UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

MARY K. JONES, Individually and on Behalf of All Others Similarly Situated, Plaintiff vs. PFIZER INC., et al., Defendants.	Civil Action No. 1:10-cv-03864-AKH CLASS ACTION PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANTS' MOTION *IN LIMINE* NO. 2 TO EXCLUDE PLAINTIFFS' DESIGNATED EXPERTS MEREDITH ROSENTHAL AND CHRISTOPHER BAUM

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Plaintiffs hereby oppose defendants' Motion *in Limine* ("MIL") No. 2 seeking to exclude the expert testimony of Dr. Meredith Rosenthal ("Professor Rosenthal") and Dr. Christopher Baum ("Professor Baum").

I. INTRODUCTION

Pfizer itself refers to Professor Rosenthal as a "credible local voice."[1] She is, without a doubt, an expert in developing economic approaches to calculating the impact of off-label promotion, including through regression analyses. She has testified in numerous cases, including on behalf of the government and against Pfizer, conducted a number of studies relating to prescription drugs, and published numerous peer-reviewed journal articles and books. Expert Report of Dr. Meredith Rosenthal ("Rosenthal Report"), ¶¶2-3 (Radcliffe Decl., Ex. 2). Her methodology of identifying portions of detailing dollars as a proxy for off-label marketing is generally accepted. *See, e.g.*, *In re Neurontin Mktg. & Sales Practices Litig.*, 712 F.3d 21, at 57-58 (1st Cir. 2013) (ruling that "[t]he use of promotional spending as a variable was a reasonable 'fit' to represent Pfizer's fraud").

Professor Rosenthal was "retained by counsel for plaintiffs to examine whether Pfizer's allegedly unlawful marketing and promotional practices had an impact on Pfizer's revenue and profits for the drugs identified in the *Complaint*." Rosenthal Report (Executive Summary) at 1.[2] She also was "asked to determine what portion of Pfizer revenue and profits was due to the allegedly unlawful behavior." *Id.* As set forth in her report, she "considered: (1) the economic incentives for off-label promotion; (2) whether empirical evidence and theory suggests that off-label promotion

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[1] *See* Declaration of Willow E. Radcliffe in Support of Plaintiffs' Memorandum of Law in Opposition to Defendants' Motion *in Limine* No. 2 to Exclude Plaintiffs' Designated Experts Meredith Rosenthal and Christopher Baum ("Radcliffe Decl."), Ex. 1 at LYRC-00840277, filed concurrently herewith.

[2] "*Complaint*" or "FAC" refers to the First Amended Consolidated Class Action Complaint for Violations of the Federal Securities Laws, filed April 15, 2011 (Dkt. No. 71).

could have increased Pfizer's revenue and profits; and (3) whether the impact of off-label promotion can be quantified using standard methods." *Id*. The testimony bears directly on defendants' fraud and the elements of plaintiffs' claims for violations of §10(b) the Securities Exchange Act of 1934. It is also based on "sufficient facts" and "data" as required by Federal Rule of Evidence 702, including promotional expenditures by Pfizer, data reflecting prescriptions by diagnosis code (ICD-9 data)[3] and a host of evidence of off-label promotion, including the detailing of physician specialties for off-label uses.

The irony – that defendants claim that they will be prejudiced if a jury hears of the availability of economic methodologies to estimate Pfizer's exposure for off-label marketing, and the fact that the resulting estimated figure is in the billions when defendants failed to disclose to investors essentially the same information during the Class Period (January 19, 2006 to January 23, 2009) – should not be lost on the Court.[4] At trial, plaintiffs will be required to prove that defendants made materially false and misleading statements, including that Pfizer had a long legacy of complying with healthcare law, which provided it with a competitive advantage to its peers. Further, plaintiffs will be required to prove that the Company failed to timely reserve for its contingent liabilities stemming from the government investigations of off-label promotion of Bextra and other drugs. The Federal Rules of Civil Procedure favor the admission of evidence that has "any tendency

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[3] *See* Rosenthal Report, ¶38 n.92 (explaining that ICD9 data refers to recognized codes used by physicians and hospitals to indicate diagnosis and indications).

[4] *Compare* FAC ¶46 ("defendants knew throughout the Class Period that Pfizer faced a significant adverse material risk to its financial well-being, and even to its existence, as a result of the illegal promotion of drugs which they concealed from investors and for which they failed to reserve for in Pfizer's financial statements filed with the SEC"), *and id*., ¶79(b) ("defendants were able to estimate the possible loss or range of loss"), *with* Dkt. No. 345 at 13 (Rosenthal and Baum's testimony "poses a significant risk of unfairly prejudicing the jury against Pfizer . . . given the eye-catching magnitude of the [] billion-dollar estimated revenue and profit calculations").

to make a fact more probable or less probable than it would without the evidence [and] the fact is of consequence in determining the action." Fed. R. Evid. 401; *Daubert v. Merrell Dow Pharms.*, 509 U.S. 579, 591 (1993) (the "'expert testimony proffered in the case is sufficiently tied to the facts of the case that it will aid the jury in resolving the factual dispute'").

