer's "off-label" profit exceeded $2 billion. As Ms. Rosenthal admitted, a change in the decision to define even a single specialty as challenged or not challenged could have radically altered the amount of off-label spending Mr. Baum put into his models and the resulting "inflated unit" calculation. To take just one example, Ms. Rosenthal, based on Dr. Finkelstein's unexplained judgment, categorized orthopedic surgery as a "challenged" specialty with respect to Bextra and Lyrica.[35] Had Dr. Finkelstein decided otherwise, it would have reduced Ms. Rosenthal's estimate of Pfizer's off-label profits by ***51.2***

[32] Dec. 10, 2014 MacDonald Decl. Ex. OO-2 (Rosenthal (Sept. 11, 2014) Dep. 90:18–91:1; *see also id.* 91:20–92:3 ("I felt it was appropriate to consult with Dr. Finkelstein particularly, again, for specialties where it was not clear that, for example, as in otolaryngology where 100 percent of prescriptions were off label. I believe it is appropriate to have clinical input at this stage of the analysis.").

[33] Dec. 10, 2014 MacDonald Decl. Ex. OO-2 (Rosenthal (Sept. 11, 2014) Dep. 118:8–14).

[34] Dec. 10, 2014 MacDonald Decl. Ex. OO-2 (Rosenthal (Sept. 11, 2014) Dep. 62:24–63:8).

[35] Dec. 10, 2014 MacDonald Decl. Ex. XX-2 (Rosenthal Rep.) at 38, Table 1, 59, Table 5.

percent for Bextra and ***43.8 percent*** for Lyrica.[36] Accordingly, Dr. Finkelstein's undisclosed opinions are the single most important basis for Ms. Rosenthal's conclusions in this case.

ARGUMENT

I. Rosenthal And Baum Must Be Excluded Because Their Opinions Rely Upon the Expertise of Another Undisclosed Expert.

Plaintiffs' failure to provide a Rule 26 expert report from Dr. Finkelstein and the fact that Ms. Rosenthal relied on his opinions in developing her own contravenes both the disclosure obligations of Rule 26(a) and the parties' stipulated agreement regarding expert discovery.[37] Rule 26(a)(2) requires that retained experts such as Ms. Rosenthal and Mr. Baum prepare a written report that contains "a complete statement of all opinions the witness will express and the basis and reasons for them" and "the facts or data considered by the witness in forming them." Fed. R. Civ. Proc. 26(a)(2)(B)(i), (ii). Ms. Rosenthal's report states that certain medical specialties are not likely to prescribe for off-label indications, but nowhere indicates that the categorizations reflected in her report are not her own "opinion," but rather reflect determinations by an undisclosed medical doctor, Dr. Finkelstein. The report thus fails to identify the "basis and reasons" for her opinions. Plaintiffs' failure to comply with the disclosure requirements of Rule 26(a)(b)(2) requires exclusion of Ms. Rosenthal as well as Mr. Baum, whose opinions depend entirely on Ms. Rosenthal's input. *See* Fed. R. Civ. P. 37(c)(1); *Giladi*, 2001 WL 388052, at *3–7 (precluding testimony of two experts for failing to comply with Rule 26 disclosures) (citation omitted).

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[36] Dec. 10, 2014 MacDonald Decl. Ex. OO-2 (Rosenthal (Sept. 11, 2014) Dep. 135:18–138:17).

[37] Dec. 10, 2014 MacDonald Decl. Ex. BB-3 (Stipulation Concerning Expert Discovery, dated April 2, 2014, ¶ 4) ("To the extent that a Testifying Expert relies upon conclusions or opinions of another expert, those conclusions or opinions shall also be disclosed in the Testifying Expert's report (or referenced, if the conclusions or opinions are disclosed in another Testifying Expert's report).").

