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. 5 TO EXCLUDE EVIDENCE RELATED TO MARKETING AND ALLEGED OFF-LABEL PROMOTION OF PFIZER PRODUCTS

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Plaintiffs have included on their proposed witness and exhibit lists over a dozen witnesses and hundreds of documents that relate to marketing and alleged off-label promotion of various Pfizer products, including Bextra, Zyvox, Geodon, and Lyrica. Such evidence is irrelevant to this securities case and is intended simply to persuade the jury to penalize Pfizer for any improper marketing conduct. It also would needlessly lengthen the trial—the Court has repeatedly urged Plaintiffs to focus on the securities claims at issue, but Plaintiffs have refused to do so. Pursuant to Federal Rules of Evidence 401, 402, 403, and 404, Defendants respectfully submit this motion *in limine* to preclude Plaintiffs from introducing this irrelevant evidence.

BACKGROUND

Between 2004 and 2008, Department of Justice ("DOJ") conducted investigations into Pfizer's marketing of several of its products, including Bextra, Zyvox, Geodon, and Lyrica. In January 2009, Pfizer and the DOJ agreed to resolve these investigations; the resolution included a criminal plea by a non-operating Pfizer subsidiary in connection with the marketing of Bextra, along with a $1.3 billion fine, and a separate $1 billion civil settlement, with no admission of liability, for claims arising out of the marketing of Bextra, Zyvox, Geodon, and Lyrica.

In connection with the DOJ investigations, and a subsequent shareholder derivative lawsuit that was pending before Judge Rakoff (the *Klein* litigation), Pfizer produced millions of pages of documents concerning the marketing of these four products. Such documents, of course, were relevant to both of those matters, because the government was investigating the marketing, and the *Klein* plaintiffs were claiming that Pfizer's executives should have done more to prevent the marketing that was the subject of the government settlement.

During discovery in this case, Plaintiffs sought and received the millions of pages of documents Pfizer had produced in connection with the DOJ investigation and *Klein*, without regard to whether those documents would be relevant to Plaintiffs' securities claims. Plaintiffs

now seek to introduce hundreds of these documents at trial as well as to present testimony from witnesses who have no knowledge of the investor disclosures at issue in this case, but who were involved in or seek to opine on the development and marketing of these four products. These witnesses include medical doctors who oversaw clinical trials of the products,[1] marketing personnel who designed materials for the sales force to use in promoting the products,[2] and sales personnel who were responsible for the actual promotion.[3] In fact, of the 42 fact witnesses Plaintiffs have listed, 20 of them are solely related to the underlying development and marketing of the products, not the securities disclosures that form the basis for Plaintiffs' claims. It is apparent from this fact alone that Plaintiffs seek to create a sideshow at trial, in which they would try to parade before the jury evidence of (they would argue) off-label marketing conduct, in hopes that would prejudice the jury with respect to the real matter at issue, i.e., whether or not there is any evidence Defendants committed securities fraud.

ARGUMENT

I. Documents and Testimony Regarding Alleged Off-Label Promotion Are Irrelevant to Plaintiffs' Securities Claims.

Plaintiffs' complaint alleges violations of the Securities Exchange Act of 1934 ("the 1934 Act"). Plaintiffs allege that Defendants disseminated "materially false and misleading information" and failed to "disclose material facts" regarding the DOJ investigation in their statements to investors between January 2006 and January 2009, (First Am. Compl. ¶ 155), resulting in the artificial inflation of Pfizer stock until Pfizer made a "corrective" disclosure. This is not a shareholder derivative case regarding allegations of off-label promotion; that case

[1] *E.g.*, Dr. Gail Cawkwell (Bextra), Dr. Anthony Loebel (Geodon), and Dr. Maria Abelardo (Zyvox).

[2] *E.g.*, Michael Gavigan (Bextra and Zyvox), Kathleen Dowd (Lyrica), and Lisa Levy (Bextra).

