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. 3 TO EXCLUDE THE TESTIMONY AND EXPERT REPORT OF BIOSTATISTICIAN NICHOLAS P. JEWELL, PH.D.

I. INTRODUCTION

Defendants' Motion *in Limine* ("MIL") No. 3 to preclude the trial testimony of plaintiffs' expert Dr. Nicholas Jewell, Ph.D. ("Dr. Jewell") along with their MIL Nos. 1-2, 4-5, 7 and 9-10 are thinly veiled motions for summary judgment seeking a ruling as a matter of law that this case does not involve the off-label marketing of Bextra, Geodon, Zyvox and Lyrica. Defendants' efforts to trumpet this losing argument over and over is futile because, as noted by other courts within this Circuit, "[a] motion in limine 'is not a proper vehicle for a party to ask the Court to weigh the sufficiency of the evidence to support a particular claim or defense, because "[t]hat is the function of a motion for summary judgment, with its accompanying and crucial procedural safeguards."'" *Pavone v. Puglisi*, No. 1:08 C 2389 (MEA), 2013 U.S. Dist. LEXIS 9140, at *3-*6 (S.D.N.Y. Jan. 23, 2013) (quoting *Bowers v. Nat'l Collegiate Athletic Ass'n*, 563 F. Supp. 2d 508, 532 (D.N.J. 2008), *C & E Servs., Inc. v. Ashland Inc.*, 539 F. Supp. 2d 316, 323 (D.D.C. 2008)).[1] As defendants raised all their arguments in their MIL Nos. 1-5, 7 and 9-10 in their seven motions for summary judgment, their arguments fail for the reasons articulated in Plaintiffs' Memorandum of Law in Opposition to Pfizer Inc.'s and the Individual Defendants' Motions for Summary Judgment. Dkt. No. 304.

As to Dr. Jewell, defendants do not contest the reliability of his testimony or report. Instead, they assert his report is irrelevant because this case does not involve the off-label promotion of Zyvox. Defendants further assert that Dr. Jewell is unnecessary because Pfizer stipulated "that as of January 2009, there was no substantial evidence to support a claim of superiority of Zyvox over vancomycin." Dkt. No. 349. Defendants are wrong on both accounts. Defendants' argument that

[1] *See also Actors Fed. Credit Union v. Cumis Ins. Soc'y, Inc.*, No. 1:11 C 2129 (MEA), 2013 U.S. Dist. LEXIS 27923, at *9-*10 (S.D.N.Y. Feb. 28, 2013).

off-label promotion is irrelevant to this case is based on the delusion that none of the statements plaintiffs allege to be false and misleading relate to off-label promotion. Pfizer's stipulation with the DOJ does not obviate the most important role Dr. Jewell's report and testimony will play in assisting the jury. Dr. Jewell will aid the jury's understanding of how the scientific articles Pfizer told the sales force to use when marketing Zyvox did not demonstrate that drug's superiority over vancomycin. This evidence will assist the jury when evaluating falsity and scienter because defendants assured investors throughout the Class Period that Pfizer did not promote its drugs off-label. Pfizer's superiority claim used to market Zyvox is a form of off-label promotion that persisted at the Company despite the 2004 CIA to cease off-label marketing. Further, the superiority claim Pfizer employed to market Zyvox during the Class Period is particularly egregious in light of the July 2005 Warning Letter from the FDA that ordered Pfizer to cease making the superiority claim for Zyvox because it was unsubstantiated. Dr. Jewell's testimony will assist the jury in understanding why the FDA found the superiority claim to be unsubstantiated. Despite Pfizer's stipulation with the DOJ, defendants still dispute that the unsubstantiated superiority claim was a headquarters-driven activity. Dr. Jewell's testimony will make clear why the clinical studies included in Pfizer's marketing and sales documents used to direct the sales force throughout the Class Period continued to not substantiate superiority. This issue goes directly to falsity, given defendants' statements that Pfizer did not engage in off-label promotion, and to scienter since the documents were created and directed from Pfizer's headquarters. The direction to market Zyvox as superior to vancomycin was approved by senior management, was not covered by the stipulation and has been hotly contested by defendants throughout this litigation.

Because Dr. Jewell's trial testimony will assist the jury in evaluating whether defendants' statements were knowingly false and misleading when made, his testimony is under Fed. R. Evid. 702. Therefore, defendants' motion to preclude Dr. Jewell should be denied.

