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 Hon. Alvin K. Hellerstein ECF Case

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION *IN LIMINE* NO. 3 TO EXCLUDE THE TESTIMONY AND EXPERT REPORT OF BIOSTATISTICIAN NICHOLAS P. JEWELL, PH.D

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Pursuant to Federal Rules of Evidence 401, 402, 403, and 702, Defendants Pfizer Inc., Henry McKinnell, Alan Levin, Jeffrey Kindler, Frank D'Amelio, Allen Waxman and Ian Read (collectively, "Defendants") respectfully move to preclude the testimony and expert report of Plaintiffs' proffered expert Nicholas Jewell, Ph.D., a biostatistician.

PRELIMINARY STATEMENT

In this securities class action, Plaintiffs challenge Pfizer's disclosures concerning certain government investigations into Pfizer's marketing of Bextra and other Pfizer products, including Zyvox. Zyvox is an anti-infective medication used primarily in hospitals for serious skin and pulmonary infections. The government investigated whether certain Pfizer employees had marketed Zyvox as "superior" to a generic competitor (vancomycin) without meeting the necessary Food and Drug Administration ("FDA") standard of "substantial evidence" to support that claim. Pfizer and the government ultimately entered into a civil settlement concerning Zyvox (as well as Bextra, Geodon, and Lyrica) in which Pfizer agreed in a stipulation of facts[1] that as of January 2009, there was no substantial evidence to support a claim of superiority of Zyvox over vancomycin for certain indications.

Plaintiffs nevertheless seek to offer expert testimony from a biostatistician, Nicholas P. Jewell, solely on this undisputed point. Dr. Jewell simply opines that as of January 2009, there was no substantial evidence that Zyvox was superior to vancomycin—exactly what Pfizer stipulated as part of its settlement with the government. Plaintiffs' securities claims have absolutely nothing to do with this issue, and in any event Defendants do not dispute the point. Dr. Jewell's testimony is therefore irrelevant and not helpful to the jury, and should be excluded

[1] December 10, 2014 Declaration of Amanda A. MacDonald in Support of Defendants' Motions *in Limine* ("Dec. 10, 2014 MacDonald Decl.") Ex. II-4 (August 31, 2009 Settlement Agreement, Attachment A at 1–2).

under Federal Rules of Evidence 401 and 702. Moreover, even if the evidence were relevant, it would be inadmissible under Federal Rule of Evidence 403 because the risk of confusion and unfair prejudice far outweighs any conceivable probative value it might have.

FACTS

In late August 2009, Pfizer executed a civil settlement agreement (the "Settlement") with the United States Department of Justice (the "DOJ") and various *qui tam* relators resolving the DOJ's investigation into the marketing of several Pfizer products, including Zyvox, an anti-infective used in hospitals to treat serious infections, including methicillin-resistant staphylococcus aureus, or MRSA. As part of the Settlement, Pfizer and the government entered into a two-page stipulation of facts regarding Zyvox, which was attached to the agreement. Specifically, Pfizer agreed that as of January 2009, there was no "substantial evidence" that Zyvox was superior to vancomycin[2]—a promotional claim the government alleged certain Pfizer sales employees had made in marketing Zyvox. Although Defendants do not believe this issue is relevant to this securities litigation, in any event Defendants do not dispute it for purposes of this case.

Despite the existing stipulation with the government, Plaintiffs seek to offer the testimony of Nicholas P. Jewell, a professor of biostatistics, whose opinion is limited to the precise, undisputed fact contained in the stipulation. The conclusion drawn in his expert report goes no further than to reiterate what the stipulation reads:

> In summary, I am unaware of any substantial evidence that existed between 2005 and January 2009 to support a claim of Zyvox being

[2] MacDonald Dec. 10, 2014 Decl. Ex. II-4 (August 31, 2009 Settlement Agreement, Attachment A at 1-2) ("Although Zyvox is approved to treat [pneumonia and skin infections caused by MRSA], it has not been demonstrated by substantial evidence to be superior to the primary competitor drug for those indications: vancomycin, an antibiotic that has been on the market for nearly fifty years.").

