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

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

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Pursuant to Federal Rules of Evidence 401, 402, and 403, Defendants respectfully submit this opposition to Plaintiffs' motion to preclude Defendants from disputing off-label promotion of Bextra and Zyvox. As an initial matter, Defendants have moved *in limine* to preclude Plaintiffs from introducing evidence concerning the off-label promotion of Bextra, Zyvox, Geodon and Lyrica. Should this Court grant Defendants' motion *in limine*, Plaintiffs' present motion will be rendered moot because Defendants will agree not to dispute at trial (i) that on August 31, 2009, a Pfizer subsidiary pled guilty to one count of felony misbranding of Bextra, and (ii) Pfizer's admissions set forth in Exhibit A, relating to Zyvox, appended to the Civil Settlement Agreement that resolved the government investigations into Bextra, Geodon, Lyrica, and Zyvox (the "Government Investigations"). If this Court denies Defendants' motion *in limine*, however, the Court should deny Plaintiffs' motion for the following reasons: ***First***, Defendants Frank D'Amelio, Jeffrey B. Kindler, Alan G. Levin, Henry A. McKinnell, Ian C. Read, and Allen Waxman (the "Individual Defendants")—who did not make any admissions concerning Bextra or Zyvox—should not be precluded from disputing off-label promotion of those products. ***Second***, Pfizer should not be precluded from disputing anything beyond the factual basis for the guilty plea relating to Bextra, and the admissions regarding Zyvox that are set forth in Exhibit A to the Civil Settlement Agreement.

BACKGROUND

On August 31, 2009, Pharmacia & Upjohn Company, Inc. ("Pharmacia") entered into a plea agreement (the "Plea Agreement") with the United States Attorney for the District of Massachusetts.[1] Rosen Decl., Ex. 1, ECF No. 369-1. Pharmacia pled guilty to one violation of the Food, Drug and Cosmetic Act, 21 U.S.C. §§ 331(a), 333(a)(2), and 352(f)(l), for conduct

[1] This was long after several of the individual Defendants were no longer employed by Pfizer.

relating to Bextra. Pharmacia did not plead guilty to any violation for conduct relating to Zyvox (or any other drug). Plea Agreement § 1. None of the Defendants in this case was a party to the Plea Agreement or pled guilty to anything.

The only obligation imposed on any of the Defendants by the Plea Agreement was that Pfizer (not the Individual Defendants) perform all of its material obligations set forth in the separate Civil Settlement Agreement, attached to the Plea Agreement, which resolved civil claims against Pfizer. Plea Agreement §§ 5, 12, 14. The Civil Settlement Agreement—to which the Individual Defendants were not a party—explicitly stated:

> This Agreement is made in compromise of disputed claims. This Agreement is not an admission of facts or liability by Pfizer, and Pfizer expressly denies the allegations of the United States and the Relators as set forth herein and in the Civil Actions and denies that it engaged in any wrongful conduct in connection with the Covered Conduct except as to: 1) such admissions as Pharmacia makes in connection with any guilty plea and as provided herein; and 2) the facts set forth in Attachment A as to Zyvox. . . . Neither this Agreement, nor the performance of any obligation arising under it, including any payment, nor the fact of settlement is intended to be, or shall be understood as, an admission of liability or wrongdoing, or other expression reflecting on the merits of the dispute by Pfizer, except as set forth in this Paragraph.

Civil Settlement Agreement § H. This provision defines Pfizer's admissions.

