IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
CHARLESTON DIVISION

IN RE: LIPITOR (ATORVASTATIN CALCIUM) MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION	**MDL No. 2:14-mn-02502-RMG** **CASE MANAGEMENT ORDER NO. 73** **This Order relates to all cases.**

This matter is before the Court on Pfizer's Motion to Exclude Testimony of John Abramson, M.D. (Dkt. No. 974). For the reasons stated below, the motion is **GRANTED IN PART AND DENIED IN PART**.

I. Background

In this MDL, Plaintiffs allege that Lipitor caused their Type 2 diabetes, that Defendant failed to adequately warn about the risk of developing Type 2 diabetes, and that Defendant misrepresented Lipitor's effectiveness for primary prevention in women. Dr. Abramson, a former family practitioner, opines that

- "Pfizer misrepresented its knowledge of the significantly increased risk of clinically meaningful hyperglycemia/new-onset diabetes association with Lipitor therapy";
- Pfizer "misrepresented the evidence of the benefit of Lipitor in women without pre-existing coronary heart disease"; and
- "As a result of Pfizer's omissions and misrepresentations, physicians and patients were not adequately, timely and sufficiently informed about the significant risks of clinically

> meaningful hyperglycemia and new-onset diabetes associated with Lipitor therapy. Nor were they informed that the chief piece of scientific evidence supporting the recommendation to initiate Lipitor therapy for the primary prevention of cardiovascular disease in women–the ASCOT trial–did not demonstrate a benefit in women."

(Dkt. No. 974-2 at 9, 11).

By previous order, the Court excluded Dr. Abramson's opinions that there is no evidence to support the efficacy of statins for women in primary prevention and that the FDA should not have approved Lipitor for primary prevention in women. (CMO 72, Dkt. No. 1511). This order concerns the remainder of Dr. Abramson's opinions. Defendant argues that Dr. Abramson's testimony should be excluded in its entirety because Dr. Abramson lacks the relevant expertise, because he does not use a recognized methodology, and because his opinions are not based on sufficient evidence. (Dkt. No. 974). Plaintiffs have filed a response to Defendant's motion, (Dkt. No. 1045), and Defendant has filed a reply. (Dkt. No. 1092).

II. Legal Standard

Under Rule 104(a) and 702, "the trial judge must ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable." *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 589 (1993). Thus, the trial court must ensure that (1) "the testimony is the product of reliable principles and methods," that (2) "the expert has reliably applied the principles and methods to the facts of the case," and (3) that the "testimony is based on sufficient facts or data." Fed. R. Evid. 702(b), (c), (d). "This entails a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid," *Daubert,* 509 U.S. at 592-93, and whether the expert has "faithfully appl[ied] the methodology to facts." *Roche v. Lincoln Prop. Co.*, 175 F. App'x 597, 602 (4th Cir. 2006).

Factors to be considered include "whether a theory or technique . . . can be (and has been) tested," "whether the theory or technique has been subjected to peer review and publication," the "known or potential rate of error," the "existence and maintenance of standards controlling the technique's operation," and whether the theory or technique has garnered "general acceptance." *Daubert,* 509 U.S. at 593-94; *accord United States v. Hassan*, 742 F.3d 104, 130 (4th Cir. 2014). However, these factors are neither definitive nor exhaustive, *United States v. Fultz*, 591 F. App'x 226, 227 (4th Cir. 2015), *cert. denied*, 135 S. Ct. 2370 (2015), and "merely illustrate[] the types of factors that will bear on the inquiry." *Hassan*, 742 F.3d at 130. Courts have also considered whether the "expert developed his opinions expressly for the purposes of testifying," *Wehling v. Sandoz Pharm. Corp.*, 162 F.3d 1158 (4th Cir. 1998), or through "research they have conducted independent of the litigation," *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995) (on remand), and whether experts have "failed to meaningfully account for . . . literature at odds with their testimony." *McEwen v. Baltimore Washington Med. Ctr. Inc.*, 404 F. App'x 789, 791-92 (4th Cir. 2010).

Rule 702 also requires courts "to verify that expert testimony is 'based on sufficient facts or data.'" *E.E.O.C. v. Freeman*, 778 F.3d 463, 472 (4th Cir. 2015) (quoting Fed. R. Evid. 702(b)). Thus, "trial judges may evaluate the data offered to support an expert's bottom-line opinions to determine if that data provides adequate support to mark the expert's testimony as reliable." *Id.* The court may exclude an opinion if "there is simply too great an analytical gap between the data and the opinion offered." *Id.* "The proponent of the [expert] testimony must establish its admissibility by a preponderance of proof." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001).