[3] *E.g.*, Mark Westlock (Geodon), Alan Greensmith (Zyvox), and Alex Alvarez (Bextra).

was litigated before Judge Rakoff in *Klein* and resolved in 2011. Therefore, the documents and testimony that Plaintiffs propose to introduce at trial to establish off-label promotion are irrelevant and should be excluded.

A. Evidence of Off-Label Promotion Is Irrelevant Because Pfizer Had No Duty Under the Securities Laws To Disclose Such Conduct.

Plaintiffs have suggested that evidence of off-label promotion of Bextra, Zyvox, Geodon, and Lyrica is relevant because Pfizer did not disclose in its securities filings that certain employees had engaged in such conduct, and thus the filings were false and misleading. *See* First Am. Compl. ¶¶ 47–77; Mem. In Support of Pls.' Mot. for Partial Summ. J. ("Pls.' Mem.") at 29. Under established Second Circuit law, however, "disclosure is not a rite of confession," *Lindsay v. Morgan Stanley (In re Morgan Stanley Info. Fund Sec. Litig.)*, 592 F.3d 347, 365 (2d Cir. 2010), and companies have no legal duty to disclose "uncharged, unadjudicated wrongdoings or mismanagement." *City of Pontiac Policemen's & Firemen's Ret. Sys. v. UBS AG (In re UBS AG Sec. Litig.)*, 752 F.3d 173, 184 (2d Cir. 2014).[4] As a result, even assuming off-label promotion occurred, and that Pfizer management was aware of, for example, internal emails, call notes, sales force survey results, and employee interview memoranda—in other words, the types of documents Plaintiffs have included on their exhibit list—containing evidence of such off-label promotion, that is irrelevant in a securities fraud lawsuit, because Pfizer was not required to disclose those facts or materials to investors.

[4] *See also In re Morgan Stanley Tech. Fund Sec. Litig.*, 643 F. Supp. 2d 366, 377 (S.D.N.Y. 2009) (companies subject to government investigations "have no duty to accuse themselves of unproven, allegedly illegal policies"), *aff'd*, 592 F.3d 347 (2d Cir. 2010); *In re Citigroup Inc. Sec. Litig.*, 330 F. Supp. 2d 367, 377 (S.D.N.Y. 2004) ("[T]he federal securities laws do not require a company to accuse itself of wrongdoing."), *aff'd sub nom. Albert Fadem Trust v. Citigroup, Inc.*, 165 F. App'x 928 (2d Cir. 2006); Pfizer Inc.'s Mem. in Support of Mot. for Summ. J. at 38–39 ("Defs.' Mem.") (describing cases).

B. Evidence of Off-Label Promotion Is Irrelevant to Pfizer's Disclosed Belief That It Had "Substantial Defenses" to the Government's Claims.

Plaintiffs also have argued that evidence of off-label promotion is relevant because it would contradict the statement in Pfizer's securities filings that the company believed it had "substantial defenses" to all legal proceedings disclosed in the filings, including the DOJ investigation. *See, e.g.,* Pls.' Mem. at 5–6, 15–23 (asserting that "substantial defenses" statement was false because Pfizer omitted "facts and evidence" including, *inter alia*, *qui tam* complaint allegations and exhibits, attempted destruction of documents, sales force surveys, call notes, and employee interviews).

This argument likewise is mistaken. It is undisputed that Pfizer's government investigations counsel handling the matter, including its outside counsel at Covington & Burling ("Covington")—the firm that conducted an internal investigation of the allegations regarding Bextra marketing conduct and collected, reviewed, and produced to the government all the alleged evidence of off-label promotion that Plaintiffs now seek to introduce—advised Pfizer (and the government) that Pfizer had numerous legal and factual defenses to any charges the government might bring, notwithstanding the fact that some employees may have engaged in off-label promotion. *See* Defs.' Mem. at 45–46. And it also is undisputed that based on government investigations counsel's views, Pfizer's securities disclosure lawyers advised the company that the "substantial defenses" language in the securities filings was appropriate as applied to the DOJ investigation. *Id.* at 33. Any testimony or documents purporting to show off-label promotion thus are irrelevant, because they could not be used to establish scienter—the record establishes that, notwithstanding such evidence, Pfizer's disclosure lawyers advised that the "substantial defenses" language complied with the securities laws.