The thrust of defendants' motion is that Professor Rosenthal's and Professor Baum's testimony should be excluded because of purported "undisclosed" reliance on the clinical input of Dr. Stan Finkelstein in reviewing physician specialties Professor Rosenthal selected. Not only do defendants overstate the role of Dr. Finkelstein as to the opinions at issue, their motion misses the mark. Economic experts, like Professor Rosenthal, often rely on input from consultants.[5] "It is common in technical fields for an expert to base an opinion in part on what a different expert believes on the basis of expert knowledge not possessed by the first expert; and it is apparent from the wording of Rule 703 that there is no general requirement that the other expert testify as well." *Dura Auto. Sys. of Indiana, Inc. v. CTS Corp.*, 285 F.3d 609, 613 (7th Cir. 2002).[6] This is particularly true in this case, where Professor Rosenthal's economic approach is one in which she is taking allegations that she assumes a trier of fact would find occurred (*i.e.*, off-label promotion to physicians).

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[5] Defendants' economic expert, Sean Nicholson, relied on several individuals at Cornerstone Research in preparing his rebuttal report who billed more than $836,000 assisting Professor Nicholson. Radcliffe Decl., Ex. 3. Further, defendants' loss causation expert relied on Cornerstone Research to perform regression analysis and Cornerstone billed $1.7 million for that consulting work. Radcliffe Decl., Ex. 4.

[6] Defendants' reliance on *Dura* to exclude the testimony of plaintiffs' experts is unfounded. There, the expert (Valkenburg) relied on the modeling that had been done by others. *Dura*, 285 F.3d at 611-12. Here, there is no question that the economic approach and the econometric modeling were created and done by Professors Rosenthal and Baum. The review, as part of a multi-part approach, of Professor Rosenthal's selection of physician specialties as part of her analysis, by Dr. Finkelstein.

Moreover, defendants, in the parties' Stipulation Concerning Expert Discovery, expressly reserved their right to seek to depose any "consulting experts," which they failed to do.[7] And while their instant motion decries the importance of Dr. Finkelstein and proclaims that they had "no opportunity to depose Dr. Finkelstein," it is telling that not once between Professor Rosenthal's deposition, on September 11, 2014, and the close of expert discovery a month later, on October 15, 2014, or even before the filing of their motion *in limine*, did they seek to raise the issue about his deposition. The reality is, defendants never had any reason to depose Dr. Finkelstein.

Further, Professor Rosenthal does not rely in any way on Dr. Finkelstein for her expert opinions that "standard economic methods" were available to Pfizer to quantify the impact of defendants' alleged off-label promotional activities or that by using regression analysis such quantifications can be made. Nor did Professor Rosenthal rely on Dr. Finkelstein regarding the methodology she used to quantify the profits from the off-label promotion of Zyvox. Defendants' motion is merely a desperate attempt to keep a jury from hearing about the methodologies available to Pfizer to estimate off-label profits, methodologies that are reliable, probative, admissible, as well as based on sufficient facts and data. Fed. R. Evid. 401, 403, 702, 703. Consequently, defendants' MIL No. 2 should be denied.

II. PROFESSOR ROSENTHAL'S AND PROFESSOR BAUM'S OPINIONS ARE ADMISSIBLE, RELEVANT AND WILL BE HELPFUL TO A JURY

Professor Rosenthal is a health economist at the Harvard School of Public Health and an academic affiliate of Greylock McKinnon Associates. Rosenthal Report, ¶1. She has a Ph.D. in Health Policy (Economics Track) and her principal research interests relate to the economics of the

[7] *See* Stipulation Concerning Expert Discovery, dated April 2, 2014. The stipulation is referenced in Professor Rosenthal's deposition. Radcliffe Decl., Ex. 5 (Rosenthal Depo.) at 27:5-8 ("we have a stipulation in this case regarding testifying experts to rely on consultants").

health care industry, including pharmaceuticals. Rosenthal Report, ¶¶1, 4. She has published extensively and is undisputedly an expert in regression analysis to estimate the correlation between fraudulent promotion of drugs by pharmaceutical companies and the prescription of those drugs off-label. She has provided expertise in prior litigation concerning the allegations of improper promotion of at least 13 drugs, including Bextra. Rosenthal Report, ¶2. Her opinions have been accepted by many courts, including the First Circuit (over the objections of Pfizer), which noted that in accepting her opinion "courts have long permitted parties to use statistical data to establish causal relationships" in antitrust, employment discrimination, and other types of cases. *Neurontin Mktg. & Sales Practices Litig.*, 712 F.3d at 42; *see also In re Actiq Sales & Mktg. Practices Litig.*, No. 07-4492, 2014 U.S. Dist. LEXIS 98441, at *33, *64 (E.D. Pa. July 21, 2014) (overruling defendants' objections to Professor Rosenthal regarding her lack of experience with cost accounting and failing to include certain categories of costs and allowing her expert opinions). This practice is widely accepted by economic experts as a practice in their field and by other courts in accepting the methodology of economic experts. *See, e.g.*, *id*. at 43-44 (accepting Professor Rosenthal's approach in a RICO action and noting that Professor Rosenthal's assumption that the off-label marketing was fraudulent is well accepted in the antitrust context). Indeed, it is generally recognized that an economist giving expert testimony regarding a but-for world can assume the unlawful conduct occurred and that "evidence allowing the jury to make a 'just and reasonable estimate' of the 'probable' amount, although only 'approximate,' suffices."[8]

In this case, Professor Rosenthal constructed an economic approach known as a "but-for world" that allows for quantification of the difference between the experience in the but-for and

[8] *See, e.g.*, ABA Section of Antitrust Law, Proving Antitrust Damages: Legal and Economic Issues, Chapter 3, "Quantifying Damages," at 55 (2d ed. 2010) (Radcliffe Decl., Ex. 15).

actual worlds to determine the amount of damages.[9] Rosenthal Report, ¶¶32, 37. Her but-for world consists of Pfizer's promotional dollars that would have been expended by the company had it not engaged in ***any*** off-label promotional behavior. The difference between Pfizer's actual promotional expenditures and Professor Rosenthal's but-for world is an estimate of Pfizer's off-label promotional expenditures. *Id*., ¶¶37, 55, 72, 85. This allows for the estimation of sales resulting from off-label promotion as discussed below.

