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

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION *IN LIMINE* NO. 13 TO EXCLUDE THE OPINIONS OF D. PAUL REGAN

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

CASES

OTHER AUTHORITIES

Pursuant to Federal Rule of Evidence 702, Defendants respectfully submit this memorandum of law in support of their motion to exclude the opinions of D. Paul Regan.

PRELIMINARY STATEMENT

Plaintiffs proffer Mr. Regan as an expert to opine that Pfizer did not properly account for, or disclose, a contingent loss associated with government investigations into the sales and marketing practices for the drugs Bextra, Geodon, Lyrica, and Zyvox (the "Government Investigations"). As Mr. Regan's deposition makes clear, however, Plaintiffs do not and cannot carry their burden of establishing that Mr. Regan's opinions are relevant and reliable under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579 (1993). This Court should exclude Mr. Regan's opinions that Pfizer did not properly account for, or disclose, a contingent loss associated with the Government Investigations for the following separate and independent reasons:

- ***First***, Mr. Regan lacks the requisite experience and expertise to evaluate whether the collective judgments of Pfizer's management and independent auditor were erroneous. He admits that he has never established or audited a loss contingency reserve; has never evaluated or estimated this type of loss contingency reserve for a government investigation into alleged off-label marketing; and has less experience in the relevant subject matter than Pfizer's management and independent auditor whom he now criticizes more than five years after the fact.

- ***Second***, Mr. Regan applies a methodology that is not generally accepted in the field. He admits that six pharmaceutical companies made judgments similar to Pfizer's concerning whether and when to record a loss contingency reserve and disclose a range of possible loss. He also concedes that the SEC repeatedly accepted the judgments of those pharmaceutical companies – the same judgment made for the same reasons by Pfizer.

- ***Third***, Mr. Regan offers an opinion that lacks the intellectual rigor required under Rule 702. He admits that the extent to which off-label marketing resulted in sales revenue or profit for Pfizer is a critical component of his opinion. Yet he concedes that he relies entirely on another Plaintiffs' expert to estimate that component without understanding, analyzing, or verifying her methodology,

which has proven demonstrably unreliable. And he also admits that, in fact, the data required to make such an estimate do not exist.

For all of these reasons and those below, this Court should exclude the opinions of Mr. Regan.[1]

LEGAL STANDARD

Under Federal Rule of Evidence 702, an expert opinion is admissible if and only if: (1) "the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue"; (2) "the testimony is based upon sufficient facts or data"; (3) "the testimony is the product of reliable principles and methods"; and (4) "the expert has reliably applied the principles and methods to the facts of the case." FED. R. EVID. 702. "When parties seek to introduce expert testimony in accordance with Rule 702, a district court must serve as a gatekeeper." *United States v. Cruz*, 363 F.3d 187, 192 (2d Cir. 2004). "The flexible *Daubert* inquiry gives the district court the discretion needed to ensure that the courtroom door remains closed to junk science while admitting reliable expert testimony that will assist the trier of fact." *Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 267 (2d Cir. 2002). "***[A]ny*** step that renders the [expert's] analysis unreliable under the *Daubert* factors renders the expert's testimony inadmissible." *Id.* (emphasis in original).

As the Supreme Court and Second Circuit have made clear, expert testimony should not be admitted if (*inter alia*):

[1] Plaintiffs also proffer Mr. Regan as an expert to opine that certain control deficiencies at Pfizer constituted a material weakness in internal controls over financial reporting from September 2006 through September 2007. Plaintiffs have failed to establish that Mr. Regan has the requisite experience and expertise to render reliable opinions concerning Pfizer's internal controls, but the Court need not reach this issue. Mr. Regan's opinions concerning Pfizer's internal controls should be excluded because (*inter alia*) Plaintiffs have abandoned any claims alleging a false or misleading statement about those internal controls. *See* Plaintiffs' Memorandum of Law in Opposition to Pfizer, Inc.'s and the Individual Defendants' Motions for Summary Judgment (Nov. 26, 2014); *Plahutnik v. Daikin Am., Inc.*, 912 F. Supp. 2d 96, 104 (S.D.N.Y.2012) ("[A]rguments not made in opposition to a motion for summary judgment are deemed abandoned.").

- the expert lacks the requisite experience and expertise, *Daubert*, 509 U.S. at 592; *Zaremba v. General Motors Corp.*, 360 F.3d 355, 359-60 (2d Cir. 2004);

- the expert applies a methodology that is not generally accepted in the relevant expert community, *Daubert*, 509 U.S. at 594; *Zaremba*, 360 F.3d at 358; or

- the expert fails to "employ[ ] in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field," *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999); *Nimely v. City of New York*, 414 F.3d 381, 396 (2d Cir. 2005).

The proponent of an expert opinion has the burden of establishing by a preponderance of the evidence that the opinion is relevant and reliable. *Daubert*, 509 U.S. at 592 n.10; FED. R. EVID. 702 advisory committee's note; *Faulkner v. Nat'l Geographic Soc'y*, 576 F. Supp. 2d 609, 619 (S.D.N.Y. 2008). As discussed below, Plaintiffs have not carried their burden.

ARGUMENT

I. THIS COURT SHOULD EXCLUDE MR. REGAN'S OPINIONS THAT PFIZER DID NOT PROPERLY ACCOUNT FOR, OR DISCLOSE, A CONTINGENT LOSS ASSOCIATED WITH THE GOVERNMENT INVESTIGATIONS.

Mr. Regan opines that "Pfizer failed to accrue for the contingent loss associated with the Government's Off-Label Promotion Investigation [*i.e.*, the Government Investigations] as of December 31, 2005 and continuing thereafter through the Class Period" and that "Pfizer failed to provide adequate disclosure associated with the Government's Off-Label Promotion Investigation as of December 31, 2005 and continuing thereafter."[2] Mr. Regan bases his opinions on an analysis of Pfizer's reserve and disclosures under Statement of Financial Accounting Standards No. 5, Accounting for Contingencies ("FAS 5").[3] Mr. Regan's opinions should be excluded under Rule 702 and *Daubert* because (1) his admissions establish that he lacks the requisite experience and expertise to render reliable opinions; (2) he applies a

[2] Dec. 10, 2014 Amanda M. MacDonald Declaration Ex. WW-2 (Regan Report at 1)
[3] Dec. 10, 2014 MacDonald Decl. Ex. WW-2 (Regan Report at 12)

methodology that is not generally accepted in the field; and (3) he offers opinions that lack the necessary intellectual rigor by relying on speculation rather than evidence.