II. FACTUAL BACKGROUND

On July 20, 2005, the FDA sent Henry McKinnell a Warning Letter demanding the Company immediately cease and desist its unlawful promotion of Zyvox.[2] To resolve the issue with the FDA, Pfizer agreed to cease making the superiority claim and to cease using any scientific articles that were being misused to make such a claim. *See* Declaration of Henry Rosen in Support of Memorandum of Law in Opposition to Defendants' Motion *in Limine* No. 3 to Exclude the Testimony and Expert Report of Biostatistician Nicholas P. Jewell, Ph.D. ("Rosen Decl."), Ex. 1 (August 3, 2005 Pfizer response to FDA Warning Letter), filed concurrently herewith. Despite receipt of the FDA Warning Letter, on September 30, 2005, Pfizer gave the sales force a detailing suggestion: "Always go back to ***ZYVOX*** proven efficacy: our data has shown that ***ZYVOX*** is better than vancomycin in the treatment of NP (including VAP) due to MRSA." Dkt. No. 369, Ex. 5 at Greensmith 0003892. Pfizer justified this detailing suggestion with a study by Wunderink *et al.* ("Wunderink").

Contrary to Zyvox's approved label and Pfizer's assurances to the FDA that it would cease and desist, Pfizer continued to instruct its sales force to market Zyvox as superior to vancomycin until February 2008:

- On October 12, 2005, Pfizer's Zyvox 2006 Operating Plan, approved by senior sales and marketing management at Pfizer's headquarters, instructed the sales force to use Key Opinion Leaders ("KOLs") to prove Zyvox was superior to vancomycin based on studies by Wunderink (Nosocmal Pneumonia "NP"), Kollef (Ventilator Acquired Pneumonia "VAP"), Weigelt (Surgical Site Infections "SSI") and Sharpe

[2] Dkt. No. 369, Ex. 4 at PZ0034666-76.

(Complicated Skin and Skin Structure Infections "cSSI"), even though Pfizer agreed to cease making superiority claims and using scientific studies for that purpose. Rosen Decl., Ex. 2 at PFE DERIV 00040546, 00040560.

- On October 9, 2006, POA slides for 2007 were circulated instructing the sales force to use the Wunderink study to establish Zyvox's superiority. Rosen Decl., Ex. 3 at PZ0054338-39.

- On March 12, 2007, slides for a Zyvox web presentation were circulated as part of the 2007 POA which showed Pfizer using the Kollef, Weigelt, Pantanwala and Mandell studies to show Zyvox's superiority. Rosen Decl., Ex. 4 at PZ0030319-24.

- On June 5, 2007, more 2007 POA slides were circulated that included a slide stating:

> Why ZYVOX is the best choice for MRSA
>
> Only Agent to show superior efficacy over vanco for MRSA infections in pneumonia & skin (WUNDERINK, KOLLEF, WEIGELT, SHARPE).

Rosen Decl., Ex. 5 at PZ0147344.

- On October 5, 2007, an Operating Plan for 2008, to be approved by Ian Read, was circulated and continued to contain the core marketing message for 2008 that Zyvox was a superior clinical and economic value versus vancomycin. Rosen Decl., Ex. 6 at PZ0028889.

Based on these directives, as Pfizer has admitted, its sales force continued to make unsubstantiated superiority claims until February 2008.

Because of the flagrant nature of the Zyvox off-label promotion, Pfizer agreed to the Zyvox facts set forth in Attachment A to the Civil Settlement Agreement. Dkt. No. 369, Ex. 1 at 38-39, 80-81. Pfizer and the DOJ agreed that certain facts regarding Pfizer's illegal promotion of Zyvox were true and accurate including:

> 9. As a result, Pfizer's sales personnel thereafter continued to make claims to physicians that Zyvox was superior to vancomycin for certain patients with MRSA, which included the claim that Zyvox would have a higher cure rate, and would save more lives, despite the fact that these claims were inconsistent with the FDA's Warning Letter and Zyvox's FDA approved label, and which were inconsistent with the manner in which Pfizer, after the receipt of the Warning Letter, agreed to present the clinical data cited by the FDA.

> 10. Moreover, certain Pfizer sales managers, including a regional manager and a headquarters-based vice president, were aware of and, in certain cases, encouraged a sales message that Zyvox was superior to vancomycin for certain patients, despite their knowledge of the FDA Warning Letter and the issues it raised.

Id. at 81. Because the facts were so strong and the drug was still on the market, not only was Pfizer required to admit the Zyvox facts, but it was also forced to inform physicians that it had illegally marketed Zyvox in a manner inconsistent with that drug's label and Pfizer's promises in 2005 to cease and desist.[3] In the letter sent to 66,000 physicians, Pfizer admitted its use of the Wunderink study to claim superiority was improper.[4]

III. DR. JEWELL'S BACKGROUND, REPORT AND TESTIMONY ARE UNCHALLENGED BY DEFENDANTS

Defendants take no issue with Dr. Jewell's credentials because they are first class. For 33 years, Dr. Jewell has been a Professor in the Division of Biostatistics, School of Public Health, and in the Department of Statistics, both at the University of California, Berkeley. He has authored a test book, "*Statistics for Epidemiology*," and over 160 peer-reviewed articles in the area of biostatistics.