In creating the but-for world, Professor Rosenthal computes a proxy for the off-label promotional dollars expended by Pfizer by identifying certain physician specialties that Pfizer would not have targeted for promotional efforts had it ceased all off-label promotion. She identifies these physician specialties using a foundation of economic theory[10] combined with her experience, the allegations at issue in the case, empirical evidence explained in her report, the percentage of prescriptions written by these physicians that are on- or off-label, review of the ICD-9 diagnosis codes and input from Dr. Finkelstein. The challenged specialties serve as a proxy for Pfizer's off-label promotional expenditures.

Professor Baum has a PhD in Economics and is an expert in econometrics. Radcliffe Decl., Ex. 6 (Baum Depo.) at 13:18-25; Expert Report of Dr. Christopher F. Baum ("Baum Report"), ¶3 (Radcliffe Decl., Ex. 7). He is a Professor of Economics and Social Work at Boston College and an academic affiliate of Greylock McKinnon Associates. Baum Report, ¶1. He has taught in the fields of econometric methods, financial econometrics, applied econometrics and economic policy. *Id*., ¶2;

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[9] ABA, Quantifying Damages, at 55.

[10] In other words, identifying physician specialties using IMS data that have so few prescriptions that it would not make economic sense for Pfizer to direct its promotional dollars. Professor Rosenthal spoke directly about her "return on investment" approach in both the Rosenthal Report, ¶¶56, 86, and in her deposition. Radcliffe Decl., Ex. 5 (Rosenthal Depo.) at 89:23-91:6, 103:10-18, 140:14-19,146:14-19.

see also id., Attachment A. He has published numerous peer-reviewed articles in journals on economics, econometrics, finance and public health. *Id*., ¶2. His principal research interests relate to the use of applied econometric techniques for model development, including in the disciplines of economics and public health. *Id*., ¶1. For this case, he developed regression models for Bextra, Lyrica and Geodon using widely accepted econometric principles to estimate the impact of promotion on Pfizer's sales (both on- and off-label) after controlling for other factors that could impact sales. *See id*., Attachment C at ¶1; *see also* Radcliffe Decl., Ex. 5 (Rosenthal Depo.) at 145:4-16. He then applied the but-for world promotional expenditures developed by Professor Rosenthal to compute the inflated unit sales for the drugs resulting from off-label promotion. Baum Report, Attachment C at ¶¶27-28.

Professor Rosenthal then performed a basic mathematical calculation using Baum's models to quantify the revenues and profits for the drugs resulting from Pfizer's off-label promotional expenditures. Her estimates were conservative in that they only considered promotional detailing dollars and not promotional spending by Pfizer on other promotional efforts, including speakers and "educational" conferences. They also do not take into account potentially off-label messages to physicians who could be considered legitimate targets for conveying information on the labeled uses. *See, e.g.*, Rosenthal Report, ¶56. Further, she did not consider certain unsubstantiated superiority claims, despite evidence of such claims, in her calculations. *Id*., ¶86 n.273.

A. Professor Rosenthal's Expert Opinions and Testimony with Respect to Revenue and Profits Caused by Pfizer's Off-Label Promotion of Zyvox are Admissible and Probative

Professor Rosenthal's expert opinions with respect to Zyvox are essentially unchallenged.[11] In estimating the off-label promotion of Zyvox as it relates to Pfizer's unsubstantiated superiority

[11] Professor Baum does not provide opinions with respect to Zyvox. Baum Report, ¶4 n.2.

claims related to Zyvox, Professor Rosenthal "adapt[ed] the damage methodology" proposed by Pfizer's lawyers Ropes & Gray LLP to the government in the course of negotiating a settlement.

Professor Rosenthal considered the allegations and evidence related to Pfizer's off-label promotion of Zyvox with regard to unsubstantiated superiority claims relative to vancomycin. Rosenthal Report, ¶¶92-102. Contrary to defendants' suggestion, she did not rely on Dr. Finkelstein to estimate the profits of Pfizer's off-label promotion of Zyvox. Radcliffe Decl., Ex. 5 (Rosenthal Depo.) at 39:15-18 (different methodology for Zyvox), 146:14-147:21 (same). Professor Rosenthal used market share as the primary metric for her economic model, as did Pfizer in the methodology proposed by Pfizer's lawyers, Ropes & Gray. Rosenthal Report, ¶¶103-104; Radcliffe Decl., Ex. 5 (Rosenthal Depo.) at 264:16-265:6. Other than quibbling about the helpfulness of Professor Rosenthal's testimony, defendants offer no other bases in their motion to exclude her expert testimony with respect to Zyvox.