A. Mr. Regan Lacks the Requisite Experience and Expertise.

For Mr. Regan's opinions to be admissible, Plaintiffs must first establish that he has the necessary experience and expertise to qualify as an expert in establishing and evaluating a pharmaceutical company's contingent liabilities under FAS 5 for a government investigation into alleged off-label marketing. *See Daubert*, 509 U.S. at 592; *Zaremba*, 360 F.3d at 359–60. Mr. Regan lacks the necessary qualifications and admits that he has ***less*** experience than Pfizer's management and independent auditor whom he now criticizes.

Mr. Regan's concessions demonstrate that he lacks the experience and expertise to establish or evaluate contingent liabilities under FAS 5 for pharmaceutical (or other) companies:

- Mr. Regan has ***never*** been involved in establishing a loss contingency reserve for a pharmaceutical (or other) company.[4]
- Mr. Regan has ***never*** audited or contemporaneously evaluated a loss contingency reserve for a pharmaceutical (or other) company, including Pfizer's loss contingency reserve in this case.[5]

In contrast, Pfizer's management and independent auditor, KPMG LLP, have extensive experience and expertise with such issues. For example, the KPMG teams were led by auditors with more than 65 years of experience, including many years with pharmaceutical companies:

- John Chapman, the lead signing partner on the 2006 and 2007 audits – and global chairman of KPMG's pharmaceutical practice prior to his transition onto the Pfizer engagement – had approximately 30 years of auditing experience at KPMG, including "many, many years" of auditing experience with some of the largest pharmaceutical companies in the world.[6]
- Larry Bradley, the lead signing partner on the 2008 audit, had approximately 25 years of auditing experience at KPMG, serving as the engagement signing

[4] Dec. 10, 2014 MacDonald Decl. Ex. MM-2 (Regan Dep. 16:7-11).
[5] Dec. 10, 2014 MacDonald Decl. Ex. MM-2 (Regan Dep. 12:23-13:13).
[6] Dec. 10, 2014 MacDonald Decl. Ex. CC-2 (Chapman Dep. 10:9-10; 44:13-19; 62:20-63:11).

partner for several publicly traded companies and as an SEC reviewing partner for more than 30 publicly traded companies.[7]

- Eric Riso, second partner on the 2006-2008 audits, had 10-15 years of auditing experience, working on the Pfizer engagement throughout the Class Period.[8]

After so many years auditing pharmaceutical (and other) companies, Mr. Chapman, Mr. Bradley, and Mr. Riso had extensive experience auditing their loss contingency reserves and disclosures.[9]

Mr. Regan admits that Mr. Chapman, Mr. Bradley, and Mr. Riso have more experience auditing large public companies, and particularly pharmaceutical companies, than he does:

- "Q. Would you agree that Mr. Chapman and Mr. Bradley have – both have more experience auditing large public companies than you do? . . . THE WITNESS: Yes."[10]

- "Q. And would you agree with me that John Chapman of KPMG has more experience than you do auditing pharmaceutical companies? . . . THE WITNESS: I would have that expectation, yes."[11]

- "Q. Do you believe that Mr. Bradley has more experience than you do auditing pharmaceutical companies? A. Yes."[12]

- "Q. And same question: You would agree that Mr. Riso has more experience than you do auditing pharmaceutical companies? . . . THE WITNESS: Yes."[13]

Mr. Regan admits that (unlike him) KPMG actually performed an audit of Pfizer's loss contingency reserves and disclosures, including its reserves and disclosures specifically associated with off-label marketing, and that every KPMG witness has testified that Pfizer was not required to take a reserve or disclose a range of possible loss before reaching an agreement in

---

7 Dec. 10, 2014 MacDonald Decl. Ex. YY-1 (Bradley Dep. 10:5-6; 10:17-11:16); Dec. 10, 2014 MacDonald Decl. Ex KK-3 (Ex. 2126).
8 Dec. 10, 2014 MacDonald Decl. Ex. NN-2 (Riso Dep. 12:16-13:8; 117:16-18).
9 Dec. 10, 2014 MacDonald Decl. Ex. MM-2 (Regan Dep. 76:11-77:2; 83:24-84:12).
10 Dec. 10, 2014 MacDonald Decl. Ex. MM-2 (Regan Dep. 18:7-11).
11 Dec. 10, 2014 MacDonald Decl. Ex. MM-2 (Regan Dep. 16:25-17:5).
12 Dec. 10, 2014 MacDonald Decl. Ex. MM-2 (Regan Dep. 17:21-23).
13 Dec. 10, 2014 MacDonald Decl. Ex. MM-2 (Regan Dep. 19:4-8).

principle with the government.[14] For example, Mr. Chapman, Mr. Bradley, and Mr. Riso all testified that no such reserve or disclosure was necessary:

- Mr. Chapman testified that he "absolutely" believed "that the company's position was appropriate with respect to accruing a reserve for the government investigation" and that, " when I signed off, I was convinced, based upon what I heard from my discussions with – as laid out in the document [*i.e.*, Statements on SAS 61 Communication with Audit Committees Report], that there was not a need under FAS 5 to record a liability at this date."[15]

- Mr. Bradley testified that "the management had made a proper determination to record the accrual in its 2008 financial statements" and that "we [*i.e.*, KPMG] did not determine that any period, any prior period financial statements or filings were materially misstated."[16]

- Mr. Riso testified that the settlement of the Government Investigations in 2009 did not cause KPMG to conclude that any prior financial statements issued by Pfizer had been materially misstated and that KPMG "believed it [*i.e.*, the reserve] belonged in 2008 . . . in the fourth quarter."[17]

To this day, KPMG stands by those judgments.[18]

Plaintiffs have not established that Mr. Regan has the requisite experience and expertise to render reliable opinions on the collective judgments of Pfizer management and KPMG concerning whether and when to reserve for, or disclose, a contingent loss associated with the Government Investigations. Therefore, this Court should exclude Mr. Regan's opinions.[19]

---

[14] Dec. 10, 2014 MacDonald Decl. Ex. MM-2 (Regan Dep. 78:13-79:11; 122:19-123:13).