ARGUMENT

I. THE INDIVIDUAL DEFENDANTS SHOULD NOT BE PRECLUDED FROM DISPUTING OFF-LABEL PROMOTION OF BEXTRA AND ZYVOX.

"Corporations are treated as entities separate from their officers, directors, and shareholders for purposes of preclusion just as for other purposes. Without more, a judgment entered in an action against any one of them is not binding on any other." 18A Charles Alan Wright et al., *Federal Practice and Procedure* § 4460 (2d ed. 2014); *accord* RESTATEMENT (SECOND) OF JUDGMENTS § 59 ("[A] judgment in an action to which a corporation is a party has

no preclusive effects on a person who is an officer, director, stockholder, or member of a non-stock corporation, nor does a judgment in an action involving a party who is an officer, director, stockholder, or member of a non-stock corporation have preclusive effects on the corporation itself."); *Levin v. Tiber Holding Corp.*, 277 F.3d 243, 246, 252-53 (2d Cir. 2002) (holding that a judgment against a "principal officer" did not bind the corporation). That principle certainly applies in this case where the Plea Agreement did not address, much less resolve, the Individual Defendants' liability with respect to any of the admissions at issue: "The United States expressly reserves the right to prosecute any individual, including but not limited to present and former officers, directors, employees, and agents of Pharmacia, in connection with the conduct encompassed by this plea agreement, within the scope of the grand jury investigation, or known to the U.S. Attorney." Plea Agreement § 5.

There are only two narrow exceptions to the rule that a corporation's admissions are not binding on its officers for purposes of issue preclusion, neither of which exists here. ***First***, issue preclusion may apply if "there is a substantive basis for litigation with an officer or director in an official capacity that does not entail individual liability." 18A *Federal Practice and Procedure* § 4460. Of course, the Individual Defendants are not being sued in an official capacity; rather, Plaintiffs are seeking to hold them individually liable. ***Second***, issue preclusion may apply where an individual was essentially a party to the prior proceeding. *See Drier v. Tarpon Oil Co.*, 522 F.2d 199, 200-01 (5th Cir. 1975) (issue preclusion applied to "the president and major stockholder of the corporation" who "admitted by deposition that he made the 'ultimate decisions'" and "was the only witness for [the company in the prior suit]"). This exception is largely limited to controlling owners of a corporation: "Ownership seems indispensable to this result; even an officer or director who absolutely controls corporate litigation but who owns a

minor interest should not be precluded by the judgment, lest the fear of personal consequences distort the decisions made on behalf of the corporation." 18A *Federal Practice and Procedure* § 4460. As the Restatement (Second) of Judgments explains:

> The concept that a corporation is a legal entity distinct from its management and stockholders implies that issues determined against a corporation are not conclusive against its directors, officers, and stockholders, and vice versa. Such a rule is appropriate with regard to a corporation whose ownership is widely held. In such a corporation, the directors and officers are charged with a fiduciary obligation to manage the corporation's affairs, including the conduct of litigation, in a manner consistent with the best interests of the enterprise, in disregard of their own personal interests. Their control of litigation on behalf of the corporation should be unfettered by concern that its outcome might be conclusive upon them in their individual capacities. In a corporation whose management is a complex organization, moreover, many or all of the officers and directors often have such a remote connection with specific litigation that they cannot be said to have participated in it beyond assuming official responsibility on behalf of the corporation. To hold them bound by determinations in litigation to which the corporation is a party would in effect deny them their own day in court.

RESTATEMENT (SECOND) OF JUDGMENTS § 59, comment e (citation omitted). There can be no dispute that none of the Individual Defendants is Pfizer's owner or controlling shareholder and, for the above reasons, this exception does not apply.

Accordingly, the Individual Defendants should not be precluded from disputing off-label promotion of Bextra and Zyvox.

II. PFIZER SHOULD NOT BE PRECLUDED FROM DISPUTING ANY ALLEGATIONS OF OFF-LABEL PROMOTION OF BEXTRA AND ZYVOX BEYOND THE COMPANY'S PRIOR ADMISSIONS.