Her testimony will assist the jury in understanding the economic effect of Pfizer's unsubstantiated superiority claims, the breadth of the impact of such claims, including the estimated $647.2 million in revenue and $513.7 million in unlawful off-label profits, and Pfizer's ability to determine such an impact. Rosenthal Report, ¶104. Indeed, Professor Rosenthal's testimony is relevant and will help a jury because defendants have denied their ability to do this in this case. Defendants' Response to Request for Admission No. 48 (denying that defendants had the ability to determine what amount of drug sales were for off-label uses).[12] Plaintiffs bear the burden of proof at trial, for example, of proving that defendants' statements that they were in compliance with FDA

[12] Pfizer's Controller and several defendants at deposition also denied that a probable loss could be estimated. Radcliffe Decl., Ex. 8 (McKinnell 2013 Depo.) at 278:11-21 ("we could not estimate"); Radcliffe Decl., Ex. 9 (Cangialosi Depo.) at 290:19-291:4 ("we still couldn't estimate it"); Radcliffe Decl., Ex. 10 (Kindler 2014 Depo.) at 111:24-112:22 ("not reasonably calculated").

rules and regulations were ***materially*** false and misleading when made. Professor Rosenthal's testimony will assist the jury, *inter alia*, in understanding the pervasiveness and magnitude of the off-label promotion – factors that bear on materiality. *Litwin v. Blackstone Grp.*, 634 F.3d 706, 717-20 (2d Cir. 2011) (in assessing materiality both quantative and qualitative factors should be considered). As such, any effort to exclude her opinions on Zyvox should be denied.

B. Professors Rosenthal's and Baum's Expert Opinions Regarding the Economic Calculation of Off-Label Revenue and Profits for Bextra, Geodon and Lyrica Are Admissible and Probative

Professor Rosenthal's methodology involved an ex-ante approach in which she identified detailing dollars as a proxy for Pfizer's off-label promotional efforts. Radcliffe Decl., Ex. 5 (Rosenthal Depo.) at 42:9-43:6, 81:13-82:6, 93:3-94:2, 140:9-19. Her methodology is also based on the theory that "there has to be a positive return on investment for marketing to make sense." *Id*. at 89:23-91:6.[13] The detailing dollars that Pfizer spent on promotion to challenged specialties serves as a proxy for the overall off-label marketing effort based on Professor Rosenthal's extensive experience in calculating off-label pharmaceutical products and fundamental economic methodology. Radcliffe Decl., Ex. 5 (Rosenthal Depo.) at 129:4-130:4; *see also Neurontin Mktg. & Sales Practices Litig.*, 712 F.3d at 57-58. The use of but-for worlds based on relevant economic theory and data is generally acceptable economic practice.[14] *See also In re Elec. Books Antitrust Litig.*, 11 MD 2293 (DLC), 2014 U.S. Dist. LEXIS 42537, at *50-*51 (S.D.N.Y. Mar. 28, 2014) ("antitrust jurisprudence . . . expressly refuses to impose extraordinary burdens on a plaintiff to construct the but-for price" because the risk of uncertainty should be borne by the wrongdoer).

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[13] *See also* Rosenthal Report, ¶26 (citing R. Dorfman and P. Steiner, "Optimal Advertising and Optimal Quality," *American Economic Review*, 44(5), December 1954, pp. 826-36).

[14] *See, e.g.*, ABA, Quantifying Damages, at 59.

In constructing her proxy for off-label promotional expenditures, she does not assume that all promotion to the challenged specialties is off-label or that all promotion to the non-challenged specialties is on-label. Radcliffe Decl., Ex. 5 (Rosenthal Depo.) at 129:9-130:4. Her "proxy is conservative in all cases" because, for example, it excludes potentially fraudulent off-label messages to non-challenged specialties and does not capture unsubstantiated superiority claims for any of the drugs despite evidence that they were made. Rosenthal Report, ¶¶56, 73 n.226, 86 n.273; Radcliffe Decl., Ex. 5 (Rosenthal Depo.) at 128:4-129:2, 162:11-163:1, 163:3-20.

Professor Rosenthal's opinion that methodologies existed to estimate or quantify the economic impact of off-label promotion and that Pfizer could have emulated her analysis has nothing to do with Dr. Finkelstein – the main subject of defendants' instant motion.[15] Defendants do not attack her experience or economic approach to estimating off-label profits for the drugs.[16] Rather, defendants' attacks, under the guise of improper reliance on Dr. Finkelstein, principally relate to the output of the approach. *See Bee v. Novartis Pharm. Corp.*, 18 F. Supp. 3d 268, 304-05 (E.D.N.Y. 2014) (finding that "questions concerning the accuracy or credibility" of evidence relied upon by an expert and whether he considered certain facts or factors in reaching his opinion "may serve as valuable ammunition for countering [his] opinion, once given on the stand" but "are insufficient . . . for purposes of establishing that [his] opinion . . . should be deemed inadmissible

[15] Radcliffe Decl., Ex. 5 (Rosenthal Depo.) at 9:7-10:18 ("It is my opinion that Pfizer could have emulated the analysis that I did to estimate the magnitude of impact that the government would have used as the basis for damages."); *id.* at 11:1-12:11.

[16] Rosenthal Report, ¶¶2-3; Radcliffe Decl., Ex. 5 (Rosenthal Depo.) at 9:7-14 ("My opinion, as set forth in my report, is with regard to the existence of a methodology for calculating impact and having operationalized that methodology . . . ."), 12:5-9 ("in matters such as this where I, for example, have been retained by the government, I have done exactly this analysis and they have used that to recover damages"), 19:20-20:6 ("I've done damages calculations associated with off-label promotion" in other lawsuits), 13:7-9 ("impact figures in my experience are part of how a settlement is reached").

altogether"); *Bazemore v. Friday*, 478 U.S. 385, 400 (1986) ("Normally, failure to [even] include variables will affect the analysis' probativeness, not its admissibility.").[17] They are also highly probative to the existence of methodologies to estimate the off-label profits stemming from Pfizer's off-label promotional strategies and the DOJ's investigation into these tactics for Bextra and other drugs. Defendants have repeatedly told this Court that "Pfizer . . . could not reasonably estimate maximum exposure." August 9, 2011 Hearing Transcript at 3:3-5; *see also id*. at 15:23-24, 17:22-23, 20:15-20.[18] Professor Rosenthal's testimony that off-label profits can be estimated based on economic theory goes directly to this point and will assist, not confuse, a jury. Fed. R. Evid. 403.