Ms. Rosenthal's undisclosed reliance on Dr. Finkelstein also violates the well-settled rule—which Plaintiffs themselves have acknowledged[38]—that one expert cannot testify as a "conduit" for the opinion of another undisclosed expert on which the first expert's opinion is based, because "an expert seeking to present opinion testimony to a jury must be 'qualified by skill, experience, training, or education.'" *Faulkner*, 2014 WL 4547824, at *17 (quoting *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579, 588 (1993) (quoting Fed. R. Evid. 702)). As a result, a witness who lacks the relevant expertise cannot testify regarding the opinion of another expert on which she has relied in forming her own opinion. *See id.* at *18–19 (excluding testimony of expert witness who "was not the sole designer" of damages model as to which he opined because he did not possess required expertise to explain it); *Malletier v. Dooney & Bourke, Inc.*, 525 F. Supp. 2d 558, 664 (S.D.N.Y. 2007) ("[T]he expert witness must in the end be giving his *own* opinion. He cannot simply be a conduit for the opinion of an unproduced expert."). For example, in *Dura*, Judge Posner affirmed the district court's decision to exclude an expert who formed his opinions based on mathematical modeling performed by colleagues as to which he himself was unqualified to opine. 285 F.3d at 615. As the court explained, "[w]ithout [the] testimony [of the previously undisclosed underlying experts] explaining and justifying the discretionary choices that they made, [excluded expert's] testimony would have rested on air." *Id*.

Here, there is no justification for Plaintiffs' omission, nor can it possibly be considered "harmless." To the contrary, it lies at the heart of the "most important" aspect of Ms. Rosenthal's analysis,[39] and thus infects Mr. Baum's as well. Dr. Finkelstein's contributions were, by Ms. Rosenthal's admission, critical. She explained that "his input absolutely influenced

[38] *See* Plfs.' Mot. for Partial Summ. J. at 39.

[39] Dec. 10, 2014 MacDonald Decl. Ex. OO-2 (Rosenthal (Sept. 11, 2014) Dep. 95:11-16).

how I chose to select drugs and specialists."[40] As a result of her failure to identify his role, Defendants had no opportunity to depose Dr. Finkelstein and discover the bases of his opinions. Accordingly, the key classification decisions underlying the assertions of both Ms. Rosenthal and Mr. Baum are unexplained, the source of those decisions is untested, and the opinions of Ms. Rosenthal and Mr. Baum rest, as the court observed in *Dura*, "on air." 285 F.3d at 615. The proper remedy is to preclude them from testifying at trial.

II. Rosenthal and Baum Must Be Excluded Because Their Testimony Lacks the Reliability Required By Rule 702.

The opinions of Ms. Rosenthal and Mr. Baum also must be excluded for the independent reason that they do not satisfy the reliability requirements of Rule 702. An expert witness may not testify unless his or her testimony "is based on sufficient facts or data," "is the product of reliable principles and methods" and "the expert has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702(b)-(d). Under this standard, the trial court "must determine whether the proffered testimony has a sufficiently reliable foundation to permit it to be considered.'" *Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 265 (2d Cir. 2002). "[*A*]*ny* step that renders the [expert's] analysis unreliable under the *Daubert factors renders the expert's testimony inadmissible*." *Id*. at 267. Plaintiffs cannot carry that burden as to either Ms. Rosenthal or Mr. Baum.

Here, as noted above, the "most important" feature of Ms. Rosenthal's analysis—the categorization of physician specialties as "challenged" or "non-challenged"—cannot be shown to have been based on "reliable principles and methods" that have been "reliably applied" because those determinations were made in part by Dr. Finkelstein, and we know nothing about the

[40] Dec. 10, 2014 MacDonald Decl. Ex. OO-2 (Rosenthal (Sept. 11, 2014) Dep. 26:3-6); *see also id*. at 24:12–25:5–19; 54:5–13; 58:12–21; 91:7–92:20; 120:24–121:15.

"principles" or "methods" that he applied in making those determinations. *See supra* Part I. Indeed, what little we do know about Dr. Finkelstein's categorizations is that they contradict the NDTI data Ms. Rosenthal relied on in that many of the specialties he deemed "off-label" wrote substantial numbers of on-label prescriptions.[41] Accordingly, Ms. Rosenthal's conclusions as to the off-label profits attained by Pfizer are inherently unreliable and inadmissible. Mr. Baum's opinions, by virtue of relying entirely on foundational assumptions and information supplied by Ms. Rosenthal, similarly must be excluded.