Pfizer should not be precluded from disputing anything beyond the admissions set forth in the Civil Settlement Agreement: Pharmacia's limited admission in connection with its guilty

plea and the facts set forth in Attachment A of the Civil Settlement Agreement as to Zyvox.[2] To the extent that Plaintiffs seek broader preclusion—*e.g.*, "an order that defendants are collaterally estopped from presenting evidence inconsistent with these admissions"[3]— there is no basis for it. As the Supreme Court has held:

> [S]ettlements ordinarily occasion no *issue preclusion* (sometimes called collateral estoppel), unless it is clear, as it is not here, that the parties intend their agreement to have such an effect. In most circumstances, it is recognized that consent agreements ordinarily are intended to preclude any further litigation on the claim presented but are not intended to preclude further litigation on any of the issues presented. Thus consent judgments ordinarily support claim preclusion but not issue preclusion. This differentiation is grounded in basic res judicata doctrine. It is the general rule that issue preclusion attaches only when an issue of fact or law is actually litigated and determined by a valid and final judgment, and the determination is essential to the judgment. In the case of a judgment entered by confession, consent, or default, none of the issues is actually litigated. Therefore, [issue preclusion] does not apply with respect to any issue in a subsequent action.

Arizona v. California, 530 U.S. 392, 414 (2000) (alterations, citations, and internal quotation marks omitted). The plain language of the Civil Settlement Agreement makes clear that Pfizer expressly denied all allegations and any wrongful conduct other than Pharmacia's admissions in connection with its guilty plea and the facts set forth in Attachment A of the Agreement as to Zyvox. Pfizer does not intend to dispute those specific admissions and facts at trial. To the extent Plaintiffs' motion seeks to preclude anything beyond that, it must be denied.

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[2] Plaintiffs purport to identify "admissions" made by Pharmacia's counsel during the September 2009 plea allocution, but they are in fact misstatements of the record in that matter. Pls' Br. at 2. For example, Plaintiffs repeatedly represent that there was an admission that "Pfizer" engaged in certain conduct. *Id*. This is false; as Mr. O'Connor repeated in each instance that Plaintiffs reference, it was Pharmacia, not Pfizer, that made any admissions in connection with the resolution of the Bextra investigation.

[3] Mem. of Law in Support of Mot. *In Limine* Precluding Defendants from Disputing Off-Label Promotion of Bextra and Zyvox at 4, ECF No. 366.

CONCLUSION

For the foregoing reasons, this Court should deny Plaintiffs' motion to preclude Defendants from disputing off-label promotion of Bextra and Zyvox.

Date: December 22, 2014

Respectfully submitted,

WILLIAMS & CONNOLLY LLP

By: /s/ Joseph G. Petrosinelli

Joseph G. Petrosinelli (admitted *pro hac vice*)
Steven M. Farina (admitted *pro hac vice*)
George A. Borden
Amanda M. MacDonald (admitted *pro hac vice*)
725 Twelfth Street, N.W.
Washington, D.C. 20005
Telephone: (202) 434-5000
Facsimile: (202) 434-5029
sfarina@wc.com
jpetrosinelli@wc.com
gborden@wc.com
amacdonald@wc.com

Counsel for Defendant Pfizer Inc.

SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP

By: /s/ Scott D. Musoff

Scott D. Musoff
Four Times Square
New York, New York 10036
Telephone: (212) 735-3000
Facsimile: (212) 735-2000
scott.musoff@skadden.com

Jennifer L. Spaziano (*pro hac vice* pending)
Michael S. Bailey (*pro hac vice* pending)
1440 New York Avenue NW
Washington, DC 20005
Telephone: (202) 371-7000
Facsimile: (202) 393-5760
Email: Jen.Spaziano@skadden.com
Email: Michael.Bailey@skadden.com

Counsel for Henry A. McKinnell

DAVIS POLK & WARDWELL LLP

By: /s/ James P. Rouhandeh

James P. Rouhandeh
Charles S. Duggan
450 Lexington Avenue
New York, New York 10017
Telephone: (212) 450-4000
james.rouhandeh@davispolk.com
charles.duggan@davispolk.com