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[3] Dkt. No. 369, Ex. 3.

[4] The letter stated:

> In the past, some Pfizer sales personnel made statements to healthcare providers that ZYVOX would have a higher cure rate and would save more lives than vancomycin, particularly with respect to nosocomial pneumonia and skin infections, despite the fact that these claims were not consistent with ZYVOX's FDA approved label. To the extent Pfizer or its employees have ever represented that ZYVOX has superior efficacy to vancomycin for any patient population during interactions with you or in marketing materials, such statements should be disregarded as they are not supported by substantial evidence. In particular, to the extent Pfizer relied upon the retrospective analysis published in *Chest* in 2003 ("Analysis of Two Double-Blind Studies of Patients With Methicillin-Resistant *Staphylococcus aureus* Nosocomial Pneumonia" by Dr. Richard Wunderink, *et al*.) to demonstrate that ZYVOX is superior to or better than vancomycin, those claims were not supported by substantial evidence.

Dkt. No. 369, Ex. 3 at PFE-JONES 00073249-50.

He has served as an editor on internationally recognized journals focused on biostatistics, is an award-winning leader in his field, and is a member of numerous statistical societies. Dr. Jewell has served as an expert in 12 matters in the past four years, including cases involving Pharmacia/Celebrex and Pfizer/Neurontin. Therefore Pfizer is certainly aware of Dr. Jewell's expertise.

Defendants have not challenged Dr. Jewell's report and testimony and take no issue with Dr. Jewell's conclusions that Pfizer misused the scientific articles mentioned in Pfizer Operating Plans and Plan of Action meetings and in other sales and marketing documents to make the superiority claim. Defendants withdrew the expert they initially named to respond to Dr. Jewell. Defendants' withdrawal of any opposition to Dr. Jewell does not make his evidence irrelevant. To the contrary, Dr. Jewell's report and testimony make clear that there was no basis for the superiority claim that was contained in and handed down to the sale force in sales and marketing documents.

In his report and during his deposition, Dr. Jewell examined each and every scientific article Pfizer used to justify the superiority messaging transmitted to the sales force. For example, Dr. Jewell examined the Wunderink (NP), Kollef (VAP), Weigelt (SSI), Sharpe (cSSSI), Pantanwala and Mandell studies in his report. Dr. Jewell concluded that none of the articles substantiated a superiority claim. This evidence will help the jury evaluate whether defendants' statements were materially false and misleading and whether the strategy was headquarters driven, which bears upon scienter.

IV. ARGUMENT

A. Dr. Jewell's Report and Testimony Are Relevant

Defendants assert that "[w]hether or not certain Pfizer employees marketed Zyvox improperly because there was not 'substantial evidence' of the drug's superiority to vancomycin is

entirely irrelevant to the claims at issue." Dkt. No. 349 at 5. Defendants' relevance argument is mistakenly based on their view of the case, which completely ignores an entire category of false and misleading statements plaintiffs allege are actionable. For example, on March 1, 2006, defendants falsely assured investors: "***Compliance with all relevant statutes and rules is both the legacy of our 150-year history and one of our most important advantages . . . [and] Pfizer observes all requirements of the U.S. Food and Drug Administration***." Defendants' Class Period False and Misleading Statements (Dkt. No. 303, Attachment 1) ("FMS") No. 2. Thereafter, defendants made repeated promises that they complied with the requirements of the FDA throughout the Class Period.[5] Defendants also ignore defendant Waxman's April 2, 2007 statement that Pfizer did not engage in off-label promotion and had internal controls in place to prevent illegal promotion. FMS No. 19. Because defendants assured investors that Pfizer marketed its drugs legally, whether Pfizer marketed Zyvox illegally throughout the Class Period goes directly to the issue of falsity.

In addition, whether Pfizer's sales and marketing materials continued to instruct the sales force to make the unsubstantiated superiority claim is also relevant to defendants' scienter. The admissible evidence in the case demonstrates that Pfizer's sales and marketing departments at the highest level flagrantly ignored the July 2005 Zyvox FDA Warning Letter and instructed the sales force to market Zyvox as superior to vancomycin even though Pfizer assured the FDA it would cease such promotion. The fact senior Pfizer sales and marketing executives continued to instruct the sales force to misbrand Zyvox indicates that the strategy was headquarters driven, a fact hotly contested by defendants.

Defendants' relevance argument also fails because Dr. Jewell's evidence fits with the issues to be decided by the Jury. Defendants cite *Deutsch v. Novartis Pharm. Corp.*, 768 F. Supp. 2d 420

[5] FMS Nos. 2, 4, 16, 18, 31, 34.