[15] Dec. 10, 2014 MacDonald Decl. Ex. CC-2 (Chapman Dep. 82:6-83:1; *see also id.* 136:5-7, 192:13-195:19 (same for Pfizer's 2005, 2006, and 2007 financial statements)).

[16] Dec. 10, 2014 MacDonald Decl. Ex. YY-1 (Bradley Dep. 92:20-93:2, 93:11-19; *see also id.* 54:5-55:24, 68:2-17).

[17] Dec. 10, 2014 MacDonald Decl. Ex. NN-2 (Riso Dep. 260:6-261:14; *see also id.* 262:24-263:3).

[18] Dec. 10, 2014 MacDonald Decl. Ex. CC-2 (Chapman Dep. 192:11-195:19); Dec. 10, 2014 MacDonald Decl. ZZ-1(Bradley Dep. 333:18-336:12).

[19] Indeed, Mr. Regan concedes that "[t]he work that I've done has all been subsequent to the establishment of the reserves and working with the company and/or counsel in connection with legal disputes that arose as a result of an argument of whether those reserves were adequate." Dec. 10, 2014 MacDonald Decl. Ex. MM-2 (Regan Dep. 16:11-15; *see also id.* 13:1-4, 13:11-13). Such work does not give Mr. Regan the necessary experience or expertise to second-guess the judgments of Pfizer management and its independent auditor in the field. *Zaremba*, 360 F.3d at 359-60. Moreover, Mr. Regan has identified only one case in all of his work in which he analyzed the reserve of a

B. Mr. Regan Applies a Methodology That Is Not Generally Accepted.

For Mr. Regan's opinion to be admissible, Plaintiffs must also establish that he has applied a methodology that is generally accepted in the field. As the Supreme Court has explained: "Widespread acceptance can be an important factor in ruling particular evidence admissible, and a known technique which has been able to attract only minimal support within the community may properly be viewed with skepticism." *Daubert*, 509 U.S. at 594 (citation and internal quotation marks omitted); *Kass v. West Bend Co.*, No. 05-0338, 158 F. App'x 352, 353 (2d Cir. Dec. 19, 2005) (summary order) (affirming the exclusion of an expert whose methodology "did not even approach[ ] the rigor associated with generally accepted testing protocols"). Mr. Regan's own testimony shows that his methodology is not generally accepted.

Mr. Regan opines that Pfizer should have been able to estimate its settlement of the Government Investigations, and consequently take a reserve for that settlement or at least disclose a range of possible loss, almost three years before reaching an agreement in principle with the government.[20] Mr. Regan offers a five-part "recipe" of information to make that estimate: (1) settlements of government investigations by other pharmaceutical companies; (2) sales data for the drugs at issue; (3) prescription data for the drugs at issue from a publicly available source such as IMS; (4) the governing law and sentencing guidelines; and (5) the government's views of the allegations and evidence.[21] If Mr. Regan's "recipe" were generally accepted, then pharmaceutical companies would have accurately established reserves or

---

pharmaceutical company, and that case involved a revenue recognition and return reserve – not a loss contingency reserve. Dec. 10, 2014 MacDonald Decl. Ex. MM-2 (Regan Dep. 13:11-14:16).

[20] Dec. 10, 2014 MacDonald Decl. Ex. MM-2 (Regan Dep. 57:9-12, 62:20-63:3, 214:1-7, 272:12-25); *see also* Dec. 10, 2014 MacDonald Decl. Ex. WW-2 (Regan Report at 51-52).

[21] Dec. 10, 2014 MacDonald Decl. Ex. MM-2 (Regan Dep. 45:5-50:2); *see also* Dec. 10, 2014 MacDonald Decl. Ex. WW-2 (Regan Report at 25-36).

disclosed ranges of possible loss before resolving government investigations – and Pfizer would have been an outlier in failing to do so. In fact, ***exactly the opposite is true***.

Settlements with the government are the product of negotiation. As Mr. Regan concedes, negotiation establishes the terms of the settlement, including (1) the entity to be charged,[22] (2) the amount of pecuniary gain,[23] and (3) the time period covered by the settlement.[24] Indeed, Defendants' expert Nicholas Theodorou, a former prosecutor in the U.S. Attorney's Office for the District of Massachusetts (*i.e.*, the U.S. Attorney's Office responsible for the Government Investigations) and chair of Foley Hoag's White Collar Crimes and Government Investigations Practice Group, explains: "In the end, determining an appropriate amount for any fine or penalty (which in the context of a settlement must be acceptable to both sides) is less a matter of simple arithmetic and more an exercise in complex negotiation and considered judgment."[25] There is simply no "recipe" to estimate accurately the settlement of a government investigation.

Mr. Regan's own testimony confirms this conclusion. During his deposition, he admitted that at least ***six*** other pharmaceutical companies – audited by the Big Four accounting firms, Deloitte & Touche, LLP, Ernst & Young LLP, KPMG LLP, and PricewaterhouseCoopers LLP – made judgments similar to Pfizer's concerning whether and when to take a loss contingency reserve and disclose a range of possible loss associated with government investigations into their alleged off-label marketing practices. Like Pfizer, those pharmaceutical companies – Eli Lilly and Company; Allergan, Inc.; Elan Corporation, plc; Merck & Co., Inc.; Abbott Laboratories; and Amgen, Inc. – settled government investigations into sales and marketing practices for their drugs during the period from October 21, 2008, through October 24, 2011. Like Pfizer, those

[22] Dec. 10, 2014 MacDonald Decl. Ex. MM-2 (Regan Dep. 123:14-23).
[23] Dec. 10, 2014 MacDonald Decl. Ex. MM-2 (Regan Dep. 197:9-18).
[24] Dec. 10, 2014 MacDonald Decl. Ex. MM-2 (Regan Dep. 198:2-13).
[25] Dec. 10, 2014 MacDonald Decl. Ex. YY-2 (Theodorou Report at 3, 11).

pharmaceutical companies did not take a loss contingency reserve or disclose a range of possible loss prior to reaching an agreement in principle with the government.[26] Specifically:

- ***Eli Lilly:*** On October 21, 2008, Eli Lilly announced that it was in advanced discussions with the U.S. Attorney's Office for the Eastern District of Pennsylvania to resolve a government investigation of more than four years into the sales and marketing practices for the drug Zyprexa.[27] Eli Lilly had reached an agreement in principle with the Government two weeks earlier on October 7, 2008.[28] After reaching that agreement, Eli Lilly – which was audited by Ernst & Young – established a loss contingency reserve for the expected settlement.[29] Eli Lilly did not take a loss contingency reserve, or disclose a range of possible loss, for the investigation prior to the agreement in principle.[30]

- ***Allergan:*** On September 1, 2010, Allergan announced that it had reached an agreement in principle with the U.S. Attorney's Office for the Northern District of Georgia to resolve a government investigation of more than two years into the sales and marketing practices for the drug Botox.[31] After reaching that agreement, Allergan – which was audited by Ernst & Young – established a loss contingency reserve for the expected settlement.[32] Allergan did not take a loss contingency reserve, or disclose a range of possible loss, for the investigation prior to the agreement in principle.[33]

- ***Elan:*** On July 15, 2010, Elan announced that it had reached an agreement in principle with the U.S. Attorney's Office for the District of Massachusetts to resolve a government investigation of 4 ½ years into the sales and marketing practices for the drug Zonegran.[34] After reaching that agreement, Elan – which

---

[26] Dec. 10, 2014 MacDonald Decl. Ex. MM-2 (Regan Dep. 148:21-149:2).

[27] Dec. 10, 2014 MacDonald Decl. Ex. MM-2 (Regan Dep. 64:11-21, 68:14-25, 86:11-14); *see also* Dec. 10, 2014 MacDonald Decl. Ex. OO-3 (Ex. 2268); Dec. 10, 2014 MacDonald Decl. Ex. RR-1 (Ex. 2269).

[28] Dec. 10, 2014 MacDonald Decl. Ex. MM-2 (Regan Dep. 72:13-20); *see also* Dec. 10, 2014 MacDonald Decl. Ex. PP-3 (Ex. 2270).

[29] Dec. 10, 2014 MacDonald Decl. Ex. MM-2 (Regan Dep. 64:22-68:25, 86:22-27); *see also* Dec. 10, 2014 MacDonald Decl. Ex. OO-3 (Ex. 2268); Dec. 10, 2014 MacDonald Decl. Ex. RR-1 (Ex. 2269).

[30] Dec. 10, 2014 MacDonald Decl. Ex. MM-2 (Regan Dep. 66:15-68:7, 72:24-73:24).

[31] Dec. 10, 2014 MacDonald Decl. Ex. MM-2 (Regan Dep. 94:21-95:25, 98:21-99:7, 99:19-21); *see also* Dec. 10, 2014 MacDonald Decl. Ex. QQ-3 (Ex. 2271); Dec. 10, 2014 MacDonald Decl. Ex. EE-1 (Ex. 2272).

[32] Dec. 10, 2014 MacDonald Decl. Ex. MM-2 (Regan Dep. 96:1-100:25); *see also* Dec. 10, 2014 MacDonald Decl. Ex. QQ-3 (Ex. 2271); Dec. 10, 2014 MacDonald Decl. Ex. EE-1 (Ex. 2272); Dec. 10, 2014 MacDonald Decl. Ex. FF-1 (Allergan Inc. Annual Report (Form 10-K) (Mar. 1, 2011) at Ex. 23.1).

[33] Dec. 10, 2014 MacDonald Decl. Ex. MM-2 (Regan Dep. 97:10-100:25); *see also* Dec. 10, 2014 MacDonald Decl. Ex. EE-1 (Ex. 2272).

[34] Dec. 10, 2014 MacDonald Decl. Ex. MM-2 (Regan Dep. 38:6-23, 42:19-43:5); *see also* Ex. Dec. 10, 2014 MacDonald Decl. Ex. LL-3 (Ex. 2263).

was audited by KPMG – established a loss contingency reserve for the expected settlement.[35] Elan did not take a loss contingency reserve, or disclose a range of possible loss, for the investigation prior to the agreement in principle.[36]

- ***Merck:*** On October 29, 2010, Merck announced the anticipated resolution with the U.S. Attorney's Office for the District of Massachusetts of a government investigation into the sales and marketing practices for the drug Vioxx.[37] At the same time, Merck – which was audited by PricewaterhouseCoopers – established a loss contingency reserve for that resolution.[38] Merck did not take a loss contingency reserve, or disclose a range of possible loss, for the investigation prior to the anticipated resolution.[39]

- ***Abbott:*** On October 21, 2011, it was announced that Abbott had reached an agreement in principle with the government to settle claims in 24 states concerning the sales and marketing practices for the drug Depakote.[40] After reaching that agreement, Abbott – which was audited by Deloitte & Touche – established a loss contingency reserve for the settlement.[41] Abbott did not take a loss contingency reserve, or disclose a range of possible loss, for the investigation prior to the agreement in principle.[42]

- ***Amgen:*** On October 24, 2011, Amgen announced that it had reached an agreement in principle with the U.S. Attorney's Offices for the Eastern District of New York and the Western District of Washington to resolve government investigations of four years into the sales and marketing practices for the drug Aranesp.[43] After reaching that agreement, Amgen – which was audited by Ernst

---

35 Dec. 10, 2014 MacDonald Decl. Ex. MM-2 (Regan Dep. 38:24-44:19); *see also* Dec. 10, 2014 MacDonald Decl. Ex. LL-3 (Ex. 2263); Dec. 10, 2014 MacDonald Decl. Ex. SS-1 (Ex. 2264); Dec. 10, 2014 MacDonald Decl. Ex. HH-1 (Elan Corporation plc, Annual and Transition Report of Foreign Private Issuers Pursuant to Sections 13 or 15(d) (Form 20-F) (Feb. 24, 2011) at 99-100).

36 Dec. 10, 2014 MacDonald Decl. Ex. MM-2 (Regan Dep. 50:3-52:9.)

37 Dec. 10, 2014 MacDonald Decl. Ex. MM-2 (Regan Dep. 130:4-131:6); *see also* Dec. 10, 2014 MacDonald Decl. Ex. UU-3 (Ex. 2278).