> superior to, or better than, vancomycin in the treatment of MRSA [methicillin-resistant staphylococcus aureus] in humans.[3]

This is the entire scope of Dr. Jewell's opinion and the sole conclusion of his report. In his July 22, 2014 deposition, Dr. Jewell acknowledged that his opinion is restricted to this uncontroversial point, agreeing that his "bottom-line opinion in this case . . . is the same as what Pfizer and the government agreed to in August 2009."[4]

Not only do the opinions offered by Dr. Jewell have no relation to any "issue of consequence," therefore failing the foundational test of relevance under Rule 401, but they also do not meet the more exacting evidentiary standards that apply to expert testimony. The Court addressed this very point during the July 7, 2014 status hearing, noting that Dr. Jewell's opinion speaks solely to "fact issues . . . not expert issues."[5] It is therefore inadmissible under Rule 702 as well.

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[3] MacDonald Dec. 10, 2014 Decl. Ex. KK-4 (Expert Report of Dr. Nicholas P. Jewell, Ph.D. dated June 10, 2014 ("Jewell Rep.")) ¶ 2.

[4] MacDonald Dec. 10, 2014 Decl. Ex. LL-4 (Jewell (July 22, 2014) Dep. 39:25-40:21). *See also id*. at 102:12-14 ("[Dr. Jewell]. My charge was to assess the evidence, um, regarding superiority, not to examine the timing and changes that were made subsequently [to promotional material].") Dr. Jewell concluded that his testimony would only affirm the undisputed fact from the government stipulation: "And I'm there to provide, uh, expertise to the court or a jury or a judge about why there was no substantive evidence, that despite many of the discussions we've had this morning about cure rates favoring one group or another, that what constitutes reasonable evidence of superiority or not." *Id*. at 136:2-7.

[5] July 7, 2014 Hearing Tr. at 8:5–23:

> MR. ROSEN: Professor Jewell is an internationally recognized biostatistician. He is a designated expert on Zyvox. Zyvox is a drug in the summer of 2005, the defendants were told by the FDA stop making a superiority claim over vancomycin. For three years undeterred they continue to make that superiority claim and they did so on the basis of scientific studies that Professor Jewel analyzes with his biostatistical background and concludes none of those studies supports the superiority claim they continue to make.
>
> THE COURT: Why would I go into the merits of a drug if the issue is whether they violated their promise not to market that drug?

ARGUMENT

It is axiomatic that "[i]rrelevant evidence is not admissible." Fed. R. Evid. 402; *see Daubert v. Merrell Dow Pharm.*, 509 U.S. 579, 591 (1993) ("Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful."). Dr. Jewell's opinions do not have "any tendency to make a fact more or less probable" that "is of consequence in determining the action," and are therefore irrelevant and inadmissible. Fed. R. Evid. 401. Even if testimony or evidence regarding this issue were relevant, no *expert* testimony about it is necessary or helpful to the jury because the point is not disputed—the 2009 stipulation with the government, as Dr. Jewell himself acknowledges, establishes the same (and only) point he makes, and Defendants do not challenge it. Expert testimony must be relevant to an issue of consequence in order to be helpful to the jury and thus admissible. *See, e.g.*, *Nook v. Long Island R.R. Co.*, 190 F. Supp. 2d 639, 641 (S.D.N.Y. 2002) ("In assessing admissibility, the Court must determine whether the proffered expert testimony is relevant, that is, whether it 'ha[s] any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence . . . .'") (internal citation omitted); *Giles v. Rhodes*, No. 94 CIV. 6385 (CSH), 2000 WL 1425046, at *4 (S.D.N.Y. Sept. 27, 2000) ("An irrelevant expert report, like any irrelevant testimony, is not admissible.");

> MR. ROSEN: Because our anticipation is that they're going to defend and say we stopped making the superiority claim and these studies supported the statements that were being made in the marketing materials even though they withdrew them and even they admitted in the civil settlement —
>
> THE COURT: These are fact issues; they're not expert issues.

see also Highland Capital Mgmt., L.P. v. Schneider, 379 F. Supp. 2d 461, 473 (S.D.N.Y. 2005) (excluding irrelevant expert evidence).

First, this securities class action has nothing to do with whether in 2005 through January 2009 there was "substantial evidence" that Zyvox was superior to vancomycin—which is the sole conclusion of Dr. Jewell's report. Dr. Jewell is a biostatistician and has no expertise in securities law or disclosures.[6] To establish their securities fraud claims, Plaintiffs must prove that the challenged statements to investors regarding the government investigations of Bextra and other Pfizer products, including Zyvox, were false, made with scienter, and caused economic loss to Plaintiffs. Whether 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, and thus testimony (expert or otherwise) about that subject is not admissible. Fed. R. Evid. 402; *Daubert*, 509 U.S. at 599 (noting that relevance is one of the "touchstones of the admissibility of expert testimony"); *see also* Defendants' Motion in Limine No. 5 (evidence of alleged off-label promotion is irrelevant to Plaintiffs' claims).