C. Evidence of Off-Label Promotion of Geodon, Lyrica, and Zyvox Is Irrelevant Because Those Products Were Not Identified In Plaintiffs' Alleged "Corrective Disclosure."

There is a separate and independent reason why evidence of off-label promotion of Geodon, Lyrica, and Zyvox is irrelevant: these products were not mentioned in the statement Plaintiffs allege is the sole "corrective disclosure" in the case. As discussed in Pfizer's Motion for Summary Judgment, "where a disclosure does not reveal the falsity of the alleged misstatements, it does not qualify as 'corrective'" and cannot establish loss causation (a required element of Plaintiffs' securities claims). *In re Omnicom Grp., Inc. Sec. Litig.*, 541 F. Supp. 2d 546, 552 (S.D.N.Y. 2008), *aff'd*, 597 F.3d 501 (2d Cir. 2010); *see also* Defs.' Mem. at 53–54 (describing cases). And as discussed in Defendants' Motion *in Limine* No. 6, filed herewith, because the alleged "corrective disclosure" does not mention those products or provide any indication that they were the subject of a portion of Pfizer's settlement with the government, any evidence relating to the products—to include evidence of alleged off-label promotion—is inadmissible.

D. Specific Testimony and Documents Reflecting Off-Label Promotion Are Irrelevant Even If the Fact of Such Promotion Is Not.

Finally, even assuming Plaintiffs were permitted to argue and offer evidence that Pfizer management was aware of instances of off-label promotion, there would be no need or basis for Plaintiffs to introduce testimony or documents from doctors, marketing personnel, or sales representatives about the off-label promotion itself. That is because Pfizer and the individual defendants have never denied that certain instances of off-label promotion occurred—that was, of course, one reason for the settlement with the government—and that the individuals who were involved in drafting and approving Pfizer's securities disclosures concerning the government investigation knew that Pfizer's own investigations had uncovered such conduct. In other words,

Plaintiffs have testimony from Pfizer and the individual defendants themselves that they were informed off-label promotion had occurred,[5] and documents confirming that fact.[6] Accordingly, the only potential fact "of consequence" for Plaintiffs is whether, assuming Pfizer's knowledge of off-label promotion, the company's securities disclosures were adequate. The thousands of documents and multiple fact and expert witnesses related to potential off-label promotion that Plaintiffs have identified are immaterial to that question.

In sum, Plaintiffs have not, and indeed cannot, articulate any reason that the vast amount of material related to alleged off-label promotion of products is relevant to their securities disclosure case. Accordingly, such evidence is inadmissible under Rule 402.

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[5] *See, e.g.*, December 10, 2014 Declaration of Amanda A. MacDonald ("Dec. 10, 2014 MacDonald Decl.") Ex. HH-2 (Lankler (Jan. 22, 2014) Dep. 265:4–266:6 (describing conversations with government investigation counsel about off-label promotion of Bextra in Northeast region)); Dec. 10, 2014 MacDonald Decl. Ex. EE-2 (Fox (Sept. 26, 2013) Dep. 63:9–69:22 (describing awareness of off-label promotion of Bextra by Pfizer employees)); Dec. 10, 2014 MacDonald Decl. Ex. XX-1 (Block (Sept. 16, 2013) Dep. 58:14–60:6 (describing conversation with Covington regarding attempted destruction of documents by Pfizer employee related to promotion of Bextra)); Dec. 10, 2014 MacDonald Decl. Ex. GG-2 (Kindler (Dec. 6, 2013) Dep. 265:7–266:1, 270:6–271:2 (stating that company was aware that certain individuals within company had engaged in off-label promotion and improperly destroyed documents)); Dec. 10, 2014 MacDonald Decl. Ex. QQ-2 (Waxman (Nov. 14, 2013) Dep. 138:12–18 (recalling that certain sales persons at Pfizer improperly attempted to destroy documents)); Dec. 10, 2014 MacDonald Decl. Ex. RR-2 (Waxman (Oct. 16, 2014) Dep. 33:9–35:22 (describing awareness of improper document destruction by Pfizer employees)); MacDonald Decl. Ex. JJ-2 (McKinnell (Nov. 11, 2013) Dep. 251:25–253:12 (describing Pfizer internal investigation that uncovered problems with off-label promotion in Brooklyn district and broader northeast region)).

