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' REPLY IN SUPPORT OF PLAINTIFFS' MOTION *IN LIMINE* PRECLUDING DEFENDANTS FROM DISPUTING OFF-LABEL PROMOTION OF BEXTRA AND ZYVOX

I. INTRODUCTION

In their motions *in limine* ("MIL") Nos. 1-5, 7, 9-10, defendants argue that no evidence related to the off-label promotion of Bextra, Geodon, Zyvox and Lyrica should be admitted at trial. Defendants assert that off-label promotion has nothing to do with this case and that delving into these issues will unduly increase the length of trial. Ironically, in opposition to Plaintiffs' Motion *in Limine* Precluding Defendants from Disputing Off-Label Promotion of Bextra and Zyvox (Dkt. No. 366) ("Motion"), defendants now assert that Pfizer and the Individual Defendants should be allowed to dispute the off-label promotion of Bextra and Zyvox. Defendants' arguments fail, however, because they neither fulfill their burden to demonstrate they did not have a full and fair opportunity to litigate the Government Investigation nor address the cases cited by plaintiffs demonstrating that the guilty plea can provide the basis for collateral estoppel. Because Pfizer and the Individual Defendants litigated the Government Investigation for over five years and agreed to the Zyvox facts, the Court should reject defendants' request that they be allowed to re-litigate the off-label promotion of Bextra and Zyvox.

II. BACKGROUND

As noted in plaintiffs' Motion, Pfizer made numerous admissions during the plea hearing regarding the marketing of Bextra. Declaration of Henry Rosen in Support of Plaintiffs' Motion *in Limine* Precluding Defendants from Disputing Off-Label Promotion of Bextra and Zyvox (Dkt. No. 369) ("Rosen Decl."), Ex. 1 (*United States v. Pharmacia & Upjohn Company, Inc.*, No. 1:09-cv-10258-DPW, Dkt. No. 2 (D. Mass. Sept. 2, 2009) ("Plea Agreement")); Rosen Decl., Ex. 2 (*United States v. Pharmacia & Upjohn Company, Inc.*, No. 1:09-cr-10258-DPW, Dkt. No. 13 (D. Mass. Sept. 21, 2009) ("Plea Transcript")). These included:

- From February 2002 through April 2005, Pfizer promoted Bextra for uses that were not within its approved label, including (a) for acute pain, (b) for pre-operative and

post-operative surgical pain and (c) as opioid sparing in the context of surgery. Plea Transcript at 51:12-17.

- Pfizer "promoted Bextra at dosages higher than the approved doses for certain indications." *Id*. at 51:17-18.
- Pfizer introduced a drug into interstate commerce that lacked adequate directions for such off-label uses and dosages. *Id*. at 51:19-21.
- Pfizer promoted Bextra with an intent to defraud or mislead. *Id*. at 51:22-23.
- Certain members of Pfizer's sales force promoted Bextra with false and misleading claims, including that it had no dose proportional increase in hypertension and edema. *Id*. at 52:1-4.
- Certain members of Pfizer's sales force submitted to their supervisors false, fake requests indicating that physicians had requested off-label information when, in fact, they had not, and then there was follow-through in providing medical information letters to those physicians. *Id*. at 52:5-9.
- Pfizer used advisory boards and consultants meetings with physicians in lavish resort locations to promote Bextra off-label. *Id*. at 52:17-54:3.
- Pfizer participated with physicians in the creation of articles with respect to off-label indications of Bextra. *Id*. at 54:19-23.

Pfizer also made admissions in the civil settlement when it agreed the Zyvox facts 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.

Plea Agreement at 81.