The Court is mindful that the *Daubert* inquiry involves "two guiding, and sometimes competing, principles." *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999). "On the one hand . . . Rule 702 was intended to liberalize the introduction of relevant expert evidence," *id.*, and "the trial court's role as a gatekeeper is not intended to serve as a replacement for the adversary system." *United States v. Stanley*, 533 F. App'x 325, 327 (4th Cir. 2013), *cert. denied*, 134 S. Ct. 1002 (2014). On the other, "[b]ecause expert witnesses have the potential to be both powerful and quite misleading, it is crucial that the district court conduct a careful analysis into the reliability of the expert's proposed opinion." *United States v. Fultz*, 591 F. App'x 226, 227 (4th Cir. 2015), *cert. denied*, 135 S. Ct. 2370 (2015); *accord Westberry*, 178 F.3d at 261.

III. Discussion

A. Dr. Abramson's Qualifications

Dr. Abramson practiced family medicine for approximately 25 years before leaving medical practice in 2002 to "devote [himself] full-time" to researching, writing, and lecturing on "the integrity of the information that doctors rely upon when making clinical decisions[,] . . . specifically in regard to the pharmaceutical industry." (Dkt. No. 974-2 at 7). He wrote a book called *Overdo$ed America: The Broken Promise of American Medicine*, which is described on its cover as "how the pharmaceutical companies are corrupting science, misleading doctors, and threatening your health." (Dkt. No. 974-3 at 2). *Overdo$ed America* was published in 2004, and Dr. Abramson has been a plaintiffs' expert in pharmaceutical litigations ever since. (Dkt. No. 974-1 at 84-85).

Dr. Abramson is board certified in family medicine. He graduated from Brown Medical School in 1976. (*Id.* at 6). After his residency and a two-year stint as a primary care physician

with the United States Public Health Service in rural West Virginia, he completed a fellowship in family medicine and earned a Master of Science in Family Practice. The first year of this fellowship consisted of "classwork in research design, statistics, epidemiology, and sociology," and the second year consisted of independent research. (Dkt. No. 974-1 at 214-15). This fellowship concluded in 1982. (Dkt. No. 974-2 at 6).

From 1982-2002, Dr. Abramson was a family medicine practitioner. (Dkt. No. 974-1 at 220-22). From 1997 to 2008, he was an instructor in primary care at Harvard Medical School, which meant that medical students came to his office several afternoons a month for nine months and then on the fourth week of the month students attended a tutorial where Dr. Abramson talked with them about their clinical experiences. (Dkt. No. 974-1 at 315). Dr. Abramson is currently a lecturer at Harvard Medical School, where he teaches a health policy class eight days a year for a few hundred dollars. (Dkt. No. 974-2 at 7; Dkt. No. 974-1 at 126-27, 316). He has also been a mentor to first-year medical students interested in primary care. (Dkt. No. 974-2 at 7).

After *Overdo$ed America* was published in 2004, Dr. Abramson appeared on The Today Show. (Dkt. No. 974-1 at 256). Some lawyers from Texas saw him on the show and asked him to come to Texas to give a presentation about Vioxx and Celebrex. (*Id.* at 255-56). Dr. Abramson has been retained by plaintiffs in multiple pharmaceutical cases since. (*See* Dkt. No. 974-1 at 84-91). Since the publication of *Overdo$ed America*, Dr. Abramson has also published several articles (all with other authors):

- "When Health Policy is the Problem," Journal of Health Politics, Policy and Law (2005);[1]

[1] This journal is a law journal.

- "The Effect of Conflict of Interest on Biomedical Research and Clinical Practice Guidelines: Can We Trust the Evidence in Evidence-Based Medicine?," Journal of the American Board of Family Practice (2005);
- "Are Lipid-lowering guidelines evidence-based?," The Lancet (2007);
- "Cholesterol Lowering, Cardiovascular Diseases, and the Rosuvastatin-JUPTIER Controversy," Archives of Internal Medicine (2010);
- "Clinical Trial Data is a Public Good," Journal of the American Medical Association (2012);
- "Should people at low risk of cardiovascular disease take a statin?," British Medical Journal (2013).[2]

(Dkt. No. 974-2 at 7-8).