[6] *See, e.g.*, Dec. 10, 2014 MacDonald Decl. Ex. AA-4 (PFE DERIV 00003754) (June 12, 2007 Memorandum from DLA Piper to Pfizer) (discussing results of Geodon internal investigation, including isolated instances of off-label promotion); Dec. 10, 2014 MacDonald Decl. Ex. CC-4 (PFE DERIV A 00003642) (Sept. 10, 2008 Memorandum from D. Lankler to Pfizer Audit Committee) (discussing results of Zyvox internal investigation, including "limited situations in which sales representatives violated Pfizer's compliance policies" and promoted Zyvox off-label); Dec. 10, 2014 MacDonald Decl. Ex. BB-4 (PFE DERIV A 00001357) (June 27, 2007 Audit Committee meeting minutes) (noting that instances of Geodon off-label promotion had been "contained and corrected"); *see also* Dec. 10, 2014 MacDonald Decl. Ex. DD-4 (PFE-JONES 00077022) (Sept. 27, 2007) (describing "probe of promotional activities related to Lyrica").

II. Evidence of Alleged Off-Label Promotion Should Be Precluded Under Rule 403.

Admitting the testimony and documents Plaintiffs propose to offer relating to off-label promotion would run afoul of virtually every prohibition contained in Rule 403: it would waste trial time, result in the needless presentation of cumulative evidence, confuse the jury, and unfairly prejudice Defendants. Any one of those things justifies exclusion; all of them are present here.

A. Admission of Evidence of Off-Label Promotion Would Waste Significant Time at Trial.

Plaintiffs' witness list reveals that of the 42 fact witnesses they intend to call at trial, 20 of them had no involvement in or awareness of Pfizer's securities disclosures; they instead would testify solely as to marketing conduct relating to Bexta, Zyvox, Geodon, or Lyrica. Plaintiffs' exhibit list is similarly bloated with materials relating solely to alleged off-label promotion—of nearly 1,000 exhibits, well over 300 of them are associated with Pfizer's development and promotion of these four products. Fully one third of Plaintiffs' exhibits, then, have absolutely nothing to do with their securities claims.

These superfluous materials, if admitted, would also affect Defendants' cases. Although Defendants agree that certain off-label conduct occurred, they deny that certain of the documents Plaintiffs have highlighted reflect any off-label promotion, deny that there was any headquarters-based strategy to off-label promote, and deny other inferences Plaintiffs seek to draw from various testimony and documents. Thus, if Plaintiffs' allegations and related evidence are introduced at trial, Defendants would be obligated to defend against and provide context for all of this material, adding numerous witnesses and documents to the evidence before the jury, none of which would be there but for Plaintiffs' insistence on presenting irrelevant evidence. The case would turn into a "trial within a trial," or multiple trials within the trial, as the parties argue about

whether particular instances of off-label promotion did or did not occur. Plaintiffs' attempt to drown the jury in extraneous, needlessly cumulative materials related to drug promotion therefore threatens to significantly expand the parties' cases and ultimately waste valuable time.