The "challenged specialties" defendants fixate on are merely variables that are used for the but-for world (*i.e.*, where no off-label promotion occurred). Radcliffe Decl., Ex. 5 (Rosenthal Depo.) at 129:4-130:4. Professor Rosenthal created her economic approach using fundamental economic principles and application of her considerable experience in calculating off-label pharmaceutical sales. *Id*. at 104:8-22 ("My analysis is entirely standard."); *see also McCullock v. H.B. Fuller Co.*, 61 F.3d 1038, 1043 (2d Cir. 1995) (testimony of an expert with "extensive practical experience" in the subject matter "easily qualifies for admission under *Daubert*").[19] The challenged specialties identified by Professor Rosenthal are not used by Professor Baum in his econometric

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[17] *See also Fleischman v. Albany Med. Ctr.*, 728 F. Supp. 2d 130, 138-39, 145-50 (N.D.N.Y 2010) (where defendants challenged the methodology of an economic expert, including his but-for analysis, the Court noted that "[t]he fact that Defendants dispute [the economist's] methodology does not render the methodology unreliable" and allowed the opinions); *RMED Int'l, Inc. v. Sloan's Supermarkets, Inc*., No. 94 Civ. 5587 (PKL) (RLE), 2000 U.S. Dist. LEXIS 4892, at *7 (S.D.N.Y. Apr. 17, 2000) ("defendants may properly explore any weaknesses in her methodology on cross-examination")

[18] *See also* n.10, *supra*.

[19] Radcliffe Decl., Ex. 5 (Rosenthal Depo.) at 48:10-20 (used challenged specialties in the Neurontin matter), 231:4-24 ("methodology is exactly what I would use as a witness in [a government case as to Bextra, Geodon and Lyrica]").

regression models. Radcliffe Decl., Ex. 6 (Baum Depo.) at 20:14-21:19, 21:20-22:20, 32:11-21. Rather, a modification of the challenged specialties merely alters Professor Rosenthal's eventual calculation of off-label revenue and profits. Professor Baum merely applies the modified challenged physician specialties to his existing model to generate the unit sales as a result. Modification of these specialties does not affect the reliability of the regression model or the economic approach developed by Professor Rosenthal. Radcliffe Decl., Ex. 5 (Rosenthal Depo.) at 136:24-137:19 ("my calculations, as we talked about earlier, could be adapted to a difference in what the fact finder ultimately concludes"), 177:21-178:11.

That Pfizer ignores the evidence component of Professor Rosenthal's analysis and does not agree with the challenged specialties she used for her models is hardly surprising, but that does not impact the admissibility of Professor Rosenthal's expert testimony.[20] At most, it goes to the weight of her opinion. *Bazemore*, 478 U.S. at 400-401 (reversing exclusion of regression analysis based on the premise that the analysis did not include proper selection of variables and failure of the court to examine the regression analysis "in light of all the evidence in the record"). Further, defendants use of their own expert's report demonstrates that they are well equipped to cross-examine her. Dkt. No. 345 at 8-9 (citing Rosenthal testimony (Radcliffe Decl., Ex. 5 (Rosenthal Depo.) at 136:24-138:9) concerning the calculations by defendants' expert Sean Nicholson); *see also Biosig Instruments, Inc. v. Nautilus Group Inc.*, No. 04-cv-6654 (ARH), 2008 U.S. Dist. LEXIS 77605, at *3 (S.D.N.Y. Oct. 3, 2008) (Hellerstein, J.) ("testimony of another expert offering a different opinion [] is not grounds of disqualification").

[20] In contrast, defendants' damage expert Kenneth Lehn relied on a third-party litigation consulting firm to conduct his regression and event studies. Radcliffe Decl., Ex. 11 (Lehn Depo.) at 28:16, 30:24-31:9.

Further, any notion that Professor Rosenthal is serving as a "conduit" for Dr. Finkelstein's testimony is patently false. *Dura*, 285 F.3d at 613 (testimony only needs to be excluded when an expert is "just parroting the opinion" of another expert).[21] In determining whether a physician specialty would not typically treat a patient for an on-label use or be the primary decision maker in prescribing a drug on-label as a variable for her model, Professor Rosenthal employed a multi-part approach. Radcliffe Decl., Ex. 5 (Rosenthal Depo.) at 167:16-168:9, 176:6-14, 202:2-203:8. This multi-part approach more than satisfies Fed. R. Evid. 702's requirement that her opinions be "based on sufficient facts or data." It also serves as an adequate basis for her opinion under Fed. R. Evid. 703. *Mannino v. Int'l Mfg. Co.*, 650 F.2d 846, 853 (6th Cir. 1981) ("Great liberality is allowed the expert in determining the basis of his opinions under Rule 703").