Counsel for Defendant Jeffrey B. Kindler

GOODWIN PROCTER LLP

By: /s/ Richard M. Strassberg

Richard M. Strassberg
Daniel Roeser
The New York Times Building
620 Eighth Avenue
New York, NY 10018
Tel.: 212.813.8800
Fax: 212.355.3333
rstrassberg@goodwinprocter.com
droeser@goodwinprocter.com

Counsel for Defendant Frank D'Amelio

SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP

By: /s/ Jay B. Kasner

Jay B. Kasner
Gary J. Hacker
Alexander C. Drylewski
Four Times Square
New York, New York 10036
Telephone: (212) 735-3000
Facsimile: (212) 735-2000

Counsel for Defendant Alan G. Levin

QUINN EMANUEL URQUHART & SULLIVAN, LLP

By: /s/ Michael B. Carlinsky

Michael B. Carlinsky
Sheila Birnbaum
Brant Duncan Kuehn (*pro hac vice* pending)
51 Madison Avenue
New York, New York 10010
(212) 849-7000

Lori Alvino McGill
777 6th Street, NW
Washington, DC 20001
(202) 538-8000

Counsel for Defendant Ian C. Read

O'MELVENY & MYERS LLP

By: /s/ Ross B. Galin

Ross B. Galin
Stuart Sarnoff
Howard E. Heiss
7 Times Square
New York, New York 10036
Telephone: (212) 326-2000
Facsimile: (212) 326-2061
rgalin@omm.com
ssarnoff@omm.com
hheiss@omm.com

Counsel for Defendant Allen Waxman

CERTIFICATE OF SERVICE

I hereby certify that, on this 22nd day of December, 2014, the foregoing Defendants' Memorandum of Law in Opposition to Plaintiffs' Motion *In Limine* Precluding Defendants from Disputing Off-Label Promotion of Bextra and Zyvox was filed with the Court through the CM/ECF system and thereby served on all parties of record.

/s/ Lauren K. Collogan
Lauren K. Collogan
Williams & Connolly LLP
725 Twelfth Street, N.W.
Washington, D.C. 20005
Telephone: (202) 434-5000
Facsimile: (202) 434-5029
lcollogan@wc.com

Regan Karstrand

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Jeffrey B. Kindler
Alan G. Levin
Henry A. McKinnell
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Allen Waxman
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1:10-cv-03864-AKH Notice has been electronically mailed to:

Alexander C Drylewski alexander.drylewski@skadden.com

Amanda M. MacDonald amacdonald@wc.com

Brant Duncan Kuehn brantkuehn@quinnemanuel.com

Charles S. Duggan charles.duggan@dpw.com, ecf.ct.papers@davispolk.com

Cynthia Margaret Monaco cmonaco@cynthiamonacolaw.com, cmmonaco@gmail.com

Daniel Prugh Roeser droeser@goodwinprocter.com

Danielle Suzanne Myers dmyers@rgrdlaw.com

Darren J. Robbins e_file_sd@rgrdlaw.com

David Avi Rosenfeld drosenfeld@rgrdlaw.com, e_file_ny@rgrdlaw.com, e_file_sd@rgrdlaw.com

Donald Alan Migliori dmigliori@motleyrice.com

Eugene Mikolajczyk genem@rgrdlaw.com

Gary John Hacker ghacker@skadden.com

George Anthony Borden gborden@wc.com

Hamilton Philip Lindley hlindley@deanslyons.com, mgoens@deanslyons.com

Henry Rosen henryr@rgrdlaw.com, dianah@rgrdlaw.com

Howard E. Heiss hheiss@omm.com, #nymanagingattorney@omm.com

Ivy T. Ngo ingo@rgrdlaw.com, e_file_sd@rgrdlaw.com

James M. Hughes jhughes@motleyrice.com, erichards@motleyrice.com, kweil@motleyrice.com, kweil@pacernotice.com, mgruetzmacher@motleyrice.com