III. Rosenthal and Baum Should Be Excluded Because Their Opinions Are Irrelevant, Will Confuse the Jury and Delay the Trial, and Will Unfairly Prejudice Defendants.

Finally, even if the testimony of Rosenthal and Baum were not inadmissible and improper under Rule 702 for the reasons discussed above, it should be excluded under Rules 402 and 403 on the grounds that it is irrelevant, will confuse the jury and unduly complicate and delay the trial, and will unfairly prejudice the jury against Defendants. As Defendants have explained elsewhere, Plaintiffs' should not be permitted to turn this securities fraud case into a lawsuit focused on Pfizer's alleged marketing improprieties. *See* Defendants' Motions *in Limine* No. 5 at 7–11. Here, the central conclusion of Ms. Rosenthal and Mr. Baum is that Pfizer made over $2 billion in profits as a result of its "fraudulent" conduct. But this calculation is irrelevant to Plaintiffs' securities disclosure claims. Ms. Rosenthal does not contend that her calculations provide any indication of the "probable" liability that Pfizer would incur in connection with any of the government investigations. Her calculations bear no resemblance to amounts of the actual fines and penalties that Pfizer and the Department of Justice agreed would be attributed to claims

[41] *E.g.,* Dec. 10, 2014 MacDonald Decl. Ex. XX-2 (Rosenthal Rep.) at 59, Table 5 (identifying cardiology and rheumatology as specialties detailed for off-label promotion despite off-label prescription rates, respectively, of 48.9% and 44%).

regarding the marketing of the four products in question.[42] Because the opinions of Ms. Rosenthal and Mr. Baum lack a "valid connection to the pertinent inquiry," they must be excluded. *See In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 540 (S.D.N.Y. 2004).

Further, to permit Plaintiffs to introduce extensive opinion testimony from two economists on the subjects of Pfizer's marketing and profits would pose a clear risk of jury confusion as to the matters truly at issue in this case. In response, Defendants likely would be required to offer fact evidence and expert testimony from their own economist in rebuttal—increasing the risk of jury confusion and needlessly lengthening and complicating the trial. Expert testimony on these subjects is particularly unnecessary given that there is no dispute here that certain employees violated Pfizer's marketing policies. None of this evidence addresses the key issue of whether Pfizer's securities disclosures were misleading or defrauded investors, and thus is properly excludable under Rule 403. *See*, *e.g.*, *United States v. Hatfield*, 685 F. Supp. 2d 320, 324 (E.D.N.Y. 2010) (rejecting prejudicial evidence that would result in delay of "conducting a 'mini-trial' as to whether Defendants lied . . . while adducing no evidence concerning whether Defendants committed the charged crimes."). It also poses a significant risk of unfairly prejudicing the jury against Pfizer by focusing attention on alleged marketing violations, particularly given the eye-catching magnitude of the (unfounded) billion-dollar estimated revenue and profit calculations, and thus should be excluded under Rule 403 as well.

CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Court grant their motion *in limine* to exclude Ms. Rosenthal's and Mr. Baum's opinions and testimony at trial.

[42] Dec. 10, 2014 MacDonald Decl. Ex. OO-2 (Rosenthal (Sept. 11, 2014) Dep. 11:2-19:18).

Dated: Washington, D.C.
December 10, 2014

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that, on December 10, 2014, the foregoing Memorandum in Support of Defendants' Motion *in Limine* No. 2 to Exclude Plaintiffs' Designated Experts Meredith Rosenthal and Christopher Baum was filed with the Court through the CM/ECF system and thereby served to all parties of record.

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Case Number: 1:10-cv-03864-AKH
Filer: Frank D'Amelio
Jeffrey B. Kindler
Alan G. Levin
Henry A. McKinnell
Pfizer, Inc.
Ian C. Read
Allen Waxman
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MEMORANDUM OF LAW in Support re: [344] MOTION in Limine *No. 2 To Exclude Plaintiffs' Designated Experts Meredith Rosenthal and Christopher Baum*. . Document filed by Frank D'Amelio, Jeffrey B. Kindler, Alan G. Levin, Henry A. McKinnell, Pfizer, Inc., Ian C. Read, Allen Waxman. (Collogan, Lauren)

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