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

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

Plaintiffs concede that ***multiple*** times, their proposed expert, Jerry Avorn, has been precluded by courts, including the Southern District of New York, from offering testimony as to the alleged "intent" of pharmaceutical companies and their employees.[1] Yet, Plaintiffs insist that this time, things are different, because whatever else he is doing, "Dr. Avorn is not opining on intent." Opp. 1; *see also id.* at 3 ("Dr. Avorn is ***not*** offering any opinions as to intent"), at 5 ("Dr. Avorn is not opining about intent"). This attempt to rewrite history should be rejected; Plaintiffs' belated promises do not change the fact that Dr. Avorn's report clearly and unambiguously sets forth the opinions he proposes to offer, that Pfizer ***intended*** to market its products off-label:

- "I am unable to reach any other conclusion but that Pfizer ***decided to ignore the traffic ticket and to keep on speeding***";[2]
- discussing "[a]dditional evidence that the Company's senior management at the highest level ***intended to market Bextra for conditions for which it was not FDA approved***";[3]
- "[Pfizer's] underlying ***intention to promote Bextra off-label*** is quite clear";[4]
- "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***";[5]
- "these documents reveal ***a clear, intentional, and consistent pattern of off-label marketing of Bextra as a corporate strategy*** which Pfizer implemented successfully";[6]

[1] Pls.' Opp. to Defs.' Mot. *in Limine* No. 1 to Exclude Pls. Designated Expert Jerome Avorn ("Opp.") 5 & n.3 (citing *In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prods. Liab. Litig.*, No. MDL 1203, 2000 WL 876900 (E.D. Pa. June 20, 2000); *Skibniewski v. Am. Home Prods. Corp.*, No. 99-0842-CV-W-FJG, 2004 WL 5628157 (W.D. Mo. Apr. 1, 2004); *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 550 (S.D.N.Y. 2004); *O'Neill v. Novartis Consumer Health, Inc.*, 147 Cal. App. 4th 1388, 1402 (2007)).

[2] Dec. 10, 2014 Declaration of Amanda M. MacDonald in Support of Defendants' Motions *In Limine* Ex. SS-2 (June 10, 2014 Avorn Report ¶ 3) (hereinafter "Avorn Rep.") (emphasis added).

[3] Dec. 10, 2014 MacDonald Ex. SS-2 (Avorn Rep. ¶ 32) (emphasis added).

[4] Dec. 10, 2014 MacDonald Ex. SS-2 (Avorn Rep. ¶ 33) (emphasis added).

[5] Dec. 10, 2014 MacDonald Ex. SS-2 (Avorn Rep. ¶ 38) (emphasis added).

- "Pfizer ***intended to, and did, promote Geodon off-label*** to children and adolescents";[7]
- "[t]his reflects a ***purposeful strategy coming from senior management explicitly to promote Lyrica for uses not approved by the FDA***";[8]
- "Lyrica Operating Plans disseminated from headquarters clearly reflect that ***Pfizer intended to promote Lyrica for unapproved indications***";[9]
- "the Operating Plan reflected ***a clear intent to promote Lyrica for that indication***";[10]
- "Pfizer's ***motivation was clear***";[11]
- "Pfizer's POAs contained core messages from the Operating Plans ***intended for the sales force to use during detailing***";[12] and
- "[i]t 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***."[13]

If Dr. Avorn's opinions as to Pfizer's alleged intent to market its products off-label were not sufficiently clear from his report, his deposition testimony confirmed that his purpose in testifying in this case is to "look[] at what someone wrote o[r] behavior and infer[] from that ***what they intended***."[14] As he stated, "I don't think one needs to be an expert in corporate intent

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[6] Dec. 10, 2014 MacDonald Ex. SS-2 (Avorn Rep. ¶ 40) (emphasis added).

[7] Dec. 10, 2014 MacDonald Ex. SS-2 (Avorn Rep. ¶ 43) (emphasis added).

[8] Dec. 10, 2014 MacDonald Ex. SS-2 (Avorn Rep. ¶ 92) (emphasis added).

[9] Dec. 10, 2014 MacDonald Ex. SS-2 (Avorn Rep. ¶ 93) (emphasis added).

[10] Dec. 10, 2014 MacDonald Ex. SS-2 (Avorn Rep. ¶ 93) (emphasis added).

[11] Dec. 10, 2014 MacDonald Ex. SS-2 (Avorn Rep. ¶ 93) (emphasis added).

[12] Dec. 10, 2014 MacDonald Ex. SS-2 (Avorn Rep. ¶ 94) (emphasis added).

[13] Dec. 10, 2014 MacDonald Ex. SS-2 (Avorn Rep. ¶ 96) (emphases added).

