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

I. INTRODUCTION

Plaintiffs seek an *in limine* ruling from the Court precluding defendants from providing testimony or putting forward any other evidence disputing that Pfizer promoted Bexra and Zyvox during the relevant time period in this case in violation of the Federal Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. §§331, 332 and 352. The basis for this ruling is simple, Pfizer pleaded guilty to felony misbranding of Bextra and admitted that its sales force illegally promoted Zyvox in the Civil Settlement Agreement executed simultaneously with the guilty plea.[1] Given their admissions and in the interests of judicial economy, plaintiffs request that defendants be estopped from denying their prior admission regarding Pfizer's illegal and improper promotion of Bextra and Zyvox.

On September 2, 2009, the U.S. Department of Justice ("DOJ") and Pfizer filed a plea agreement in *United States v. Pharmacia & Upjohn Company, Inc.*, No. 1:09-cr-10258-DPW to resolve criminal charges relating to the off-label promotion of Bextra. *See* Declaration of Henry Rosen in Support of Plaintiffs' Motion *in Limine* Precluding Defendants from Disputing Off-Label Promotion of Bextra and Zyvox ("Rosen Decl."), Ex. 1 (*United States v. Pharmacia & Upjohn Company, Inc.*, No. 1:09-cr-10258-DPW, Dkt. No. 2 (D. Mass. Sept. 2, 2009) ("Plea Agreement")), filed concurrently herewith.[2] As part of that settlement, Pfizer agreed to enter a guilty plea to the misbranding of Bextra in violation of 21 U.S.C. §§331, 332 and 352 as set forth in an Information attached to the Plea Agreement. *Id.* at 13-33. Thereafter, on September 15, 2009, Pfizer pleaded guilty, admitting to the misbranding of Bextra from February 2002 to April 2005.

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[1] "Pfizer" or the "Company" refers to Pfizer Inc. and its wholly-owned subsidiaries, as well as any entities that later became its wholly-owned subsidiaries.

[2] Hereinafter Government Investigation.

An examination of the settlement agreement (Rosen Decl., Ex. 1; 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")) further reveals that the issues of the off-label marketing of Bextra and Zyvox were actually decided in the Government Investigation. During the September 2009 plea allocution, Pfizer representative, James Gibney, admitted under oath that Pfizer wilfully promoted Bextra off-label and agreed that the amount of the ill-gotten gain was $664 million. Plea Transcript at 24:15-37:7. Pfizer's outside investigation counsel, Brien O'Connor, also made several significant admissions during the colloquy including:

- 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. *Id.* 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.

Part of the criminal disposition that Pfizer and the government submitted for Judge Woodlock's acceptance under Fed. R. Crim. P. 11(c)(1)(C) was a "Civil Settlement Agreement."

Plea Agreement at 3. Under the Civil Settlement Agreement, Pfizer further admitted that its sales personnel, from 2005 to 2008, continued to make claims that Zyvox was superior to vancomycin. These superiority claims were inconsistent with Zyvox's label and with the manner Pfizer assured the FDA it would present Zyvox data after receipt of the July 2005 U.S. Food and Drug Administration ("FDA") Warning Letter which instructed Pfizer to cease and desist making the superiority claims. *Id.* at 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.

During the September 15, 2009 plea hearing colloquy, the Court noted that the Zyvox settlement was reduced to a writing attached to the settlement agreement. Plea Transcript at 22:9-23:10. The Assistant United States Attorney ("AUSA"), Sara Bloom, who prosecuted Pfizer, explained why the Zyvox off-label investigation settlement was reduced to writing:

> THE COURT: Why was it done for Zyvox?
>
> MS. BLOOM: There was no criminal resolution as to Zyvox.
>
> THE COURT: I understand. It's attachment A to the settlement agreement.
>
> MS. BLOOM: As to resolution, the government felt it was important to get into the public record what had happened. Part of the resolution with respect to Zyvox is actually a letter to go out to the doctors to tell them that this promotion,

> incorrect promotion had occurred and reminding them of the correct promotion consistent with the label.
>
> Bextra is no longer on the market, Zyvox is still on the market. It was more recent conduct. So there was some sense that we needed to make sure that those facts – in a civil agreement of what facts do not get laid out in the sense of an information or other form, so that we felt it was important that the facts that had been admitted by the company in connection with negotiations by the company be made public, be made clear.

Id. at 23:6-24.