First, Professor Rosenthal relied on plaintiffs' allegations and the ***"evidence"*** that she had seen and sets forth in her report. This evidence "suggests that there's improper marketing to the specialties [she] exclude[s]." Radcliffe Decl., Ex. 5 (Rosenthal Depo.) at 130:1-4; Rosenthal Report, ¶¶6, 46-54 (Bextra), 62-71(Geodon), 79-84 (Lyrica); *see also* Rosenthal Report, Attachments E.1, E.2, E.3. This evidence supports the choices that Professor Rosenthal made as to whether the dollars directed by Pfizer towards certain physicians should be considered part of Pfizer's off-label

[21] The fact pattern defendants rely on in *Louis Vuitton Malletier v. Dooney & Bourke, Inc.*, 525 F. Supp. 2d 558 (S.D.N.Y. 2007), is inapposite. In *Malletier*, the expert presented (Anson) did not conduct the regression analysis himself; instead, it was conducted by another analyst (Torres) who was not produced at trial. Anson admitted he "essentially had nothing to do with the preparation of the regression analysis"; instead, it was his practice to "turn this over to an economist." *Malletier*, 525 F. Supp. 2d at 664. "With respect to the regression analysis, Anson was not an expert but rather a 'mouthpiece.' Louis Vuitton thus produced the wrong expert to prove the reliability of the regression analysis." *Id*. at 666. Here, Professor Rosenthal will testify as to the economic approach, and Professor Baum will testify as to the econometric model used.

marketing effort.[22] Her inclusion of, for example, orthopedic surgeons or allergists, as challenged specialties (*i.e.*, specialties that would not typically treat menstrual cramps or osteoarthritis or rheumatoid arthritis) for Bextra is also confirmed by the evidence. If defendants want to cross-examine Professor Rosenthal on why she included surgeons and allergists or any other challenged specialty, as specialists who would not typically treat menstrual cramps,[23] osteoarthritis or rheumatoid arthritis when common sense as well as Pfizer's own documents concede as much, then so be it.[24] Likewise, with Geodon (an atypical antipsychotic approved for schizophrenia and acute mania associated with bipolar disorder), defendants can cross-examine Professor Rosenthal as to why Pfizer expended promotional dollars on anyone other than psychiatrists where off-label prescriptions of the challenged specialties ranged from 57.2% to 100% and the empirical evidence details Pfizer's off-label promotional tactics. Rosenthal Report, ¶¶60-75, and ¶73 (Table 3). Similarly, Pfizer's own documents evidence that orthopedic surgeons do not write on-label prescriptions for Lyrica, yet 10.6% of Pfizer's detailing dollars were focused on this specialty.[25] She has already told defendants what the bases of her expert testimony are, including a review of

[22] Defendants' own expert economist, Sean Nicholson, agreed that in building an economic model, as Professors Rosenthal and Baum have done here, "providing evidence that supports the believability and plausibility and consistency of your assumptions is something that strengthens a model." Radcliffe Decl., Ex. 12 (Nicholson Depo.) at 15:15-21.

[23] Menstrual cramps are also referred to as primary dysmenorrhea.

[24] Radcliffe Decl., Ex. 5 (Rosenthal Depo.) at 91:14-92:3 (indicating that for some specialties it was "clear"), 97:7-98:9 (explaining that her understanding of why anesthesiologists would typically treat acute pain relating to surgery was based on the "literature," "specific allegations related to marketing to anesthesiologists," "Pfizer's own strategy documents . . . in terms of their role in managing operative pain" and "from Dr. Finkelstein"); *see also* Rosenthal Report, Attachments E.1, E.2, E.3 (describing evidence to support the challenged specialties).

[25] Rosenthal Report, ¶85 (Table 5); Declaration of Jason A. Forge in Support of Plaintiffs' Memorandum of Law in Support of Omnibus Opposition to Defendants' Motion *in Limine* Nos. 4-12, Ex. 48, filed December 22, 2014 ("very rarely do I find that an Ortho will treat" the on-label indications for which Lyrica was approved).

empirical evidence and her assumption that a trier of fact will find that Pfizer had engaged in the off-label promotion alleged.[26]

Second, Professor Rosenthal looked at the percentage of off-label uses by a particular specialty to determine, in part, whether a specialty should be challenged. Radcliffe Decl., Ex. 5 (Rosenthal Depo.) at 126:17-127:1, 201:3-203:8. For example, based on data she reviewed, 100% of Pediatric Specialists prescribed Geodon (an anti-psychotic approved for adult schizophrenia and bipolar disorder) off-label, 100% of Urologists prescribed Bextra (approved for osteoarthritis and rheumatoid arthritis as well as primary dysmenorrhea) off-label, and nearly 91% of orthopedic surgeons prescribed Lyrica (approved for diabetic peripheral neuropathy (nerve damage caused by diabetes), post herpetic neuralgia (shingles), or after June 2007 fibromyalgia) off-label. Rosenthal Report, ¶55 (Table 1), ¶73 (Table 3), and ¶85 (Table 5). Whether a prescription was for on- or off-label use is principally based on ICD-9 codes. Professor Rosenthal has direct experience with ICD-9 codes and she has unequivocally testified that some codes were "obvious." *See id*. at 119:4-120:15 (experience with ICD-9 codes), 118:17-119:3 (some codes are obvious).