However, if the Court excludes Plaintiffs' proffered evidence on this topic, the trial would be streamlined substantially—a result supported by Rule 403. *See* 22A *Federal Practice and Procedure* § 5216, at 286 (2d ed. 2014) (citing 2 John Henry Wigmore, *Wigmore on Evidence* § 443, at 428 (3d ed. 1940);[7] *see also 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 the Defendants lied . . . while adducing no evidence concerning whether the Defendants committed the charged crimes"). The enormous amount of this material, coupled with the fact that it has no bearing on Plaintiffs' securities claims, warrant its exclusion.

B. Evidence of Alleged Off-Label Promotion Is Unfairly Prejudicial and Misleading.

Plaintiffs' exhibit and trial witness lists expose Plaintiffs' desire to parade before the jury a hodgepodge of inflammatory and out-of-context evidence related to off-label promotion. Plaintiffs' emphasis on these materials, almost all of which concern events that took place years before the Class Period and were authored by individuals with no connection to the investor statements at issue in this case, is designed to goad jurors into finding Defendants liable not because they violated the 1934 Act, but because certain of Pfizer's employees and affiliates engaged in marketing conduct that (Plaintiffs will argue) was impermissible. Courts routinely

[7] *See id.* ("[I]n attempting to dispute or explain away the evidence thus offered, new issues will arise as to the occurrence of the instances and the similarity of conditions, new witnesses will be needed whose cross-examination and impeachment will lead to further issues; and thus that the trial will be unduly prolonged, and the multiplicity of minor issues will be such that the injury will lose sight of the main issue, and the whole evidence will be only a mass of confused data from which it will be difficult to extract the kernel of controversy.").

prohibit parties from offering this type of unfairly prejudicial evidence under Rule 403, which provides the Court with broad discretion to "exclude relevant evidence if its probative value is substantially outweighed by a danger of," *inter alia*, "unfair prejudice," "confusing the issues," or "misleading the jury." Fed. R. Evid. 403.

"'Unfair prejudice' within its context means an undue tendency to suggest decision on an improper basis, commonly, . . . an emotional one." Fed. R. Evid. 403 advisory committee's note; *see also United States v. Miller*, 641 F. Supp. 2d 161, 166 (E.D.N.Y. 2009) ("The term 'unfair prejudice' . . . 'speaks to the capacity of some concededly relevant evidence to lure the factfinder into declaring guilt on a ground different from proof specific to the offense charged.'" (quoting *Old Chief v. United States*, 519 U.S. 172, 180 (1997))). Here, alleged evidence of off-label promotion by Pfizer employees is prejudicial not only because it invites the jury to infer that Pfizer had a propensity to act without regard to rules and regulations, but also because of the looming—and entirely unsubstantiated—specter of patient harm. Plaintiffs seek to invite the jury to punish Defendants as bad actors, regardless of the fact that these alleged acts bear no relation to the claims at issue in this case. *See, e.g.*, *United States v. Al-Moayad*, 545 F.3d 139, 161 (2d Cir. 2008) (admission of "inflammatory" testimony "almost entirely unrelated" to government's case amounted to "blatant appeal to the jury's emotions and prejudices" and was improper); *United States v. Lauersen*, No. S298CR1134 (WHP), 2000 WL 1677931, at *4–5 (S.D.N.Y. Nov. 8, 2000) (in case involving alleged health care and mail fraud, rejecting evidence of alleged witness tampering that would cause jury to "learn the disturbing details of a complicated delivery" of a baby, "possibly resulting in brain damage," because such information would "without a doubt, unfairly prejudice [defendant] in defending the offenses charged").