Defendant claims that Dr. Abramson is "not qualified in any field relevant to this litigation." (Dkt. No. 974 at 13). It points out that Dr. Abramson has no experience in designing or conducting a clinical trial on any pharmaceutical product and has never published the results of a clinical trial in a peer-reviewed journal. (Dkt. No. 974-1 at 271, 273, 275). He is "not a regulatory expert" and "not a labeling expert." (Dkt. No. 974-8 at 214). Defendant also notes that Dr. Abramson has "no non-litigation expertise regarding pharmaceutical marketing." (Dkt. No. 974 at 16). Finally, Dr. Abramson also readily admits that he is not an epidemiologist or statistician, but he points to his two-year fellowship for formal training in these areas and states that he has "skills in [these] areas greater than most physicians have." (Dkt. No. 974-1 at 283, 286).

The Court agrees that Dr. Abramson is not a statistician or epidemiologist. However, he does not purport to be. He did not conduct a statistical analysis of the NDA data or the ASCOT data but relied on statisticians in the case who did. (*See, e.g.*, Dkt. No. 974-8 at 42 ("There are

[2] This article "include[d] a misinterpretation of an epidemiological study," and the BMJ subsequently withdrew particular statements in the article about the incidence of side effects. (Dkt. No. 974-1 at 549-550, 552).

statisticians in this case. I trust them as responsible and competent statisticians and I rely upon their analyses of patient-level data."); *id.* at 110 ("I left it to the statisticians.")).

The Court also agrees that a two-year fellowship over 30 years ago, standing alone, does not qualify someone as an expert in a field. However, this is not the sole basis of Dr. Abramson's expertise for comparing scientific data to marketing materials or for opining as to how practicing physicians rely on such information. In addition to his years in family medical practice and as an instructor in primary care, Dr. Abramson has also co-authored papers criticizing the original analyses of clinical trials and re-analyzing data from clinical trials, (Dkt. No. 974-8 at 63-64, 228; Dkt. No. 974-1 at 138), and published a book regarding the ways in which, in Dr. Abramson's opinion, pharmaceutical companies have misrepresented data, including data regarding statins. (Dkt. No. 974-3). Dr. Abramson is not opining on Defendant's marketing in a vacuum but in the context of how it impacts physicians and prescribing decisions and how it compares to scientific data. (*See, e.g.*, Dkt. No. 974-2 at ¶¶ 327, 479).

While Dr. Abramson might not be qualified to conduct a statistical analysis of patient-level data or to design a clinical trial, this Court agrees with others and finds that he does have the expertise to compare scientific data to marketing claims. *See In re DePuy Orthopaedics, Inc. Pinnacle Hip Implant Products Liab. Litig.*, No. 3:11-MD-2244-K, 2014 WL 3557345, at *7 (N.D. Tex. July 18, 2014) ("Dr. Abramson's opinions about DePuy's marketing involve a comparison of DePuy's marketing messages and what he opines the underlying scientific research actually showed. He is more than qualified to make this comparison . . ."); *In re Yasmin & YAZ (Drospirenone) Mktg., Sales Pract. & Prods. Liab. Litig.*, No. 3:09-MD-02100-DRH, 2011 WL 6302287, at *6 (S.D. Ill. Dec. 16, 2011) ("Dr. Abramson's qualifications support his conclusion that his knowledge, skill, experience, training, and education qualify him to testify as

an expert about the marketing of prescription drugs."). His years of experience in primary care, both as a practioner and an instructor, also qualify him to opine on the "sources of information that physicians rely upon," how a practicing physician would interpret published studies, and the types of information that practicing physicians would take into account when making prescribing decisions. (*See* Dkt. No. 974-2 at 13-20).

B. Methodology

Defendant argues that Dr. Abramson fails to employ a recognized methodology. (Dkt. No. 974 at 16). Dr. Abramson describes his methodology as follows: he "examine[s] the data that's available publicly, . . . the data that's in the FDA, . . . the proprietary data, . . . the marketing research, . . . the marketing plans, . . . the marketing programs and the publications to see how they comport with the scientific evidence and whether they represent accurately and reasonably completely the scientific evidence." (Dkt. No. 974-8 at 55-56). Dr. Abramson testifies that he is determining "what actually is the message that's delivered to doctors and patients in the privacy of a doctor's office to make a decision, and how that information that is relied upon reflects the scientific evidence that's available." (*Id.* at 56). In sum, "[w]hat Dr. Abramson did was to review the data and studies and other information available to [defendant] that formed the basis of [defendant's] marketing claims and compare them to the claims actually made to conclude whether such claims were accurate." *In re DePuy*, 2014 WL 3557345 at *7.