Second, because the sole conclusion for which Plaintiffs seek to offer Dr. Jewell is not in dispute (or at issue), Dr. Jewell's testimony cannot have "any tendency to make a fact more or less probable than it would be without the evidence" and is thus inadmissible. Fed. R. Evid. 401(a); *see also* Fed. R. 702(a) (expert may only offer testimony if it will "help the trier of fact . . . to determine a fact in issue"). A comparison of Pfizer's stipulation with the government and

[6] MacDonald Dec. 10, 2014 Decl. Ex. KK-4 (Jewell Rep.) ¶ 3 ("For the past 33 years, I have been a Professor in the Division of Biostatistics, School of Public Health, and in the Department of Statistics, both at the University of California, Berkley. Prior to that, I was an Assistant Professor in the Department of Statistics at Princeton University, Princeton, New Jersey (1979-1982) where I also served as Director of the Statistical Laboratories.").

Dr. Jewell's report (containing all of the opinions he is prepared to offer at trial) demonstrates that his opinions would provide absolutely no additional information to a factfinder:

Pfizer-DOJ Settlement Agreement	Dr. Jewell's Report
Although Zyvox is approved to treat [MRSA], it has not been demonstrated by substantial evidence to be superior to the primary competitor drug for those indications: vancomycin, an antibiotic that has been on the market for nearly fifty years.	In summary, I am unaware of any substantial evidence that existed between 2005 and January 2009 to support a claim of Zyvox being superior to, or better than, vancomycin in the treatment of MRSA in humans.

Because Dr. Jewell's opinions do not advance the issues—and in fact, do not even speak to the issues underlying Plaintiffs' claims—his testimony should be excluded from consideration by the jury. *See, e.g.*, *Deutsch v. Novartis Pharm. Corp.*, 768 F. Supp. 2d 420, 461 (E.D.N.Y. 2011) (excluding expert opinion where the "proposed testimony is irrelevant to the Plaintiffs' underlying claims" because subject of testimony "[wa]s not in dispute").

Even if the Court determines that his opinions are relevant, Dr. Jewell's testimony should be excluded under Rule 403 because whatever its conceivable probative value, it is far outweighed by the risk that it would waste time, create issue confusion, and unfairly prejudice Defendants. *See* Fed. R. Evid. 403 ("Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, . . . wasting time, or needless presentation of cumulative evidence."). As discussed in Defendants' Motion in Limine No. 5, evidence of alleged improper promotion, including superiority claims regarding Zyvox, has no bearing upon Defendants' disclosures, scienter, or the underlying securities claims, and the provocative nature of such evidence risks wasting valuable trial time as well as tainting the jury and distracting them from the facts at issue in this case. *Id.* at 3–11. Accordingly, because Dr. Jewell's opinions are not only irrelevant, but their presentation to the jury would risk prolonging an already lengthy trial, biasing the jurors, and

obscuring the actual issues to be decided at trial, they should be excluded. *See* Fed. R. Evid. 403; *see also United States v. Vallejo*, 237 F.3d 1008, 1016 (9th Cir. 2001) ("If the district court 'finds that the testimony would waste time, confuse or not materially assist the trier of fact, or be better served through cross-examination or a comprehensive jury instruction,' it has the discretion to exclude the testimony.") (internal citation omitted).

CONCLUSION

Because the opinion testimony of Dr. Jewell would neither illuminate an issue of consequence for the jury, as required to establish relevance under Federal Rules of Evidence 401 and 402 or admissibility under Rule 702, much less offer sufficient probative value to withstand the balancing test created by Rule 403, Defendants respectfully request that the Court grant their foregoing motion *in limine* and exclude the report of and any testimony by Dr. Nicholas Jewell.

Dated: December 10, 2014
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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. 3 to Exclude the Testimony and Expert Report of Biostatistician Nicholas P. Jewell, Ph.D. was filed with the Court through the CM/ECF system and thereby served to all parties of record.

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