Introducing evidence of alleged off-label marketing also poses an unacceptable risk of "confusing the issues [and] misleading the jury." Fed. R. Evid. 403. The sheer amount of evidence Plaintiffs intend to introduce on this topic threatens to mislead the jury as to the issues it must decide. This case is about whether Defendants deliberately made false and misleading statements to investors that resulted in financial harm to Plaintiffs. Inundating the jury with documents and testimony related to Pfizer's promotion of Bextra and other products, much of it from outside the Class Period and relating to individuals unconnected to Defendants' disclosures, suggests to the jury that alleged off-label promotion somehow factors into the decisions it must make. In other words, the jurors could conclude, improperly, that such evidence would not be admitted in the case were they not obligated to consider it in deciding Defendants' liability—a result not countenanced by Rule 403. *See, e.g., SEC v. Badian,* 822 F. Supp. 2d 352, 366 (S.D.N.Y. 2011) (excluding admission of earlier criminal complaint against defendant because it could "lead the jury to make improper propensity inferences" and "confuse the allegations in the criminal [c]omplaint with the allegations in the instant case"); *Hatfield*, 685 F. Supp. 2d at 324 (rejecting prejudicial evidence that "st[ood] a good chance of confusing the jury as to the actual crimes charged, which a curative instruction may not alleviate").

III. Rule 404(b) Prohibits Plaintiffs' Use of Evidence of Alleged Off-Label Promotion To Attack Defendants.

Plaintiffs' gambit to improperly influence the jury is also prohibited by Rule 404(b), which proscribes the introduction of "evidence of a crime, wrong, or other act . . . to prove a person's character in order to show that on a particular occasion the person acted in accordance with the character." Fed. Rule Evid. 404(b). Plaintiffs seek to introduce evidence of alleged off-label promotion to suggest to the jury that because Pfizer employees acted improperly with

respect to promotion of products, they must have likewise acted improperly with respect to securities disclosures.

Rule 404(b) prevents Plaintiffs from engaging in this tactic. Plaintiffs may not ask the jury to "generaliz[e] a defendant's earlier bad act into bad character and [to take] that as raising the odds that he did the later bad act now charged." *Old Chief*, 519 U.S. at 180; *see also United States v. Scott*, 677 F.3d 72, 79 (2d Cir. 2012) (admission of "prejudicial extrinsic act evidence" improper where "offered to prove propensity"); 1 Christopher B. Mueller & Laird C. Kirkpatrick, *Federal Evidence* § 4.40, at 884 (4th ed. 2013) ("To sum it up, prior acts are broadly excludable in civil cases, and proof of prior acts should be excluded when they are relevant only because they support a propensity inference."). This proscription is especially important when, as in this case, the prior bad act "involve[s] conduct 'more sensational or disturbing'" than the acts alleged. *United States v. Nachamie*, 101 F. Supp. 2d 134, 145 (S.D.N.Y. 2000) (quoting *United States v. Roldan-Zapata*, 916 F.2d 795, 804 (2d Cir. 1990)) (excluding evidence of prior arson conviction in case involving alleged Medicare fraud). Establishing the elements of securities fraud through examination of thousands of pages of securities disclosures and financial information is much less likely to grab the attention of a jury than, for example, trumpeting documents that Plaintiffs argue suggest a sensational, headquarters-driven conspiracy to promote products contrary to law. For example, one of Plaintiffs' proffered experts, Jerry Avorn, claims that documents suggest that Pfizer purposefully marketed Geodon to "old people with Alzheimer's disease" even though the drug "doesn't really help those patients; and it increases their risk of death and metabolic disorders."[8] Although Pfizer of course denies this irresponsible accusation, the Court should prohibit Plaintiffs' blatant effort to mislead the jury in this manner.

[8] Dec. 10, 2014 MacDonald Decl. Ex. WW-1 (Avorn (Aug. 7, 2014) Dep. 310:15–24).

CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Court grant their motion *in limine* to exclude reference at trial to evidence of marketing and alleged off-label promotion of Pfizer products.

Date: December 10, 2014
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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that, on this 10th day of December, 2014, the foregoing Memorandum in Support of Defendants' Motion *In Limine* No. 5 to Exclude Evidence Related to Marketing and Alleged Off-Label Promotion of Pfizer Products, was filed with the Court through the CM/ECF system and thereby served to all parties of record.

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