Defendant's arguments regarding methodology are directed at "purely scientific testimony," which "is characterized by 'its falsifiability, or refutability, or testability.'" *United States v. Wilson*, 484 F.3d 267, 274 (4th Cir. 2007). However, Dr. Abramson is not conducting a statistical analysis, employing a method of forensic pathology, or otherwise providing such "[p]urely scientific testimony" based on an established scientific method. While Dr. Abramson's

opinions are based in part on scientific knowledge, they are also based in part on experience. Thus, Dr. Abramson must explain how he reached his conclusions, why his experience and scientific knowledge are a sufficient basis for the opinions, and how they are reliably applied to the facts of the case. *Wilson*, 484 F.3d at 274.

Relying on his experience as well as his training and research, Dr. Abramson adequately explained his methodology, the basis of his opinions and how he reached them. As another court has held, "[w]hile the methodology and principles he applies are certainly subject to scrutiny, they have been subjected to peer review and publication and the record does not indicate that the methodology and principles Dr. Abramson relies upon for coming to his conclusions are unreliable." *In re Yasmin & YAZ*, 2011 WL 6302287, at *8 (S.D. Ill. Dec. 16, 2011).

Defendant also argues that Dr. Abramson's testimony presents improper narrative and speculation. (*See* Dkt. No. 974 at 17-20). Under Rule 26, Dr. Abramson was required to explain the facts or data considered by him and to explain the basis and reasons for his opinion. Fed. R. Evid. 26(a)(2). Dr. Abramson will not simply read his Rule 26 report at trial but his opinions will be brought out on direct examination. At trial, the Court has broad discretion "over the mode and order of examining witnesses and presenting evidence" at trial. *See* Fed. R. Evid. 611; *see also United States v. Woods*, 710 F.3d 195, 200 (4th Cir. 2013) ("District courts generally enjoy broad discretion in ruling on the admissibility of evidence, [citation omitted], as well as in the realm of trial management, which is quintessentially the province of the district courts.") (internal quotation omitted). Furthermore, expert narrative testimony is "entirely permissible" in particular circumstances. *In re DePuy*, 2014 WL 3557345 at *7; *accord In re Yasmin & YAZ*, 2011 WL 6302287 at *8 ("[T]he Court . . . may allow testimony in narrative form at trial if the Court finds that it would helpful to the jury.") (collecting cases). However, such questions are

not the province of Rule 702 and *Daubert*.[3] They are issues for the Court to take up in the context of trial. Therefore, the Court reserves ruling on objections to particular statements as improper narrative and speculation until trial.

Finally, Defendant also argues that Dr. Abramson "is an ardent critic and advocate for reform of the pharmaceutical and medical industries," and that his advocacy calls into question his reliability. (Dkt. No. 974 at 21). However, testifying "about matters growing naturally and directly out of research [he has] conducted independent of the litigation" is a factor ***in favor*** of an expert's reliability. *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995) (on remand); *accord Thomas v. City of Chattanooga*, 398 F.3d 426, 431 n.1 (6th Cir. 2005); *Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 886 (10th Cir. 2005); *Lauzon v. Senco Products, Inc.*, 270 F.3d 681, 692 (8th Cir. 2001). Courts are skeptical when experts "develop[] their opinions expressly for purposes of testifying." *Daubert*, 43 F.3d at 1317.

To the extent that Defendant argues Dr. Abramson has a bias against pharmaceutical companies, "it is well-established that an expert's bias is not a proper basis to bar testimony under *Daubert*." *Cage v. City of Chicago*, 979 F. Supp. 2d 787, 827 (N.D. Ill. 2013) (collecting cases); *see also Adams v. Lab. Corp. of Am.*, 760 F.3d 1322, 1332 (11th Cir. 2014) ("Bias in an expert witness's testimony is usually a credibility issue for the jury."); *DiCarlo v. Keller Ladders, Inc.*, 211 F.3d 465, 468 (8th Cir.2000) ("Determining the credibility of a witness is the jury's province, whether the witness is lay or expert, and an expert witness's bias goes to the

[3] Dr. Abramson testifies that he does not intend to offer any opinions about Pfizer's state of mind or the intentions or motivations of any author of any documents. (Dkt. No. 974-8 at 151). The Court will not allow Dr. Abramson to engage in such speculation at trial. *In re Trasylol Products Liab. Litig.*, 709 F. Supp. 2d 1323, 1338 (S.D. Fla. 2010) ("[C]ourts have held that the question of (corporate) intent or motive is a classic jury question and not one for experts.").

weight, not the admissibility of the testimony, and should be brought out on cross-examination.") (citations omitted). Therefore, the Court finds Dr. Abramson's methodology acceptable under Rule 702.