Third, Professor Rosenthal looked at whether it made economic sense for Pfizer to expend detailing dollars towards a particular physician specialty. Rosenthal Report, ¶¶56, 73, 86; Radcliffe Decl., Ex. 5 (Rosenthal Depo.) at 40:1-19, 42:16-43:6, 89:23-91:6, 202:10-19. In other words, for example, where a physician specialty writes such few on-label prescriptions, any return on

[26] *See, e.g.*, Rosenthal Report, ¶6; *see also* Radcliffe Decl., Ex. 5 (Rosenthal Depo.) at 62:24-63:9 ("Q. So basically, and you've done in this other cases, too, I gather, of this ilk, that you are assuming that the allegations in the complaint with respect to off-label promotion and detailing and so on could be proven? . . . A. That's correct. I believe that's what damages experts always do. Q. Yes.").

investment of promotional detailing dollars would be economically irrational.[27] This also accounts for situations where the percentage of sales for on-label uses may be high but the actual number of overall prescriptions is small (*e.g.*, 80% on-label but only 10 prescriptions) and thus, it would not make sense to detail those physician specialties. Radcliffe Decl., Ex. 5 (Rosenthal Depo.) at 102:2-103:18.

Fourth, her limited clinical input from Dr. Finkelstein was a means of ensuring she was taking a conservative approach to her determination of specialties. *Id*. at 119:4-120:1, 128:5-129:2, 162:14-163:1.[28] As to deference she afforded Dr. Finkelstein, with respect to ICD-9 codes she testified that if Dr. Finkelstein indicated that "it's a gray area, then I made the decision to go conservative and put all of those in the on label. ***So the decision was always mine***." Radcliffe Decl., Ex. 5 (Rosenthal Depo.) at 213:7-214:11. It is widely accepted economic theory and defendants' off-label promotion that underlies the basis for Professor Rosenthal's opinions, not Dr. Finkelstein's review of her choices. As Professor Rosenthal testified: "my analysis proceeds based on a conclusion about challenged specialties that . . . I understand plaintiffs intend to use to prove the allegations, the observation that the vast majority of uses by these challenged specialties, including surgeons, were for off-label uses. ***Inclusion or exclusion of one code or another doesn't change the overall pattern***." *Id*. at 125:15-126:14. Whether a particular ICD-9 code might be considered on-label goes, at most, to the weight of her testimony, not its admissibility.

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[27] *E.g.*, Rosenthal Report, ¶56 ("These physicians simply would not see enough of these patients to be effective conduits for increased sales.").

[28] Professor Rosenthal's use of ICD-9 codes has been accepted. *In re Neurontin Mktg. & Sales Practices Litig.*, 810 F. Supp. 2d 366, 374-75 (D. Mass. 2011) (explaining Rosenthal's use of ICD-9 codes and noting that where there was promotion for illegal off-label indications).

Professor Rosenthal, as an economist, relied on input from Dr. Finkelstein "***to review my categorization of these specialties***," not as defendants claim to "conduct her analysis." *Compare id*. at 92:5-20, *with* Dkt. No. 345 at 1.[29] This testimony is consistent with the vast evidence Professor Rosenthal relied on demonstrating the off-label promotional efforts to the challenged specialties as well as common sense from someone with her expertise in the analysis of off-label promotion and as a health economist. Rosenthal Report, ¶¶6, 33-36, 46-54 (Bextra), 62-71(Geodon), 79-84 (Lyrica). For example, Professor Rosenthal specifically explained in her report there is no reason for Pfizer to have spent more than 20% of its detailing dollars promoting Bextra to orthopedic surgeons. She justified her conclusion based on the evidence that orthopedic surgeons wrote Bextra prescriptions off-label 83.6% of the time. Rosenthal Report at Table 1, ¶¶49-51, 56. She testified that "if I had to say which specialty is most important in these allegations of off-label detailing, as they pertain to ***empirical data*** [] I would say orthopedic surgeons first and foremost." Radcliffe Decl., Ex. 5 (Rosenthal Depo.) at 135:9-136:6. Further, she explained specifically why anesthesiologists would not typically treat for acute pain, including her understanding based on the "literature," the allegations in the FAC, and Pfizer's "own strategy documents," in addition to her understanding

[29] *See also* Radcliffe Decl., Ex. 5 (Rosenthal Depo.) at 26:10-13 ("He's a medical expert and it was important to me to have him review those decisions from that point of view, yes."), 89:17-91:6 ("reviewing the extent to which the evidence supporting the complaint was focused on marketing to those particular specialties"), 91:14-92:3 (indicating that with some specialties it was "clear" without review by Dr. Finkelstein), 92:5-15 ("could have" made determinations of challenged specialties without input from Dr. Finkelstein), 103:1-18 (considered what was "plausible"), 129:9-130:4 ("the evidence that I have seen as a layperson suggests that there's improper marketing to the specialties I exclude"), 130:5-22 ("I believe there's evidence related to promotion to these specialists for off-label uses"), 131:15-132:1 ("as an economist, I am standing by the theory that these specialties would not have been targets for on-label marketing, and the evidence that plaintiffs have brought"), 134:8-19 ("[b]ased on my analysis of what oncologists prescribe for, what Bextra is labeled for, with clinical input"), 175:2-5 ("taking into account the evidence"), 217:22-218:2 ("I asked him to . . . help me identify which specialties were consistent with the idea as an economist I was trying to characterize.").

from Dr. Finkelstein. *Id*. at 97:8-98:9.[30] Given these facts as well as that Pfizer was specifically denied an indication for the use of Bextra in surgical settings, there is no fundamental flaw in the methodology employed by Professor Rosenthal. Her selection of orthopedic surgeons or anesthesiologists or any of her other challenged specialties is well supported by facts or data as required by Fed. R. Evid. 702.[31]

Professor Rosenthal's input from Dr. Finkelstein to "review those decisions" is entirely permissible under Fed. R. Evid. 703. Radcliffe Decl., Ex. 5 (Rosenthal Depo.) at 26:10-13; Fed. R. Evid. 703 ("If experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion on the subject, they need not be admissible for the opinion to be admitted."). The "drafters of the Federal Rules specifically contemplated that experts would rely on others with

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[30] She also specifically pointed to her years of experience along with her consultation with Dr. Finkelstein as well as empirical data that verified her selection of challenged specialties with respect to Geodon. Radcliffe Decl., Ex. 5 (Rosenthal Depo.) at 167:16-168:10. And testified: "What I know is that for serious mental illness like schizophrenia and bipolar disorder, patients may see their general practitioner to get a refill, but they are not the primary decision-makers for treating those conditions . . . ." *Id*. at 172:5-11.