38 Dec. 10, 2014 MacDonald Decl. Ex. MM-2 (Regan Dep. 130:20-132:3); *see also* Dec. 10, 2014 MacDonald Decl. Ex. UU-3 (Ex. 2278); Dec. 10, 2014 MacDonald Decl. Ex. JJ-1 (Ex. 2279); Dec. 10, 2014 MacDonald Decl. Ex. II-1 (Merck & Co. Annual Report (Form 10-K) (Feb. 28, 2011) at Ex. 23.1).

39 Dec. 10, 2014 MacDonald Decl. Ex. MM-2 (Regan Dep. 131:7-132:13); *see also* Dec. 10, 2014 MacDonald Decl. Ex. UU-3 (Ex. 2278), Dec. 10, 2014 MacDonald Decl. Ex. JJ-1 (Ex. 2279).

40 Dec. 10, 2014 MacDonald Decl. Ex. MM-2 (Regan Dep. 166:10-167:1); *see also* Dec. 10, 2014 MacDonald Decl. Ex. YY-3 (Ex. 2283).

41 Dec. 10, 2014 MacDonald Decl. Ex. MM-2 (Regan Dep. 167:2-168:19); *see also* Dec. 10, 2014 MacDonald Decl. Ex. YY-3 (Ex. 2283); Dec. 10, 2014 MacDonald Decl. Ex. CC-1 (Ex. 2284); Dec. 10, 2014 MacDonald Decl. Ex. DD-1 (Abbott Laboratories Annual Report (Form 10-K) (Feb. 21, 2012) at Ex. 23.1).

42 Dec. 10, 2014 MacDonald Decl. Ex. MM-2 (Regan Dep. 168:11-19); *see also* Dec. 10, 2014 MacDonald Decl. Ex. YY-3 (Ex. 2283); Dec. 10, 2014 MacDonald Decl. Ex. CC-1 (Ex. 2284).

43 Dec. 10, 2014 MacDonald Decl. Ex. MM-2 (Regan Dep. 53:3-60:10); *see also* Dec. 10, 2014 MacDonald Decl. Ex. MM-3 (Ex. 2265).

> & Young – established a loss contingency reserve for the expected settlement.[44] Amgen did not take a loss contingency reserve, or disclose a range of possible loss, for the investigation prior to the agreement in principle.[45]

In Mr. Regan's own words, "[t]hese companies chose not to record a reserve until there was a settlement reached," which was "[c]onsistent with what Pfizer did."[46] Although Mr. Regan could not identify ***any*** information that these companies lacked in order to use his five-part "recipe" to estimate a settlement, ***their judgments were all similar to Pfizer's*** concerning whether and when to establish a loss contingency reserve or disclose a range of possible loss.[47] Remarkably, Mr. Regan concedes that he did not consider ***any*** of this conflicting evidence.[48]

Instead, Mr. Regan points to two pharmaceutical companies that took a loss contingency reserve before reaching an agreement in principle: GlaxoSmithKline and Schering-Plough. Yet even those examples do not support Mr. Regan's methodology:

- ***GlaxoSmithKline:*** GlaxoSmithKline established a loss contingency reserve of $400 million associated with a government investigation into the sales and

---

[44] Dec. 10, 2014 MacDonald Decl. Ex. MM-2 (Regan Dep. 54:11-57:20); *see also* Dec. 10, 2014 MacDonald Decl. Ex. MM-3 (Ex. 2265); Dec. 10, 2014 MacDonald Decl. Ex. TT-1 (Ex. 2266); Dec. 10, 2014 MacDonald Decl. Ex. GG-1 (Amgen, Inc. Annual Report (Form 10-K) (Feb. 29, 2012), at Ex. 23 F-1)).

[45] Dec. 10, 2014 MacDonald Decl. Ex. MM-2 (Regan Dep. 54:16-22, 56:23-57:12, 57:21-58:8).

[46] Dec. 10, 2014 MacDonald Decl. Ex. MM-2 (Regan Dep. 166:1-4).

[47] Dec. 10, 2014 MacDonald Decl. Ex. MM-2 (Regan Dep. 72:24-73:24, 86:15-88:9, 152:11-156:13) and Dec. 10, 2014 MacDonald Decl. Ex. OO-3 (Ex. 2268); Dec. 10, 2014 MacDonald Decl. RR-1 (Ex 2269); Dec. 10, 2014 MacDonald Decl. Ex. VV-3 (Ex. 2280) (Eli Lilly); Dec. 10, 2014 MacDonald Decl. Ex. MM-2 (Regan Dep. 115:10-124:10, 162:5-164:12) and Dec. 10, 2014 MacDonald Decl. Ex. QQ-3 (Ex. 2271); Dec. 10, 2014 MacDonald Decl. Ex. EE-1 (Ex. 2272); Dec. 10, 2014 MacDonald Decl. Ex. XX-3 (Ex. 2282) (Allergan); Dec. 10, 2014 MacDonald Decl. Ex. MM-2 (Regan Dep. 39:11-20, 44:20-50:14, 157:5-158:15) and Dec. 10, 2014 MacDonald Decl. Ex. LL-3 (Ex. 2263); Dec. 10, 2014 MacDonald Decl. Ex. SS-1 (Ex. 2264), Dec. 10, 2014 MacDonald Decl. Ex. WW-3 (Ex. 2281) (Elan); Dec. 10, 2014 MacDonald Decl. Ex. MM-2 (Regan Dep. 132:9-134:25) and Dec. 10, 2014 MacDonald Decl. Ex. UU-3 (Ex. 2278); Dec. 10, 2014 MacDonald Decl. Ex. JJ-1 (Ex. 2279) (Merck); Dec. 10, 2014 MacDonald Decl. Ex. MM-2 (Regan Dep. 168:11-173:6) and Dec. 10, 2014 MacDonald Decl. Ex. YY-3 (Ex. 2283), Dec. 10, 2014 MacDonald Decl. Ex. CC-1 (Ex. 2284) (Abbott); Dec. 10, 2014 MacDonald Decl. Ex. MM-2 Regan Dep. 54:16-55:2, 60:11-63:10, 158:18-162:4) and Dec. 10, 2014 MacDonald Decl. Ex. MM-3 (Ex. 2265); Dec. 10, 2014 MacDonald Decl. Ex. TT-1 (Ex. 2266); Dec. 10, 2014 MacDonald Decl. Ex. NN-3 2267 (Amgen)).