Based on the admitted Zyvox facts, the letter Pfizer was forced to send to over 66,000 physicians admitting that they promoted Zyvox off-label and the inclusion of these terms in the proposed criminal disposition, was clearly part of the Bextra criminal litigation.[3]

Plaintiffs now seek an order that defendants are collaterally estopped from presenting evidence inconsistent with these admissions. "The principal virtue of collateral estoppel is self-evident: it promotes judicial economy by reducing the burdens associated with revisiting an issue already decided." *SEC v. Monarch Funding Corp.*, 192 F.3d 295, 303 (2d Cir. 1999) (citing *Parklane Hosiery Co. v. Shore*, 439 U.S. 322, 326 (1979); *Gelb v. Royal Globe Ins. Co.*, 798 F.2d 38, 44 (2d Cir. 1986)). Because plaintiffs can establish all the elements of issue preclusion, they should not be forced to revisit whether Bextra and Zyvox were promoted off-label.[4]

II. ARGUMENT

Issue preclusion, or collateral estoppel, bars re-litigation of an issue when:

> "(1) the identical issue was raised in a previous proceeding; (2) the issue was actually litigated and decided in the previous proceeding; (3) the party had a full and fair

[3] *See* Rosen Decl., Ex. 3 (November 6, 2009 Letter to Boston Assistant U.S. Attorney, Zachary Cuhna regarding sending 66,000 letters to physicians).

[4] It is worth noting that defendants admitted that Pfizer agreed to certain facts regarding the marketing of Zyvox as described in Attachment A to the 2009 Settlement Agreement. Defendants' Amended Answer to Plaintiffs' First Amended Consolidated Class Action Complaint, ¶53 (Dkt No. 160 in this action).

> opportunity to litigate the issue; and (4) the resolution of the issue was necessary to support a valid and final judgment on the merits."

Proctor v. LeClaire, 715 F.3d 402, 414 (2d Cir. 2013) (quoting *Ball v. A.O. Smith Corp.*, 451 F.3d 66, 69 (2d Cir. 2006)). In this case, when Pfizer pleaded guilty to the misbranding of Bextra, it had the same effect as a conviction after trial. "Although a 'conviction should not support the preclusion issue if there was little effort to defend vigorously, particularly if the prosecution was for a trivial offense, the full allocution under oath of a plea of guilty normally provides ample protection to the defendants.'" *See 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) (quoting *United States v. U.S. Currency in the Amount One Hundred Forty-Five Thousand, One Hundred Thirty-Nine Dollars*, 803 F. Supp. 592, 598 (E.D.N.Y. 1992), *aff'd*, 18 F.3d 73 (2d Cir. 1994)). Here plaintiffs can establish all the necessary elements to invoke issue preclusion based on the Bextra guilty plea and the Zyvox settlement.

Pfizer's off-label promotion of Bextra and Zyvox were key issues at the heart of the Government Investigation settlement. By Pfizer's entry into the Plea Agreement, the issue was litigated and decided after Pfizer had full and fair opportunity to contest the issue. Defendants cannot now re-litigate whether Bextra and Zyvox were promoted off-label.

The burden of proof to establish the elements of issue preclusion is divided. Plaintiffs have the burden to establish the issues were identical and necessary to the resolution of the government investigation. *Kulak v. City of New York*, 88 F.3d 63, 72 (2d Cir. 1996). "In contrast, the burden of showing that the prior action did not afford a full and fair opportunity to litigate the issues rests" with defendants. *Id.* Defendants cannot sustain their burden and demonstrate they were not afforded a full and fair opportunity to litigate the Government Investigation.

Again, the September 15, 2009, plea colloquy demonstrates Pfizer's full and fair opportunity. Mr. Gibney and Pfizer's counsel affirmatively confirmed to the court that:

- Mr. Gibney understood the crimes to which Pfizer would plead guilty and was familiar with the guilty plea. Plea Transcript at 25:20-26:18, 27:18-23.

- Pfizer had a full discussion with its counsel about corporate responsibility for the crimes committed by its employees. *Id.* at 26:19-27:2.

- Pfizer had a full discussion with its counsel about the various types of defenses that it would have to the off-label allegations. *Id.* at 27:3-6.

- Pfizer understood that the guilty plea to the off-label marketing allegations would result in very heavy penalties. *Id*. at 27:18-28:14.

- Pfizer understood how the parties had reached an agreement about the amount of illegal sales obtained from the off-label marketing of Bextra ($664 million), agreed with the methodology, understood how the fines based on that amount were calculated ($1.328 billion) and understood that the parties had stipulated to a fine slightly below the maximum allowed ($1.195 billion). *Id*. at 28:3-15.

- Pfizer understood that it was also paying a forfeiture of $105 million. *Id*. at 30:13-14.

- Pfizer had an adequate opportunity to discuss with its counsel the prospects of an appeal and it understood the consequences of waiving its right to appeal. *Id*. at 32:2-10.

- Pfizer understood that it was paying $1.3 billion to settle the criminal case and another $1 billion to resolve the civil allegations. *Id*. at 33:22-34:10.

- Pfizer agreed to plead guilty of its own free will without the threat of coercion. *Id*. at 35:23-36:20.