III. ARGUMENT

The only issue raised by defendants is what preclusive effect the Bextra and Zyvox admissions have on Pfizer and the Individual Defendants. Pfizer asserts that it denied all the criminal allegations other than Pharmacia's admissions when it resolved the Government Investigation and that a holding against Pharmacia does not bind Pfizer. Dkt. No. 399 at 3-5. Defendants' reliance on *Levin* is confusing given the clear pronouncement therein that "'to be bound by a prior judgment, a party in the subsequent litigation must have been a party to, or represented by a privy in, the prior action.'" *Levin v. Tiber Holding Corp.*, 277 F.3d 243, 252 (2d Cir. 2002) (quoting *Haitian Ctrs. Council, Inc. v. McNary*, 969 F.2d 1350, 1355 (2d Cir. 1992) (citing *Parklane Hosiery Co. v. Shore*, 439 U.S. 322, 327 & n.7 (1979))). Here, Pfizer was clearly both a party to the Government Investigation and in privy with Pharmacia Upjohn & Company, the wholly-owned subsidiary that pleaded guilty.

Furthermore, defendants ignore that when Pfizer pleaded guilty to the misbranding of Bextra, it had the same effect as a conviction after trial. This is especially appropriate because Pfizer vigorously defended the Government Investigation in which the prosecutors threatened criminal indictments for both Pfizer and certain of the Individual Defendants. Cases clearly hold that under these circumstances, the allocution under oath of a guilty plea affords ample protection. *Van Limburg Stirum v. Whalen*, No. 90-CV-1279, 2000 U.S. Dist. LEXIS 9786, at *14-*18 (N.D.N.Y July 12, 2000).

Defendants further assert that Pfizer's admissions should not bind the Individual Defendants. Dkt. No. 399 at 3-4. This argument ignores that the Individual Defendants controlled and appointed the Pfizer employees who were responsible for running the litigation. As noted, in addition to Pfizer having litigated the Government Investigation for over five years, many of the Individual Defendants

directed the litigation in the senior most positions at Pfizer from the time the investigation was instigated in early 2004 to the time it was resolved in 2009. It is worth noting that defendants, not plaintiffs, have the burden to establish that defendants did not have a full and fair opportunity to litigate the Government Investigation. *Kulak v. City of New York*, 88 F.3d 63, 72 (2d Cir. 1996). Mr. Gibney and Pfizer's counsel during the plea colloquy clearly indicated to the court accepting the plea that they understood the consequences of making the plea, that they understood the crimes to which Pfizer would plead and had discussed the plea with counsel. Plea Transcript at 25-36.

Faced with these facts, defendants do not even address the cases cited by plaintiffs which encourage collateral estoppel where the issues were "'really disputed and that the loser will have put out his best efforts.'" *SEC v. Monarch Funding Corp.*, 192 F.3d 295, 307 (2d Cir. 1999) (quoting *The Evergreens v. Nunan*, 141 F.2d 927, 929 (2d Cir. 1944) (Hand, J.)). This also applies to the stipulated Zyvox facts which were clearly related to and necessary to resolve the Government Investigation. Pfizer itself insisted as a term of settlement that the government wrap the Bextra investigation together with the Zyvox investigation. Combined with the stipulated Zyvox facts and the admissions the Company made to 66,000 doctors, defendants cannot sustain their burden to demonstrate they were not afforded an opportunity to defend. As noted, the Second Circuit clearly holds that the doctrine of collateral estoppel will apply "where parties intend a stipulation to be binding in future litigation, issues to which the parties have stipulated will be considered 'actually litigated' for collateral estoppel purposes." *Uzdavines v. Weeks Marine, Inc.*, 418 F.3d 138, 146-47 (2d Cir. 2005) (quoting *Cent. Hudson Gas & Elec. Corp. v. Empresa Naviera Santa S.A.*, 56 F.3d 359, 369 n.4 (2d Cir. 1995)).

Defendants did not address these decisions because they cannot dispute they did not have an adequate opportunity to litigate.

IV. CONCLUSION

For these reasons, plaintiffs seek an order that defendants, Pfizer and the Individual Defendants, are precluded from re-litigating the Bextra and Zyvox off-label marketing allegations.

DATED: December 30, 2014

Respectfully submitted,

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