[48] Dec. 10, 2014 MacDonald Decl. Ex. MM-2 (Regan Dep. 63:18-64:10) (Eli Lilly); 94:25-95:2 (Allergan); 50:15-50:18 (Elan); 130:6-14 (Merck); 53:11-13 (Amgen)).

marketing practices for several drugs in January 2009 – almost five years into an ongoing government investigation (which was longer than the Government Investigations in this case were ongoing before Pfizer established a reserve).[49] In November 2011, the government investigation was resolved for $3 billion, which was 7 ½ times the amount of the initial reserve.[50] Mr. Regan admitted that he did not have any idea why GlaxoSmithKline could not establish an initial reserve that reasonably estimated the amount of the settlement using his "recipe" and conceded that he was "not familiar with the facts and circumstances inside GSK" despite relying on the company's judgment as an example of his methodology.[51]

- ***Schering-Plough:*** Schering-Plough established a loss contingency reserve of $150 million associated with a government investigation into the sales and marketing practices for the drugs Temodar and Intron A in February 2003 – almost two years into an ongoing government investigation.[52] In August 2006, the government investigation was resolved for $435 million, which was almost three times the amount of the initial reserve.[53] Mr. Regan provided no explanation why Schering-Plough could not establish an initial reserve that reasonably estimated the amount of the settlement using his "recipe."

That Mr. Regan identifies two pharmaceutical companies that established a loss contingency reserve before reaching an agreement in principle to resolve government investigations into their sales and marketing practices does not establish that Mr. Regan's methodology is generally accepted in the field. Instead, it underscores that the majority of pharmaceutical companies did not follow Mr. Regan's methodology and made a judgment similar to Pfizer's concerning whether and when to record a loss contingency reserve and disclose a range of possible loss with respect to such government investigations. Moreover, that the two pharmaceutical companies held up as examples by Mr. Regan established their loss contingency reserves only after years of government investigation and, even then, were wrong by hundreds of millions of dollars, confirms that Mr. Regan's "recipe" for reasonable settlement estimates does not work.

---

[49] Dec. 10, 2014 MacDonald Decl. Ex. MM-2 (Regan Dep. 178:3-25); Dec. 10, 2014 MacDonald Decl. Ex. UU-1 (Ex. 2286); Dec. 10, 2014 MacDonald Decl. Ex. VV-1 (Ex. 2287).

[50] Dec. 10, 2014 MacDonald Decl. Ex. MM-2 (Regan Dep. 175:3-16, 179:1-180:3); Dec. 10, 2014 MacDonald Decl. Ex. UU-1 (Ex. 2286); Dec. 10, 2014 MacDonald Decl. Ex. VV-1 (Ex. 2287).

[51] Dec. 10, 2014 MacDonald Decl. Ex. MM-2 (Regan Dep. 179:10-14).

[52] Dec. 10, 2014 MacDonald Decl. Ex. KK-1 (Schering Plough Form 10-Q (May 15, 2001); Dec. 10, 2014 MacDonald Decl. Ex. LL-1 (Schering Plough Form 8-K (Feb. 25, 2003)).

[53] Dec. 10, 2014 MacDonald Decl. Ex. MM-1 (Schering Plough Form 8-K (Aug. 29, 2006)).

Indeed, Mr. Regan admits that the SEC has refused to follow his "recipe" and instead accepted the judgment of companies that did not take a loss contingency reserve for government investigations into sales and marketing practices before reaching an agreement in principle ***for the very reasons that Pfizer chose not to do so***. Specifically, Eli Lilly and Allergan took loss contingency reserves at the same point in the investigation process as Pfizer: when an agreement in principle with government had been reached after years of investigation. The SEC inquired into the timing of the Eli Lilly and Allergan reserves and, after receiving explanations from those companies that tracked Pfizer's reasoning, took no further action:

- ***Eli Lilly:*** On August 20, 2009, the SEC sent Eli Lilly a comment letter.[54] The SEC asked Eli Lilly to explain (*inter alia*) its decision not to take a loss contingency reserve for the government investigation into Zyprexa prior to reaching an agreement in principle to resolve the investigation.[55] In its response, Eli Lilly explained that it could not establish a reserve or disclose any range of possible loss because, "[a]t all of these quarter ends prior to the third quarter of 2008 when the liability was recorded, the significant uncertainty around the scope of the investigation and its ultimate resolution led us to conclude that we did not have a probable and reasonably estimable loss at that time."[56] Upon receipt of Eli Lilly's explanation, the SEC "have no further comments."[57]

- ***Allergan:*** On August 12, 2011, the SEC sent Allergan a comment letter.[58] The SEC asked Allergan to explain (*inter alia*) its judgment not to take a loss contingency reserve for the government investigation into Botox prior to reaching an agreement in principle to resolve the investigation.[59] In its response, Allergan explained that it could not reasonably estimate the possible losses associated with the government investigation for purposes of establishing a reserve or disclosing a range of possible loss because of "the inherent difficulty of predicting regulatory fines and other monetary and non-monetary penalties associated with multiple government agencies, the strength of evidence presented, the various remedies

---

54 *See* Dec. 10, 2014 MacDonald Decl. Ex. PP-3 (Ex. 2270).

55 Dec. 10, 2014 MacDonald Decl. Ex. MM-2 (Regan Dep. 71:17-21); Dec. 10, 2014 MacDonald Decl. Ex. PP-3 (Ex. 2270).

56 Dec. 10, 2014 MacDonald Decl. Ex. MM-2 (Regan Dep. 71:22-72:6); Dec. 10, 2014 MacDonald Decl. Ex.PP-3 (Ex. 2270).

57 Dec. 10, 2014 MacDonald Decl. Ex. MM-2 (Regan Dep. 103:18-105:20); Dec. 10, 2014 MacDonald Decl. Ex. RR-3 (Ex. 2274).

58 Dec. 10, 2014 MacDonald Decl. Ex. EE-4 (Ex. 2273).

59 Dec. 10, 2014 MacDonald Decl. Ex. MM-2 (Regan Dep. 105:21-106:1); Dec. 10, 2014 MacDonald Decl. Ex. EE-4 (Ex. 2273).

> and levels of judicial review available to the Company in the event a penalty was assessed, and the political motivations or desires to shift regulatory policy."[60] After the SEC asked for more information,[61] Allergan further explained that it did not establish a reserve or disclose a range of possible loss because the government always had the discretion to impose an unpredictable range of monetary and criminal penalties and, if the government had insisted on bringing felony criminal charges and excluding Allergan from federal healthcare programs, the company was prepared to reject a settlement and defend itself vigorously.[62] The SEC did not pursue the matter after receiving Allergan's explanation.[63]

Mr. Regan concedes that ***Pfizer followed the same practice for the same reasons***.[64] Just as this practice was acceptable for Eli Lilly and Allergan, it was acceptable for Pfizer.

