UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

MARY K. JONES, Individually and on Behalf of All Others Similarly Situated, Plaintiff, v. PFIZER INC., et al., Defendants.	Civil Action No. 1:10-cv-03864-AKH Hon. Alvin K. Hellerstein ECF Case

MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION *IN LIMINE* NO. 1 TO EXCLUDE PLAINTIFFS' DESIGNATED EXPERT JEROME AVORN

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At least four courts, including Judge Kaplan in this district, have precluded Plaintiffs' designated expert, Jerome L. Avorn, M.D., from offering the type of unfounded and improper "opinion" he proposes to provide in this case: that Pfizer's alleged "intent" was to pursue a "corporate strategy" to promote its products off-label.[1] Ignoring the admonitions of these courts, which rejected Dr. Avorn's qualifications concerning pharmaceutical promotional regulations and condemned his opinions about intent as "outside the bounds of expert testimony," *In re Rezulin Prods. Liab. Litig.*, 309 F.Supp.2d 531, 547 (S.D.N.Y. 2004), Plaintiffs nevertheless propose to have Dr. Avorn tell the jury that Pfizer intended to violate FDA regulations and engaged in "a clear, intentional, and consistent pattern of off-label marketing" of Bextra and other products.[2] They also propose to have Dr. Avorn "narrate" company emails, slide decks, and other documents that Plaintiffs claim show off-label promotion, simply to read them to the jury. Such testimony is not expert opinion, and is inadmissible under Federal Rule of Evidence 702.

Judge Kaplan—never one to mince words—described Dr. Avorn's impermissible "intent" and "narration" testimony as follows:

> A practice reminiscent of wager of law has become fashionable among some well-financed litigants—the engagement of "expert" witnesses whose intended role is more to argue the client's cause

[1] *In re Rezulin Prods. Liab. Litig.*, 309 F.Supp.2d 531, 549 (S.D.N.Y. 2004) (Dr. Avorn is "not qualified to render opinions describing or interpreting" pharmaceutical company's adherence to FDA regulations); *In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prods. Liab. Litig.*, No. MDL 1203, 2000 WL 876900, at *8-9 (E.D. Pa. June 20, 2000) (finding "trouble in the qualifications" of Dr. Avorn and granting motion to preclude him from "testifying about the corporate intent" of pharmaceutical company); *Skibniewski v. Am. Home Prods. Corp.*, No. 99-0842-CV-W-FJG, 2004 WL 5628157, at *7 (W.D. Mo. Apr. 1, 2004) (applying holding from *In re Diet Drugs*court and excluding portions of Dr. Avorn's testimony); *O'Neill v. Novartis Consumer Health, Inc.*, 147 Cal. App. 4th 1388, 1405, 55 Cal. Rptr. 3d 551, 565 (2007) (affirming decision of trial court to exclude Dr. Avorn's testimony that withdrawing allegedly harmful product from market "was politically impossible" for defendant manufacturers).

[2] Dec. 10, 2014 Declaration of Amanda M. MacDonald in Support of Defendants' Motions *In Limine* Ex. SS-2 (June 10, 2014 Avorn Report ¶ 40) (hereinafter "Avorn Rep."); *see also id.* ¶¶ 1, 43, 87, 93.

> from the witness stand than to bring to the fact-finder specialized knowledge or expertise that would be helpful in resolving the issues of fact presented by the lawsuit. These "experts" thus are loosely analogous to compurgators, also known as oath helpers, in that they lend their credentials and reputations to the party who calls them without bringing much if any relevant knowledge to bear on the facts actually at issue. . . .
>
> . . . .
>
> [P]laintiffs' experts propose improperly to assume the role of advocates for the plaintiffs' case by arguing as to the intent or motives underlying the conduct of Warner-Lambert or others, a transgression that has resulted in the exclusion of "expert" testimony as to the "real motive" behind certain business transactions.