[31] Defendants' cherry-picked testimony regarding Dr. Finkelstein's experience and qualifications to provide input on off-label uses and physician specialties that would not typically treat for on-label uses is a red herring. Dr. Finkelstein works as an academic affiliate along with Professors Baum and Rosenthal at Greylock McKinnon Associates. Radcliffe Decl., Ex. 5 (Rosenthal Depo.) at 24:6-8. He is a general internist in the treatment of all kinds of medical conditions who is qualified to opine on pharmaceutical treatment broadly. *Id*. at 24:12-18, 158:1-9. He is a professor at Harvard Medical School who teaches physicians and "certainly knows what subspecialists do." *Id*. at 24:19-25:1, 98:14-21. He also understands "the clinical norms of coding practices." *Id*. at 123:12-124:5. The Second Circuit has cited his published works. *See United States v. Caronia*, 703 F.3d 149, 180 n.7 (2d. Cir. 2010) (Livingston, J., dissenting) (noting that "experts have concluded that most prescriptions for off-label use have little or no scientific support") (citing David C. Radley, Stan N. Finkelstein & Randall S. Stafford, *Off-Label Prescribing Among Office-Based Physicians*, 166 Archives of Internal Med. 1021 (2006)). Further, defendants have not one but three experts they seek to have testify as to why Professor Rosenthal's selections of challenged specialties are wrong. Radcliffe Decl., Ex. 13 (Panchal Depo.) at 136:18-22 (disagreeing with Rosenthal regarding specialties); Radcliffe Decl., Ex. 14 (Feigal Depo.) at 18:25-19:18 (disagreeing with classifications); Radcliffe Decl., Ex. 12 (Nicholson Depo.) at 117:17-118:8 (criticizing Professor Rosenthal's identification of physician specialties).

specialized knowledge." *United States v. Stapleton*, No. 12-11-ART, 2013 U.S. Dist. LEXIS 160442, at *25-*26 (E.D. Ky. Nov. 8, 2013) (citing Fed. R. Evid. 703 and finding that a detective could reasonably rely on the conclusions of non-testifying medical experts); *Waldorf v. Shuta*, 142 F.3d 601, 627 n.12 (3d Cir. 1998) (upholding the determination by the district court that expert's testimony was properly based where he based his testimony, in part, on a letter he received from a vocational expert). Professor Rosenthal's expert opinions are her own. Defendants' attempt to characterize her opinions as a "conduit" of Dr. Finkelstein are absurd. She repeatedly told defendants in deposition what she considered in determining whether physicians should be considered "challenged" (*i.e.*, do not typically treat for the approved label of the drugs): (1) the allegations at issue and the evidence of off-label promotion, (2) the percentage of off-label sales by physician specialties, (3) the magnitude of on-label sales by physician specialties (*i.e.*, would not make economic sense to detail physicians who have few on-label prescriptions), and (4) clinical input from Dr. Finkelstein.[32] There is no question that "the decision[s] [were] always [hers]." Radcliffe Decl., Ex. 5 (Rosenthal Depo.) at 213:22. Moreover, she explained the conservative nature of her selection of challenged specialties, testifying that for a given specialty, if there were no specific allegations and no documentary evidence of off-label detailing then those specialties were treated as non-challenged (*i.e.*, the primary clinicians responsible for treating the approved conditions). *Id*. at 281:9-219:1.

Moreover, while defendants make much ado about the importance of the classification of specialties in connection with any reliance on Dr. Finkelstein, Professor Rosenthal explained "[t]he point is that there's an approach here and the order of magnitude of impact comes from that

[32] Radcliffe Decl., Ex. 5 (Rosenthal Depo.) at 87:19-88:17 ("My analysis proceeds on a couple of fronts."), 176:6-14 (a different set of three criteria), 201:3-203:8 (three criteria).

approach. ***Whether one specialty is included or excluded would not change the order of magnitude of these damage estimates***." *Id*. at 96:2-10. As explained above, the fact she consulted with Dr. Finkelstein to confirm her selections does not stand alone. The evidence supports that her selections and her opinions, along with Professor Baum's, are admissible. *In re Sulfuric Acid Antitrust Litig*., 446 F. Supp. 2d 910, 915, 921-25 (N.D. Ill. 2006) ("the claimed failure seasonably to have named Dr. Boyd as an expert was meaningless from a Rule 26 perspective unless Rule 703 prohibited . . . reliance on the Boyd data," which it did not); *see also* Fed. R. Evid. 702(b) ("sufficient facts or data").

Importantly, the selection of challenged specialties impacts the quantification of off-label revenues and profits, not the methodology itself. Accordingly, the testimony of Professors Rosenthal and Baum is admissible.

III. CONCLUSION

For the reasons set forth herein, defendants' MIL No. 2 should be denied.

DATED: December 22, 2014

Respectfully submitted,

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I certify under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on December 22, 2014.

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