(E.D.N.Y. 2011), for the unremarkable proposition that "'[e]xpert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful.'" *Id.* at 461-62 (quoting *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579, 591 (1993)). In truth, this decision demonstrates why Dr. Jewell's evidence is helpful in this case. Defendants ignore that Dr. Jewell's testimony will assist the jury in understanding complex issues related to Pfizer's illegal promotion of Zyvox as superior to vancomycin. This understanding will assist the jury in evaluating whether defendants' statements that Pfizer did not engage in off-label promotion, that it complied with all rules and regulations regarding the marketing of its drugs, and that it complied with all requirements of the FDA were false and misleading when made.

Although defendants try, they cannot hide from these statements. Whether they like it or not, there is a valid scientific connection between Dr. Jewell's opinion – that none of the articles Pfizer instructed the sales force to use provided a scientific basis for a superiority claim – and the issues of falsity, materiality and scienter. Thus, his evidence is a good fit and will be helpful to the jury. "In *Daubert*, the Court described the Rule 401 relevance consideration as one of 'fit,' requiring a 'valid scientific connection' between the subject matter of the expert's testimony and the factual issues to be determined by the jury." *Deutsch*, 768 F. Supp. 2d at 426-27 (quoting *Daubert*, 509 U.S. at 591-92; *Lidle v. Cirrus Design Corp.*, No. 08 Civ. 1253 (BSJ) (ABP), 2010 U.S. Dist. LEXIS 67031, at *12 (S.D.N.Y. July 6, 2010)).

B. Plaintiffs Are Allowed to Introduce Damning Evidence as Long as It Is Properly Admitted

Additionally, defendants argue that Dr. Jewell's testimony would waste time, create confusion or be unfairly prejudicial to defendants. Dkt. No. 349 at 5-7. Defendants' unfair prejudice argument is based on the faulty premise that the illegal promotion of Zyvox has nothing to do with this case. Pfizer's illegal promotion of Zyvox goes to the heart of the case, given

defendants' assurances to investors that Pfizer, unlike companies it acquired, did not promote its drugs off-label. Because this issue is relevant to plaintiffs' case, defendants' prejudice argument fails:

> The fact that such evidence is prejudicial by itself does not militate against its admission. Any evidence that gives support to one party's position is to the prejudice of the opposing side. To quote the familiar statement of Chief Judge Learned Hand, "If (the testimony) 'prejudiced' (the defendant), that was precisely its entirely laudable purpose." Or, as stated more recently, "while the testimony may very likely have worked to the prejudice of the appellant, it did so because the evidence was damning, not because its introduction was error."

Brink's, Inc. v. New York, 539 F. Supp. 1139, 1140-41 (S.D.N.Y. 1982) (quoting *United States v. Compagna*, 146 F.2d 524, 530 (2d Cir. 1944), *aff'd*, 717 F.2d 700 (2d Cir. 1983); *United States v. Cirillo*, 468 F.2d 1233, 1234 (2d Cir. 1972)).

Lastly, defendants' reliance on *United States v. Vallejo*, 237 F.3d 1008 (9th Cir. 2000), for the assertion that Dr. Jewell's testimony would waste time or confuse the jury also fails. Dkt. No. 349 at 7. *Vallejo* involved the appeal of a conviction for importation and possession with intent to distribute marijuana. That court considered whether expert testimony detailing the structure of drug trafficking organizations may be routinely introduced in drug importation cases, regardless of whether the defendant is charged with a drug trafficking conspiracy or otherwise charged with membership in such an organization. The *Vallejo* court held that expert testimony concerning the structure of drug trafficking organizations was not relevant, as the Government never articulated – either in its briefs or at oral argument – how the testimony was relevant to Vallejo's particular case. This is distinguishable from the evidence that Pfizer instructed the sales force to misbrand Zyvox at issue here because plaintiffs have articulated how the unsubstantiated superiority claim is related to the elements of their §10(b) case against defendants.

V. CONCLUSION

For the foregoing reasons, this Court should reject defendants' assertions that Dr. Jewell's report and testimony are irrelevant and deny their motion to exclude Dr. Jewell.

DATED: December 22, 2014

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on December 22, 2014, I authorized the electronic filing of the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the e-mail addresses denoted on the attached Electronic Mail Notice List, and I hereby certify that I caused to be mailed the foregoing document or paper via the United States Postal Service to the non-CM/ECF participants indicated on the attached Manual Notice List.

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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Docket Text:
MEMORANDUM OF LAW in Opposition re: [347] MOTION in Limine *No. 3 To Exclude the Testimony and Expert Report of Biostatistician Nicholas P. Jewell, Ph.D.*. . Document filed by Mary K. Jones(Individually), Stichting Philips Pensioenfonds. (Rosen, Henry)

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