Plaintiffs have not established that Mr. Regan's methodology is generally accepted in the field by pharmaceutical companies, Big Four accounting firms, or the SEC. Accordingly, this Court should exclude Mr. Regan's opinions. *See Wills v. Amerada Hess Corp.*, 379 F.3d 32, 49 (2d Cir. 2004) (affirming the exclusion of expert testimony where the district court found that another theory of causation was more generally accepted in the scientific community).[65]

C. Mr. Regan Offers Opinions That Lack the Necessary Intellectual Rigor.

For Mr. Regan's opinion to be admissible, Plaintiffs must further establish that he uses the same level of intellectual rigor as Pfizer's management and independent auditor. "[W]hen an expert opinion is based on data, a methodology, or studies that are simply inadequate to support

---

60 Dec. 10, 2014 MacDonald Decl. Ex. SS-3 (Ex. 2276); Dec. 10, 2014 MacDonald Decl. Ex. MM-2 (Regan Dep. 106:24-108:1).

61 Dec. 10, 2014 MacDonald Decl. Ex. MM-2 (Regan Dep. 121:13-17); Dec. 10, 2014 MacDonald Decl. Ex. SS-3 (Ex. 2276).

62 Dec. 10, 2014 MacDonald Decl. Ex. MM-2 (Regan Dep. 121:18-123:4); Dec. 10, 2014 MacDonald Decl. Ex. SS-3 (Ex. 2276).

63 Dec. 10, 2014 MacDonald Decl. Ex. MM-2 (Regan Dep. 125:25-126:14); Dec. 10, 2014 MacDonald Decl. Ex. TT-3 (Ex. 2277).

64 Dec. 10, 2014 MacDonald Decl. Ex. MM-2 (Regan Dep. 72:24-76:5, 78:13-80:9) (Eli Lilly); 123:5-124:10 (Allergan)).

65 *Accord E.E.O.C. v. Bloomberg L.P.*, No. 07-cv-8383, 2010 WL 3466370, at *12 (S.D.N.Y. Aug. 31, 2010) (excluding an expert's opinions "unsupported by any professional literature or other source that would suggest his methodology is recognized by other statisticians"); *Colon ex rel. Molina v. BIC USA, Inc.*, 199 F. Supp. 2d 53, 78 (S.D.N.Y. 2001) (excluding expert opinions because the plaintiffs failed to show (*inter alia*) that "the methodology underlying [them] would be generally accepted in the engineering community").

the conclusions reached, *Daubert* and Rule 702 mandate the exclusion of that unreliable opinion testimony." *Amorgianos*, 303 F.3d at 266. According to Mr. Regan, "one component of the recipe that's very important" to estimate a settlement – and consequently to establish a loss contingency reserve or disclose a range of possible loss – is: "To what extent did the off-label marketing behavior actually result in revenue to the company?"[66] Mr. Regan's own concessions make clear that his methodology and the data are wholly inadequate to answer that question.

First, Mr. Regan concedes that, if there is a dispute about the extent to which off-label marketing resulted in sales revenue, "[t]he recipe doesn't work."[67] Mr. Regan admits that there was just such a dispute between Pfizer and the government: "I know . . . that that percentage was negotiated and discussed and disputed between Pfizer and the Government. The Government . . . initially had a much higher percentage than what was eventually included in the settlement. The settlement was 37 percent. And it started at a higher level. And I believe Pfizer had a much lower level."[68] Given that dispute, Mr. Regan's "recipe" does not work in this case.

Second, Mr. Regan concedes that he does not know the basis for the estimate of sales revenue or profit from off-label marketing that he uses in his own model. Mr. Regan admits that (1) he does not opine on "a reasonable estimate of the profit associated with Pfizer's improper off-label promotion"; (2) that information comes from Dr. Meredith Rosenthal, another of Plaintiffs' experts, and his estimate "is dependent upon Dr. Rosenthal's analysis and findings"; (3) "I don't know how she has made the determination that Pfizer's improper off-label promotion drove profits at these levels for these drugs," and "I've not attempted to validate or analyze her determinations"; and (4) he has not read the report of Defendants' expert on Dr. Rosenthal's

---

66 Dec. 10, 2014 MacDonald Decl. Ex. MM-2 (Regan Dep. 109:8-11; *see also id.* 106:9-13).
67 Dec. 10, 2014 MacDonald Decl. Ex. MM-2 (Regan Dep. 108:23-109:5).
68 Dec. 10, 2014 MacDonald Decl. Ex. MM-2 (Regan Dep. 109:12-110:2; *see also id.* 189:15-20).

estimate.[69] Since Mr. Regan does not know the basis of this "very important" component of his "recipe," his opinion should be excluded. *Amorgianos*, 303 F.3d at 267 (requiring that an expert have "'good grounds' for his or her conclusions").[70]

Moreover, Mr. Regan effectively concedes that Dr. Rosenthal's methodology does not provide a reasonable estimate of sales profit. In 2004, Pfizer settled ongoing investigations into its predecessor's off-label marketing of the drug Neurontin.[71] According to Mr. Regan, the Neurontin settlement was "a settlement of a similar issue with similar . . . circumstances" to the settlement of the Government Investigations in this case.[72] Mr. Regan's testimony makes clear, however, that Dr. Rosenthal's methodology would not provide a reasonable estimate of sales profit from off-label marketing for Neurontin; it would instead result in an estimated sales profit of approximately $3.5 billion for Neurontin, ***more than 23 times larger*** than the actual sales profit of $150 million to which the government and Pfizer agreed as part of the Neurontin settlement.[73] Since Mr. Regan provides no basis to conclude that Dr. Rosenthal's estimates would be any more reasonable with respect to the settlement of the Government Investigations in this case, his methodology – which depends on Dr. Rosenthal's methodology – is unreliable.