[14] Dec. 10, 2014 MacDonald Decl. Ex. WW-1 (Avorn (Aug. 7, 2014) Dep. 57:1–6) (hereinafter "Avorn Dep.") (emphasis added); *see also id.* at 64:19–21 ("Because if it that [sic] was not [Pfizer's] intent, why were they circulating this information?"), 82:13–15 ("Q. So is it Doctor Cawkwell's intent you're

to see that this was a strategy of the company there [sic] came from the highest levels."[15] Plaintiffs cite Dr. Avorn's testimony that he "had no way of knowing what was in [Defendants'] mind" as support for their claim that Dr. Avorn is not opining as to Pfizer's intent. Opp. 3 (quoting MacDonald Decl. Ex. WW-1 (Avorn Dep. 313:6–13)). But Plaintiffs fail to cite Dr. Avorn's full testimony on this topic, including his admission that he ***is*** offering opinions as to Pfizer's corporate intent:

> Q. Mr. Rosen asked you whether you were opining about Pfizer or Pfizer management's intent; correct?
>
> A. That's right.
>
> Q. And you said you weren't; correct?
>
> A. I said that I had no way of knowing what was in their mind; and I was not in closed-door meetings. ***But I think I also said that if you look at the documents, and the data, and the behaviors, a fairly clear pattern emerges that I think does speak to what a—if you can speak of a company intending something, yes***.
>
> Q. All right. Because your report uses the word "intent" a number of times; doesn't it?
>
> A. Yes. Right.[16]

In short, there is simply no denying that, just as he has in a number of other cases where his testimony was precluded, Dr. Avorn offers inadmissible opinions as to Pfizer's intent.

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referring to in paragraph 32? A. She and her colleagues."), 125:5–10 ("Was I ever in a room when a sales rep was doing illegal, off-label marketing? Of course not. But I am aware of the corporate vision, plan of action statements about what it intended to do with BEXTRA; how BEXTRA was, indeed, being used, as per the company's own information."); Declaration of Amanda MacDonald, dated Dec. 31, 2014, Ex. DD-5 (Avorn Dep. 76:21–77:1) ("the sentence before the one that we're discussing indicated the – I won't say 'intent' but the—the corporate vision to support new indications, including acute pain, migraine, and chronic pain").

[15] Dec. 10, 2014 MacDonald Decl. WW-1 (Avorn Dep. 56:15–18); *see also id.* 58:14–18 ("Q: Do you have specialized knowledge or training in determining what human beings at a corporation in the pharmaceutical industry intend when they do something? A. I think it's fair to say that I do.").

[16] Dec. 10, 2014 MacDonald Decl. WW-1 (Avorn Dep. 313:6–20) (emphases added).

Plaintiffs' effort to soften the blow of Dr. Avorn's prior preclusions by arguing that in those cases, he was not prevented from testifying *entirely*, Opp. 2, 5, is unavailing. Those cases were products liability matters in which the courts found that Dr. Avorn's background in pharmacoepidemiology was relevant to some particular medical or scientific aspect of the case. Dr. Avorn has no such role to play in a securities fraud case, in which there are no issues of pharmacoepidemiology.

For example, in *Diet Drugs*, the court found that Dr. Avorn was "qualified to opine on the medical facts and science regarding the risks and benefits of the diet drugs in question and to compare that knowledge with what was provided in the text of labeling and warnings on the diet drugs in question." *Diet Drugs*, 2000 WL 876900, at *11 (E.D. Pa. June 20, 2000). However, ***the court precluded him from offering opinions identical to those he seeks to offer here***, *inter alia*, concerning "the content of third party documents," "the intent of [defendants] as evidenced by the words and conduct of their agents, servants or employees," and "the extent to which there was legal compliance with any laws or regulations governing the preparation, including the content of labeling or other warnings furnished by [defendants] in conjunction with the marketing of the diet drugs at issue." *Id.* at 12. Similarly, in *O'Neill*, Dr. Avorn testified about the "purpose and protocol" of an "epidemiological study," but was not allowed to opine on the defendant's motives in failing to withdraw the product at issue from the market. 147 Cal. App. 4th at 1391, 1401–02, 1405. In *Rezulin*, although the court made a passing reference to Dr. Avorn's "expertise in pharmacoepidemiology," 309 F. Supp. 2d at 550, it did not specify any topics on which Dr. Avorn would be permitted to testify. Instead, the court listed the topics on which he was *not* qualified to opine, including "describing or interpreting FDA regulations, or commenting on [defendant's] adherence to those regulations," "interpreting [defendant's]

conduct in disclosing information to the FDA," and relating a series of "non-technical factual allegations" about the product at issue. *Id.* at 549–550, 552–53.

None of the opinions Dr. Avorn proposes to offer in this case involve his experience in pharmacoepidemiology or concern complex medical or scientific concepts with which the jury might need assistance. As discussed above and in Defendants' opening brief, the entirety of Dr. Avorn's proposed testimony is exactly what he has been prevented by multiple courts from proffering previously: how he believes Pfizer intended to promote its products off-label based on his reading of Pfizer's internal documents.[17] This is improper and inadmissible under Rule 702. Accordingly, as in those earlier cases, the Court should exclude Dr. Avorn's opinions and testimony.

Dated: Washington, D.C.
December 31, 2014

Respectfully submitted,

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[17] *See* Defs.' Mot. *in Limine* No. 1 to Exclude Pls. Designated Expert Jerome Avorn 2–5, 7–9.

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CERTIFICATE OF SERVICE

I hereby certify that, on this 31st day of December, 2014, the foregoing Reply 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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