309 F. Supp. 2d at 538, 546.

Although Rule 702 alone mandates that Dr. Avorn be prohibited from offering his opinions to the jury, his testimony is also irrelevant to Plaintiffs' securities claims and unfairly prejudicial. Accordingly, pursuant to Federal Rules of Evidence 401, 402, 403, and 702, Defendants respectfully submit this motion *in limine* to exclude Dr. Avorn's opinions and testimony.

BACKGROUND

Dr. Avorn[3] is a professor at Harvard Medical School whose principal field is pharmacoepidemiology, which he described as "the study of the patterns of medication utilization by doctors and by patients, as well as the risks and benefits of those medications once they are in use."[4] Dr. Avorn is not an expert in corporate criminal liability, healthcare regulatory compliance, or marketing, and he has never been employed by the FDA, a pharmaceutical

[3] Though Dr. Avorn is a medical doctor, he has not treated patients in nearly 15 years. Dec. 10, 2014 MacDonald Decl. Ex. WW-1 (Avorn (Aug. 7, 2014) Dep. 17:1-3) (hereinafter "Avorn Dep.").

[4] Avorn Dep. 17:15-18.

company, or a marketing firm.[5] He has no personal knowledge of any of the underlying facts at issue in this case. Nonetheless, Plaintiffs tasked Dr. Avorn with "examin[ing] the marketing materials, internal documents, and other information relating to the promotional activities of Pfizer Inc. . . . to determine whether these activities constituted inappropriate and illegal off-label promotion of drugs, in violation of Food and Drug Administration ("FDA") regulations."[6] In response, Dr. Avorn reviewed certain Pfizer documents and testimony selected for him by Plaintiffs' counsel and, based on that review, purports to infer that Pfizer engaged in a "coordinated pervasive campaign" to illegally market Bextra, Geodon, Lyrica and Zyvox.[7] Specifically, Dr. Avorn concludes that:

- "Pfizer's conduct to illegally promote its drugs were activities that were integral components of the corporate marketing strategy for these drugs";
- Pfizer's illegal "activities were authorized and guided at senior levels of management within the Company";
- "[R]esponsible officials were aware that these activities contravened both FDA regulation and the Company's own supposed policies concerning proper marketing practices";
- Pfizer's illegal conduct was "so widespread that it cannot be attributed to the activities of a small number of 'rogue' salespeople in the field"; and
- Pfizer's activities "were designed to, and succeeded in, increasing sales of Bextra, Geodon, Zyvox, and Lyrica beyond what would have been possible had they been marketed according to their actual indications as determined by the FDA."[8]

Dr. Avorn also reaches multiple conclusions about about Pfizer's "intent" to commit illegal acts.[9]

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[5] Avorn Rep. Ex. B (resume).

[6] Avorn Rep. ¶ 1.

[7] Avorn Rep. ¶ 107.

[8] Avorn Rep. ¶ 2.

[9] *E.g.*, Avorn Rep. ¶¶ 38 ("Pfizer's marketing plans make it clear that the Company intended to stay the course in continuing to expand the use of Bextra for off-label pain indications."); 40 ("Taken together, these documents reveal a clear, intentional, and consistent pattern of off-label marketing of Bextra[.]"); 43

The sole support Dr. Avorn offers for his sweeping opinions about Defendants' conduct and intent are his background and his own interpretations of documents and testimony provided to him by Plaintiffs' counsel.[10] As Dr. Avorn conceded, the "inferences" he purports to draw from Pfizer's documents require no specialized knowledge or expertise, just common sense:

> Q. All right. Now a number of places in your report you say that Pfizer or Pfizer management intended to do something; correct?
>
> A. That's right. Yes, I'm sorry. Yes.
>
> Q. And a number of places in your report you say that Pfizer or Pfizer management had a corporate strategy to do something; correct?
>
> A. Right.
>
> Q. You're not an expert on the intent of a corporation; are you?
>
> A. I think I am an expert on marketing and communication strategies in relation to prescription drug use. And when I see a statement, Let's really increase our revenues from GEODON for—and I'm paraphrasing—for use in older people, or kids, or, Let's go for a pain indication for BEXTRA or LYRICA that was not approved, and it comes from very high in the company, I don't think one needs to be an expert in corporate intent to see that this was a strategy of the company [that] came from the highest levels.
>
> Q. Well, in fact, in that scenario you don't need to be an expert in anything.
>
> A: Right.
>
> Q: You can make an inference from the document; correct?
>
> A: Right.[11]