Moreover, after Mr. Gibney confirmed the information above, AUSA Bloom outlined the proof the DOJ had assembled against Pfizer. *Id.* at 37:10- 50:18.[5]

After he completed his admissions, the Court noted that Mr. O'Connor agreed there was a factual basis for the guilty plea based on his admissions. *Id.* at 55:17-8. The court then asked Mr. Gibney: "Do you dispute the fundamental contention of the government that your company

[5] Later in the plea hearing, Pfizer's outside counsel Mr. O'Connor made the Pfizer admissions listed above. Plea Transcript at 50:20-55:15.

engaged in illegal off-label marketing, promotion of the drug Bextra?" He replied: "I don't dispute it, your Honor." *Id*. at 55:19-22.

Finally, it is axiomatic that the admission that Bextra had been promoted in violation of 21 U.S.C. §352, was necessary for the DOJ to obtain a valid and final judgment on the merits of the case in late 2009. It is clear from the September 15, 2009 plea hearing, that the court obtained the admissions outlined above. In addition, before Judge Woodlock could enter final judgment, the court obtained a guilty plea as follows:

> Mr. Gibney, in criminal number 09-10258 on behalf of Pharmacia and Upjohn Company, Inc. you are charged in Count 1 of the information with introduction into commerce of a misbranded drug in violation of Title 21 United States Codes 331(a), 333(a)(2), and 352. What say you as to Count 1, guilty or not guilty?
>
> Mr. Gibney: Guilty.

Id. at 62:9-15.

The foregoing analysis applies with equal force to Pfizer's Zyvox admissions because Pfizer made these admissions as part of the same criminal disposition. Plus, leading up to that disposition Pfizer also had a full and fair opportunity to contest the off-label promotion of Zyvox. It is worth emphasizing Pfizer's admission that it promoted Zyvox off-label from 2005 to 2008 in blatant disregard of the FDA warning to cease and desist. On July 20, 2005, the FDA sent Henry McKinnell a Warning Letter demanding the Company immediately cease and desist its unlawful promotion of Zyvox.[6] Despite receipt of the FDA Warning Letter, Pfizer instructed its sales force on September 30, 2005, that when detailing doctors, to "[a]lways go back to ZYVOX proven efficacy [and that]

[6] Rosen Decl., Ex. 4 at PZ0034666-76.

ZYVOX is better than vancomycin." Rosen Decl., Ex. 5 at Greensmith0003892.[7] The Company's sales force listened to this directive and continued making unsubstantiated superiority claims.

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. Plea Agreement at 38-39, 80-81. As explained by AUSA Bloom, 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 over 66,000 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.[8] During the September 15, 2009 plea hearing, a wholly-owned subsidiary Pharmacia & Upjohn Company, created after Bextra was removed from the market, agreed to plead guilty to the misbranding of Bextra and to be excluded from participating in government drug reimbursement programs. So that Pfizer could avoid exclusion, a death knell to a pharmaceutical company, the DOJ and Pfizer's attorney Mr. O'Connor submitted an agreement not to prosecute Pfizer Inc., reflected in a side letter that was not presented to that court until the plea hearing. Plea Transcript at 56:1-58:7. The Court considered the letter "clearly material" to the decision to enter the guilty plea and Mr. Gibney took it into account when considering the "totality" of the plea agreement. *Id.* at 57:23, 58:5-7. In that side agreement, the DOJ agreed not to prosecute Pfizer Inc. for the off-label marketing of Bextra, Zyvox or other drugs as long as Pfizer fulfilled its obligations in the Civil Settlement Agreement which included the Zyvox admitted facts. Rosen Decl., Ex. 7 at 2 (*United States v. Pharmacia & Upjohn Company, Inc.*, No. 1:09-cr-10258-DPW, Dkt. No. 24 (D. Mass. Sept. 15, 2009)).

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[7] Thereafter, Pfizer was forced to admit that despite the Warning Letter and Pfizer's promise to cease, "Pfizer's sales personnel thereafter continued to make claims to physicians that Zyvox was superior to vancomycin." Rosen Decl., Ex. 6 at 2

[8] Rosen Decl., Ex. 3.

Accordingly, under the doctrine of collateral estoppel, these facts establish the necessity requirement which "'protects' against unfairness, by ensuring that the issue will be 'really disputed and that the loser will have put out his best efforts.'" *Monarch Funding*, 192 F.3d at 307 (quoting *The Evergreens v. Nunan*, 141 F.2d 927, 929 (2d Cir. 1944) (Hand, J.).

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)). These facts clearly demonstrate that Pfizer intended to be bound by the stipulated Zyvox facts.

III. CONCLUSION

Because plaintiffs can establish each required element of collateral estoppel, defendants should not be allowed to litigate in this action whether Pfizer illegally promoted Bextra and Zyvox off-label.

DATED: December 10, 2014

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on December 10, 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 10, 2014.

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Filer: Mary K. Jones
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Document Number: 366

Docket Text:
MEMORANDUM OF LAW in Support re: [365] MOTION in Limine *Precluding Defendants from Disputing Off-Label Promotion of Bextra and Zyvox*. . Document filed by Mary K. Jones(Individually), Stichting Philips Pensioenfonds. (Rosen, Henry)

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