Third, Mr. Regan concedes that the data required to determine the sales revenue or profit from Pfizer's alleged off-label marketing do not exist. Mr. Regan admits that (1) physicians are permitted to, and do, prescribe medications for off-label uses; (2) no publicly available data records the reasons that a particular doctor prescribed a particular drug to a particular patient

---

69 Dec. 10, 2014 MacDonald Decl. Ex. MM-2 (Regan Dep. 182:22-185:3).

70 *Accord Dolphin v. Synthes USA Ltd.*, No. 06-cv-7719, 2011 WL 1345334, at *5-7 (S.D.N.Y. Mar. 25, 2011) (excluding the opinions of an expert who failed to perform the testing necessary to validate them).

71 Dec. 10, 2014 MacDonald Decl. Ex. WW-2 (Regan Report at 4).

72 Dec. 10, 2014 MacDonald Decl. Ex. MM-2 (Regan Dep. 203:23-204:2).

73 Dec. 10, 2014 MacDonald Decl. Ex. MM-2 (Regan Dep. 194:20-24, 195:20-199:19).

(*e.g.*, as a result of off-label marketing or otherwise); and (3) therefore, "[t]here's no actual data that tells you the certain answer" of the revenue or profit caused by off-label marketing.[74]

Mr. Regan argues that "[y]ou have to make a reasonable estimate"; but his "estimate" relies entirely on government presentations to Pfizer.[75] Mr. Regan concedes that those presentations did not adjust for off-label uses unrelated to any alleged off-label marketing, and he identifies no information from which one can differentiate between off-label uses caused by off-label marketing and all other off-label uses (or even between off-label and on-label uses for the drugs at issue here).[76] Since there are no data to support an estimate of Pfizer's sales revenue or profit from alleged off-label marketing – a "very important" component of Mr. Regan's "recipe" – this Court should exclude his opinions. *Buckley v. Deloitte & Touche USA LLP*, No. 12-3522, 541 F. App'x 62, 64 (2d Cir. Oct. 16, 2013) (summary order) (affirming the exclusion of expert opinions as unduly speculative where they lacked a sufficient factual basis).[77]

Plaintiffs have not established that Mr. Regan applies the intellectual rigor required under Rule 702 and *Daubert*. Consequently, his opinions should be excluded.

CONCLUSION

For the foregoing reasons, this Court should grant Defendants' motion to exclude the opinions of Mr. Regan.

---

74 Dec. 10, 2014 MacDonald Decl. Ex. MM-2 (Regan Dep. 137:24-139:22).

75 Dec. 10, 2014 MacDonald Decl. Ex. MM-2 (Regan Dep. 139:3-146:20).

76 *Id.*

77 *Accord Macaluso v. Herman Miller, Inc.*, No. 01-cv-11496, 2005 WL 563169, at *8 (S.D.N.Y. Mar. 10, 2005) (excluding an expert opinion based on incorrect factual assumptions that rendered the conclusions "purely speculative"); *Three Crown Ltd. P'ship v. Salomon Bros., Inc.*, 906 F. Supp. 876, 893-94 (S.D.N.Y. 1995) (excluding expert testimony because it was based on assumptions unsupported by the factual record).

Date: December 10, 2014

Washington, D.C.

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
jay.kasner@skadden.com
gary.hacker@skadden.com
alexander.drylewski@skadden.com

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 10th day of December, 2014, the foregoing Memorandum of Law in Support of Defendants' Motion *in Limine* No. 13 to Exclude the Opinions of D. Paul Regan 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

From: NYSD_ECF_Pool@nysd.uscourts.gov
Sent: Wednesday, December 10, 2014 9:28 PM
To: CourtMail@nysd.uscourts.gov
Subject: Activity in Case 1:10-cv-03864-AKH Jones et al v. Pfizer, Inc. et al Memorandum of Law in Support of Motion

This is an automatic e-mail message generated by the CM/ECF system. Please DO NOT RESPOND to this e-mail because the mail box is unattended.
*****NOTE TO PUBLIC ACCESS USERS*** Judicial Conference of the United States policy permits attorneys of record and parties in a case (including pro se litigants) to receive one free electronic copy of all documents filed electronically, if receipt is required by law or directed by the filer. PACER access fees apply to all other users. To avoid later charges, download a copy of each document during this first viewing. However, if the referenced document is a transcript, the free copy and 30 page limit do not apply.**

U.S. District Court

Southern District of New York

Notice of Electronic Filing

The following transaction was entered by Collogan, Lauren on 12/10/2014 at 9:28 PM EST and filed on 12/10/2014

Case Name: Jones et al v. Pfizer, Inc. et al
Case Number: 1:10-cv-03864-AKH
Filer: Frank D'Amelio
Jeffrey B. Kindler
Alan G. Levin
Henry A. McKinnell
Pfizer, Inc.
Ian C. Read
Allen Waxman
Document Number: 378

Docket Text:
MEMORANDUM OF LAW in Support re: [376] MOTION in Limine *No. 13 To Exclude the Opinions of D. Paul Regan*. . Document filed by Frank D'Amelio, Jeffrey B. Kindler, Alan G. Levin, Henry A. McKinnell, Pfizer, Inc., Ian C. Read, Allen Waxman. (Collogan, Lauren)

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

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, david.carney@skadden.com

Seema Mittal smittal@wc.com

Sheila L. Birnbaum sheilabirnbaum@quinnemanuel.com

Sidney Bashago sidney.bashago@dpw.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

The following document(s) are associated with this transaction:

Document description: Main Document
Original filename:n/a
Electronic document Stamp:
[STAMP dcecfStamp_ID=1008691343 [Date=12/10/2014] [FileNumber=13989847
-0] [4972d2e3ebdd8ef6ea4c975d06777dcbb72982677bbe0934e60426893a65fc71a
3622fe889803150f3acf91d4e7a29be673060482b05b435820d125c74373f1f]]