("That Pfizer intended to, and did, promote Geodon off-label to children and adolescents was documented early on in the drug's time on the market."); 93 ("Lyrica Operating Plans disseminated from headquarters clearly reflect that Pfizer intended to promote Lyrica for unapproved indications."); 96 ("It is clear that Pfizer headquarters' unauthorized comparative and off-label strategy for promoting Lyrica effectively cascaded down to the sales force as the Company intended.").

[10] Avorn Rep. ¶ 1.

[11] Avorn Dep. 55:22-56:25.

Dr. Avorn further admitted that his review of these materials was incomplete; he considered only items pointed out to him by Plaintiffs' counsel[12] and ignored the rest, even when those materials bore directly on the contents of the documents on which he opined.[13] He also conceded that he had based certain of his opinions on draft, rather than final, versions of documents.[14] Finally, he allowed that he did not know how many Pfizer employees had engaged in off-label marketing or had even received the emails and memos that were among his bases for concluding that off-label promotion was "intentional" and "pervasive."[15]

ARGUMENT

I. AVORN'S PERSONAL VIEWS ABOUT PFIZER'S MARKETING PRACTICES OR THE COMPANY'S "INTENT" ARE NOT PERMISSIBLE EXPERT TESTIMONY.

A. Avorn's Opinions About What Inferences Should Be Drawn from Pfizer's Documents Convey No Expert Knowledge that Would Assist the Jury.

The opinions Dr. Avorn seeks to offer in this case are indistinguishable from those he attempted to offer in *Rezulin*, *Diet Drugs*, and the other pharmaceutical litigation in which he was precluded from testifying. The reasons he was excluded in those cases apply equally here. Although Plaintiffs proffer Dr. Avorn as an expert, his intended function at trial is not to supply any specialized knowledge that would assist the jury, but rather to serve as a narrator for Plaintiffs' presentation of evidence regarding Pfizer's marketing practices and Plaintiffs' argument that certain documents reflect Pfizer's intent to promote off-label. That is not a proper

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[12] Avorn Dep. 11:8-19.

[13] *E.g.,* Avorn Dep. 103:14-19; 160:22-161:12; 230:2-11; 251:5-253:9 (Avorn did not read or does not recall reading deposition testimony from authors of documents concerning those documents); *id.* at 169:20-170:4 (Avorn did not read or does not recall reading document informing sales force to market on-label).

[14] *E.g.,* Avorn Dep. 80:4-11 (Avorn did not read final version of document on which he opined and "would have liked to" before offering his opinion)

[15] Avorn Dep. 62:4-6, 111:23-114:18, 119:15-121:15, 122:4-123:3.

expert function. It is the job of the *jury*, not experts, to make inferences of intent from a review of the evidence. *See, e.g.*, *Bd. of Trs. Of AFTRA Ret. Fund. v. JP Morgan Chase Bank, N.A.*, No. 09 Civ. 686(SAS), 2011 WL 6288415, at *8 (S.D.N.Y. Dec. 15, 2011) (precluding expert from making statements speculating about the state of mind and motivations of defendants and individual witnesses); *Highland Capital Mgmt., L.P. v. Schneider*, 551 F. Supp. 2d 173, 187-88 (S.D.N.Y. 2008); *Taylor v. Evans*, No. 94 Civ. 8425 (CSH), 1997 WL 154010, at *2 (S.D.N.Y. Apr. 1, 1997) (describing "musings as to defendants' motivations [that] would not be admissible if given by any witness—lay or expert"); *see also In re Rezulin*, 309 F.Supp. 2d at 551 (courts reject expert testimony that is "merely a narrative of the case which a juror is equally capable of constructing" (internal quotation marks omitted)).