James P. Rouhandeh james.rouhandeh@dpw.com, ecf.ct.papers@davispolk.com

James R. Harper coljamesrharper@me.com

Jason A. Forge jforge@rgrdlaw.com, e_file_SD@rgrdlaw.com, tholindrake@rgrdlaw.com

Jay B. Kasner jkasner@skadden.com

Jennifer Lynn Spaziano jen.spaziano@skadden.com

Joe Kendall administrator@kendalllawgroup.com, hlindley@kendalllawgroup.com, jkendall@kendalllawgroup.com

John K. Villa jvilla@wc.com

Joseph F. Rice jrice@motleyrice.com

Joseph G. Petrosinelli jpetrosinelli@wc.com

Juliana Newcomb Murray juliana.murray@davispolk.com, ecf.ct.papers@davispolk.com, lisa.hirakawa@davispolk.com

Keir Nicholas Dougall kdougall@dougallpc.com

Kevin Anthony Burke kaburke@sidley.com, efilingnotice@sidley.com, nyefiling@sidley.com

Lauren Kristina Collogan lcollogan@wc.com

Leigh R. Lasky lasky@laskyrifkind.com

Lori McGill lorialvinomcgill@quinnemanuel.com

Matthew Melamed mmelamed@rgrdlaw.com

Michael Barry Carlinsky michaelcarlinsky@quinnemanuel.com, brantkuehn@quinnemanuel.com, jomairecrawford@quinnemanuel.com

Michael Joseph Dowd miked@rgrdlaw.com, e_file_sd@rgrdlaw.com, e_file_sf@rgrdlaw.com, tome@rgrdlaw.com

Michael Scott Bailey michael.bailey@skadden.com

Mitchell M.Z. Twersky mtwersky@aftlaw.com

Paul T. Hourihan phourihan@wc.com

Richard Mark Strassberg rstrassberg@goodwinprocter.com, nymanagingclerk@goodwinprocter.com

Ross Bradley Galin rgalin@omm.com, lisachen@omm.com, mochoa@omm.com, neverhart@omm.com

Ryan A. Llorens ryanl@rgrdlaw.com, kirstenb@rgrdlaw.com, nbear@rgrdlaw.com

Samuel Howard Rudman srudman@rgrdlaw.com, e_file_ny@rgrdlaw.com, e_file_sd@rgrdlaw.com, mblasy@rgrdlaw.com

Scott D. Musoff smusoff@skadden.com

Seema Mittal smittal@wc.com

Sheila L. Birnbaum sheilabirnbaum@quinnemanuel.com

Sidney Bashago sidney.bashago@dpw.com, ecf.ct.papers@davispolk.com, jennifer.kan@davispolk.com

Steven M.. Farina sfarina@wc.com

Stuart Michael Sarnoff ssarnoff@omm.com

Trig Randall Smith trigs@rgrdlaw.com, e_file_sd@rgrdlaw.com, nhorstman@rgrdlaw.com

William E. Schurmann wschurmann@wc.com

William H. Narwold bnarwold@motleyrice.com, ajanelle@motleyrice.com, vlepine@motleyrice.com

Willow E. Radcliffe willowr@rgrdlaw.com, ptiffith@rgrdlaw.com

1:10-cv-03864-AKH Notice has been delivered by other means to:

Catherine J. Kowalewski
Robbins Geller Rudman & Dowd LLP (San Diego)
655 West Broadway
Suite 1900
San Diego, CA 92101

Daniel E. Hill
Kendall Law Group, LLP
3232 McKinney Avenue
Suite 700
Dallas, TX 75204

David C. Walton
Robbins Geller Rudman & Dowd LLP (SANDIEGO)
655 West Broadway
Suite 1900
San Diego, CA 92101

Jamie J. McKey
Kendall Law Group, LLP
3232 McKinney Avenue
Suite 700
Dallas, TX 75204

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