

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ILLINOIS

)
IN RE YASMIN AND YAZ (DROSPIRENONE))
MARKETING, SALES PRACTICES AND)
PRODUCTS LIABILITY LITIGATION)
_____)

3:09-md-02100-DRH-PMF

MDL No. 2100

This Document Relates to:

ALL CASES

**BAYER’S MOTION TO EXCLUDE OPINIONS IN THE SECOND SUPPLEMENTAL
REPORT OF DAVID A. KESSLER, M.D.**

(Filed under seal)

Defendants Bayer HealthCare Pharmaceuticals Inc. and Bayer Pharma AG (“Bayer”) moves to exclude the proposed testimony contained in the Second Supplemental Report of David A. Kessler, M.D. (Dec. 26, 2011) (Ex. A). Fed. R. Evid. 401-403, 702.

BACKGROUND

In his Second Supplemental Report, Dr. Kessler offers opinions about the December 8, 2011 “joint meeting of [FDA’s] Advisory Committees for Reproductive Health Drugs and [FDA’s] Drug Safety and Risk Management Committee [hereinafter ‘Joint Advisory Meeting’].” 2d Supp. Rep. ¶ 2. Dr. Kessler opines that “this joint advisory committee was required to be in compliance with Federal ethics and conflict of interest laws.” *Id.* ¶ 6. Based on his review of documents available to him “that may not have been available to the Food and Drug Administration,” Dr. Kessler opines that “certain members of the Advisory Committee did have conflicts of interest such that a reasonable person with knowledge of the relevant facts could question the member’s impartiality.” *Id.* ¶¶ 11, 12.

Thereafter, Dr. Kessler purports to discuss and characterize a series of documents that Dr. Kessler states involve or mention certain members of the Advisory Committee. *Id.* ¶¶ 14-31 (discussing documents with respect to Dr. Paula Hillard); *id.* ¶¶ 32-34 (addressing documents with respect to Dr. Anne Burke); *id.* ¶¶ 35-36 (discussing documents with respect to Dr. Melissa Gilliam); *id.* ¶¶ 37-42 (discussing documents with respect to Dr. Julia V. Johnson). After this narrative discussion of these documents, Dr. Kessler opines that “[d]ue to the complex dynamics that are part of FDA advisory committee meetings, and in light of the fact that a reasonable person with knowledge of the relevant facts could question the above members’ impartiality, it is my opinion that the FDA advisory committee was not independent of Bayer, and its recommendations and votes need to be viewed as such.” *Id.* ¶ 43.

ARGUMENT

The opinions contained in Dr. Kessler’s Second Supplemental Report are inadmissible and should not be permitted at trial.

1. Dr. Kessler may not testify whether or not “‘circumstances would cause a reasonable person with knowledge of the relevant facts to question [the member’s] impartiality.’” 2d Supp. Rep. ¶ 10 (emphasis omitted); *see also id.* ¶ 12 (“[I]t is my opinion that certain members of the Advisory Committee did have conflicts of interest such that a reasonable person with knowledge of the relevant facts *could* question the member’s impartiality,” (emphasis added)); *accord id.* ¶ 43 (“it is my opinion that the FDA advisory committee was not independent of Bayer, and its recommendations and votes need to be viewed as such”).

First, Dr. Kessler’s supplemental report is not expert testimony at all, but largely a recitation of facts. But he has not demonstrated that he has “knowledge of the relevant facts.” Instead, his opinions are mainly based on a group of documents hand-picked from Bayer’s

production and made “available to [Dr. Kessler].” 2d Supp. Rep. ¶ 11. *See In re Trasylol Prods. Liab. Litig.*, 709 F. Supp. 2d 1323, 1337 (S.D. Fla. 2010) (Middlebrooks, J.) (excluding expert whose “opinions fall outside the proper scope of expert testimony because they consist of a narrative of selected regulatory events”).

Second, Dr. Kessler’s status as a former FDA Commissioner does not authorize him to ignore the procedures and standards that FDA applies to address conflict of interest questions for members of advisory committees. *See* Letter from John E. Galvin to the Honorable David R. Herndon at 3-4 & n.1 (Dec. 20, 2011) (Ex. B) (describing process conducted by FDA to address and evaluate possible conflicts of interest). Dr. Kessler makes no effort to apply the standards and procedures that the FDA employs to address these conflict of interest issues and instead applies his own set of unidentified standards.

Third, as Bayer has addressed previously, Dr. Kessler may not offer legal opinions because that is contrary to Seventh Circuit precedent and because he is not qualified to do so. *See Good Shepherd Manor Foundation, Inc. v. City of Mومence*, 323 F.3d 557, 564 (7th Cir. 2003) (“expert testimony as to legal conclusions that will determine the outcome of the case is inadmissible”); *Bammerlin v. Navistar Int’l Transp. Corp.*, 30 F.3d 898, 900 (7th Cir. 1994) (the meaning of federal regulations “is not a question of fact, to be resolved by the jury after a battle of experts” but “is a question of law, to be resolved by the court”).

Finally, Dr. Kessler has no special expertise to opine about what a “reasonable person with knowledge of the relevant facts” would conclude. His opinion improperly attempts to usurp the role of the jury. *See Bouchard v. American Home Prods. Corp.*, 213 F. Supp. 2d 802, 809 (N.D. Ohio 2002) (Katz, J.) (excluding expert’s “personal belief as to the weight of the evidence”).

2. To the extent that Dr. Kessler seeks to opine that the FDA has been defrauded in some manner by the advisory committee members whose impartiality he questions, that is nothing more than rank speculation and innuendo that has no proper place in this trial. *See Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 350-51 (2001). Indeed, Dr. Kessler's status as a former FDA Commissioner does not authorize him to testify as a shadow FDA, second-guessing determinations by the agency, and opining about the weight to be afforded to evidence, including his opinion that "the FDA advisory committee was not independent of Bayer, and its recommendations and votes need to be viewed as such." 2d Supp. Rep. ¶ 43. *See Bouchard*, 213 F. Supp. 2d at 809.

CONCLUSION

For these reasons, the opinions in Dr. Kessler's Second Supplemental Report are inadmissible and should be excluded.

Dated: December 30, 2011

Respectfully submitted,

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