This invasion of the jury's role is precisely why Dr. Avorn's opinions have been excluded several times in the past. As the court in *Diet Drugs* explained:

> Regarding expert opinions as to [defendant's] corporate intent, the court finds trouble in the qualifications of both Drs. Rubin and Avorn. The court also finds trouble with the admissibility of an opinion on this subject. Even if such an opinion was relevant, there are serious problems with the reliability of these opinions. The witnesses are qualified in particular scientific disciplines. ***These disciplines do not include knowledge or even experience in the manner in which corporations and the pharmaceutical marketplace react, behave or think regarding their non-scientific goals of maintaining a profit-making organization that is subject to rules, regulations, standards, customs and practices among competitors and influenced by shareholders or public opinion.*** If the witnesses' bases for the opinions concerning improper intent come from other evidence such as letters, admissions of [defendant's] officers or employees, or other admissible evidence, *that* is what the jury should hear and the question of [defendant's] intent would flow from such evidence to be determined by the jury. . . . ***The question of intent is a classic jury question and not one for experts, and clearly not these experts***.

In re Diet Drugs, 2000 WL 876900, at *9 (emphases added). Judge Kaplan echoed this sentiment in excluding Dr. Avorn's opinions in *Rezulin*, a lawsuit against Pfizer:

> [Dr. Avorn's] view that [defendant] failed to disclose information to the FDA boils down to a contention that [defendant] "buried" certain lab results in an Appendix to [a drug application]. This opinion does not implicate Dr. Avorn's expertise in pharmacoepidemiology. It is a simple inference drawn from his review of two documents—the [drug application] and its Appendix—which, if admissible, plaintiffs' counsel may present directly to the fact-finder while arguing his or her view as to their significance. Expert testimony interpreting [defendant's] conduct in disclosing information to the FDA therefore will not assist the fact-finder in these cases.

In re Rezulin, 309 F. Supp. 2d at 550 (footnote omitted).

Ignoring these unambiguous holdings, Plaintiffs seek to have Dr. Avorn parrot to the jury their views of the evidence, and particularly of Pfizer's intent, under the guise of expert testimony. As set forth in his report, Dr. Avorn's proposed testimony consists of discussing the documentary evidence selected by Plaintiffs' counsel and arguing for the "inferences" that he believes should be drawn from them about Pfizer's activities and intentions.[16] Like the testimony excluded from *Rezulin* and *Diet Drugs*, these opinions "do[] not implicate Dr. Avorn's expertise in pharmacoepidemiology," but are simply inferences drawn from company documents. *In re Rezulin*, 309 F. Supp. 2d at 550. These are "lay matters which a jury is capable of understanding and deciding without the expert's help" and therefore cannot be offered by an expert under Rule 702. *Andrews v. Metro North Commuter R.R. Co.*, 882 F.2d 705, 708 (2d Cir. 1989).

By way of example, Dr. Avorn cites multiple documents in his report that contain language instructing the recipient not to use the document for promotional purposes and/or to

[16] *See supra* n.9 (quoting multiple opinions offered by Dr. Avorn as to Pfizer's intent to commit off-label promotion); *see also* Avorn Rep. ¶3 ("Based on my review of the materials listed, I am unable to reach any other conclusion but that Pfizer decided to ignore the traffic ticket and to keep on speeding.").

otherwise abide by Pfizer's policies.[17] Dr. Avorn opines that "[w]hile these documents and similar materials often contained the requisite pro forma caveats that such materials should be used according to Pfizer policy and codes of conduct, ***the underlying intention to promote [the drugs] off-label is quite clear***" from the documents.[18] When asked about the disconnect between explicit instructions not to use in promotion and his opinion that the documents are evidence of an intent to promote illegally, Dr. Avorn conceded that he was simply offering personal views, not expert opinions based on any specialized knowledge:

> Q. So what I'm—but the answer to my question is, with the two conflicting statements, as you've put it—
>
> A. Right.
>
> Q. —you've chosen to interpret it in the way that it is the inappropriate suggestion—the—the way the author is suggesting something inappropriate.
>
> A. Right. And it seems to me analogous to coming upon a bank that has just been robbed and seeing somebody with a burglar mask holding a sack of money and you have either the fact that the bank was robbed, and a bunch of money is missing, and a statement that the burglar or bank robber is saying, I'm innocent. You know, you've got to decide which you think is more relevant.[19]

Dr. Avorn also testified that these instructions to comply with Pfizer policies were just "cover-your-ass" statements by Pfizer employees.[20] The inadmissibility of this testimony is obvious;

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[17] *E.g.,* Dec. 10, 2014 MacDonald Decl. Ex. HH-3 (PFE-JONES 00004216) ("We have, through Karen Katen, directly communicated to Carrie Cox our Pfizer behavior values, need to abide to our Bextra label and adhere to the FDA promotional guidelines."); Dec. 10, 2014 MacDonald Decl. Ex. JJ-3 (BEX006335049) ("This information is not for detailing.").

[18] Avorn Rep. ¶ 33 (emphasis added); *see also id.* ¶ 36 ("Including the perfunctory phrase, '[t]his information is not included for detailing,' in the document does not undo the explicit meaning of the message—that Pfizer was encouraging its sales representatives to ask the physicians they were detailing to include Bextra in protocols for pre- and post-operative care even though the FDA-approved label did not support marketing the drug in this manner.").

[19] Avorn Dep. 92:3–17.

[20] Avorn Dep. 65:1–14.

Dr. Avorn is weighing the evidence in the case and deciding that Pfizer committed wrongdoing. As Judge Kaplan held when evaluating Dr. Avorn's proffered testimony, and as other courts have echoed, a witness cannot, under the guise of expert testimony, "supplant the role of counsel in making argument at trial, and the role of the jury in interpreting the evidence." *In re Rezulin*, 309 F. Supp. 2d at 541 (internal quotation marks omitted); *see also LinkCo, Inc. v. Fujitsu Ltd.*, 00 Civ. 7242(SAS), 2002 WL 1585551, at *2 (S.D.N.Y. Jul. 16, 2002) (excluding expert testimony that "[did] no more than counsel for [plaintiff would] do in argument, i.e. propound a particular interpretation of [defendant's] conduct.'" (citation omitted)).

Here, jurors are fully capable of evaluating Pfizer's documents and drawing their own conclusions. They do not need Dr. Avorn to explain the documents or to tell them what to think—as Dr. Avorn himself conceded during his deposition.[21]

Dr. Avorn's opinions about Pfizer's conduct and intentions convey no specialized knowledge or information and would impermissibly invade the province of the jury as the finder of fact. They must be excluded.

B. Avorn's Opinions About Pfizer's Marketing Practices Lack A Reliable Analytical and Factual Basis.

Dr. Avorn's testimony is inadmissible for the additional reason that it does not satisfy the reliability requirements of Rule 702. An expert witness may not testify unless his or her testimony "is based on sufficient facts or data" and "is the product of reliable principles and methods" and "the expert has reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702(b)-(d). These requirements seek "to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the

[21] *See supra* p. 4.

courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999).

Dr. Avorn's testimony does not meet these standards. No analytical or scientific method undergirds his testimony. As noted above, he has merely reviewed documents supplied by Plaintiffs' counsel and offered a view as to what inferences those documents support—an exercise that requires no specialized expertise, as he himself concedes. His conclusions do not *follow* from any method or process, and thus the "rigorous analytical connection" that must exist between the methodology and the conclusion is lacking. *Nimely v. City of New York*, 414 F. 3d 381, 396 (2d Cir. 2005); *see also id.* at 398 (finding inadmissible purported expert testimony regarding fact witnesses' credibility and lack of motivation to lie); *In re Fresh Del Monte Pineapples Antitrust Litig.*, 04-md-1628 (RMB)(MHD), 2009 WL 3241401, at *16 (S.D.N.Y. Sept. 30, 2009) (rejecting expert testimony that "[did] not demonstrate any particular scientific expertise that [could] be assessed for reliability" (citation omitted)), *aff'd sub nom., Am. Banana Co. v. Bonafede Co.*, 407 F. App'x 520 (2d Cir. 2010).

Further, Dr. Avorn's review was not "based on sufficient facts" or conducted in a sufficiently rigorous or principled manner to make his conclusions reliable. To the contrary, his review was incomplete and defective in numerous respects, including a failure to review the entire record (*e.g.*, documents and testimony bearing directly on his opinions), and reliance on draft or otherwise incomplete documents.[22] He also extrapolated documents across Pfizer without any knowledge of how widely they were distributed or from where within the company they had originated.[23] These shortcomings, among others, demonstrate that Dr. Avorn's review lacked analytical rigor and methodological soundness, and thus fails the test of reliability that is a

[22] *See supra* pp. 4–5 & nn. 11-14.

[23] *See supra* p. 5 & n.15.

prerequisite to admissibility under Rule 702. Even if Dr. Avorn's method were sound in principle—and as explained above, it is not—it was not "reliably applied." Fed. R. Evid. 702(d).

II. AVORN'S TESTIMONY ABOUT PFIZER'S MARKETING PRACTICES IS IRRELEVANT AND PREJUDICIAL.

Even if Dr. Avorn's opinions were not blatantly improper and inadmissible under Rule 702, they are irrelevant and unfairly prejudicial and accordingly inadmissible under Rules 402 and 403. As Defendants have argued more generally, this trial concerns solely Plaintiffs' securities fraud claims. Plaintiffs should not be permitted to distract, confuse and potentially prejudice the jury with a sideshow trial regarding Pfizer's marketing activities. *See* Defendants' Motion *in Limine* No. 5. This Court should exclude Dr. Avorn's testimony for the same reasons that it should limit Plaintiffs' marketing evidence generally. Dr. Avorn's opinions about Pfizer's marketing practices and intentions, aside from being baseless, are irrelevant to the securities disclosure issues that are the basis for Plaintiffs' claims and accordingly are not admissible under Rules 401 and 402. *See In re Rezulin*, 309 F.Supp.2d at 540 (expert testimony lacking a "valid connection to the pertinent inquiry" must be excluded). Further, if admitted, his testimony would risk confusing the jury, require a time-consuming rebuttal by fact and expert witnesses, and needlessly lengthen and complicate the trial—particularly in view of the fact that no one disagrees that certain employees violated Pfizer's prohibitions against off-label marketing. *See Daubert v. Merrell Dow Pharm.*, 509 U.S. 579, 595 (1993); *United States v. Hatfield*, 685 F. Supp. 2d 320, 324 (E.D.N.Y. 2010) (rejecting prejudicial evidence that would result in delay of "conducting a 'mini-trial' as to whether Defendants lied . . . while adducing no evidence concerning whether the Defendants committed the charged crimes"). All of these considerations support exclusion under Rule 403. Finally, Dr. Avorn's accusations of marketing misconduct—and in particular his suggestion that Pfizer's sales force put patients at risk by promoting

products for unapproved uses, patient populations and doses—only further raise the specter of unfair prejudice, and are thus subject to exclusion under Rule 404(b) as well. *See Old Chief v. United States*, 519 U.S. 172, 180 (1997). All of these considerations require that Dr. Avorn be excluded from trial.

CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Court grant their motion *in limine* to exclude Dr. Avorn's opinions and testimony at trial.

Dated: Washington, D.C.
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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that, on this 10th day of December, 2014, the foregoing Memorandum in Support of Defendants' Motion *In Limine* No. 1 To Exclude Plaintiffs' Designated Expert Jerome Avorn was filed with the Court through the CM/ECF system and thereby served to all parties of record.

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