C. Opinions Regarding the NDA Data

Dr. Abramson relies "heavily" on Dr. Jewell's statistical analysis of the NDA data for his opinions regarding the NDA data. (Dkt. No. 974-1 at 161; *see also id.* at 146; Dkt. No. 974-8 at 42, 110). Dr. Abramson also testifies that he would change his opinion "[i]f it turns out that there are parts of Dr. Jewell's analyses that are found to be flawed." (Dkt. No. 974-8 at 112). By separate order, the Court has excluded Dr. Jewell's analysis of the NDA data as unreliable. (CMO 54, Dkt. No. 1258; CMO 67, Dkt. No. 1412). Therefore, Dr. Abramson's testimony based on this analysis is unreliable and must be excluded under Rule 702. *See United States v. Nacchio*, 555 F.3d 1234, 1241 (10th Cir. 2009) ("Under *Daubert*, any step that renders the expert's analysis unreliable . . . renders the expert's testimony inadmissible.") (internal quotations omitted); *accord Paz v. Brush Engineered Materials, Inc.*, 555 F.3d 383, 388 (5th Cir. 2009); *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1245 (11th Cir. 2005); *Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 267 (2d Cir. 2002).

D. Opinions Regarding Pfizer's "Obligations," "Duties," and the Acts of "Responsible Drug Manufacturers"

In portions of his report, Dr. Abramson opines about Pfizer's "obligations," "duties," and the acts of "responsible drug manufacturers." For example, Dr. Abramson opines that "[w]ith [regulators] able to monitor only a small fraction of drug marketing and promotional activities, the responsibility of drug makers to stay within the boundaries of permissible marketing and promotion is heightened," (Dkt. No. 974-2 at ¶ 50), and that "Pfizer's knowledge of the

significant worsening of glycemic control in the PROVE-IT 22 substudy created an ***obligation*** to make this finding known to physicians and patients . . ." (*Id.* at ¶ 103 (emphasis added). Such testimony is not based on any particular legal standard, (*see* Dkt. No. 974-1 at 78), and Dr. Abramson has not articulated ***any*** standard or guidelines for stating what a corporation's "obligations" or "duties" are. (*See generally* Dkt. No. 974-2). Thus, there is no apparent basis for these statements other than Dr. Abramson's personal opinion.

Such opinions could confuse the jury and usurp its role. To the extent that Dr. Abramson intends to opine about the corporation's legal duties and obligations, it would usurp the role of the Court to instruct on the law and the jury's role to apply the facts to the law. *See Nutley v. River Falls Mach. Sales, Inc.*, No. 09-CV-215-JHP, 2011 WL 11573074, at *1 (E.D. Okla. June 30, 2011) (excluding expert testimony that "would infringe upon the role of the court at trial to instruct the jury on the law"); *Shoemake v. Rental Serv. Corp.*, No. CIVA106CV426HSOJMR, 2008 WL 215824, at *1 (S.D. Miss. Jan. 22, 2008) ("It is the Court's duty to instruct the jury on Defendant's obligations and duties under the law, and the jury's role to determine whether Defendant has violated a legal duty."); *Arredondo v. Flores*, No. CIV.A. L-05-191, 2007 WL 4563419, at *1 (S.D. Tex. Feb. 15, 2007) ("Expert testimony regarding the interpretation of law would usurp the role of the Court."). Furthermore, he lacks expertise in the field of a corporation's legal duties. (*See* Dkt. No. 974-8 at 214 (admitting he is not a regulatory expert)).

To the extent that Dr. Abramson is simply espousing his personal opinion, the Court excludes such testimony under Rule 403. When such opinions are not based on any particular standard, opinions that Defendant had a "duty" or "obligation" to take a specific action has the potential to mislead or confuse the jury and lead the jury to believe that such statements are based on legal duty. Furthermore, the probative value of such statements is minimal, if it exists

at all. When such an opinion "is not based on any standard," it "amounts to no more than Dr. [Abramson's] personal opinion," which requires no specialized knowledge or expertise. *In re Trasylol Products Liab. Litig.*, 709 F. Supp. 2d 1323, 1338 (S.D. Fla. 2010). Therefore, the Court excludes such opinions under Rule 403.

The Court's holding is a narrow one. Dr. Abramson may opine on whether particular marketing materials are misleading and may opine as to whether physicians would want to know certain information in making prescribing decisions. He may not, however, opine that Defendant has a "duty" or "obligation" to take specific action.

IV. Conclusion

Pfizer's Motion to Exclude Testimony of John Abramson, M.D., (Dkt. No. 974), is **GRANTED IN PART AND DENIED IN PART**. Dr. Abramson's opinions regarding the NDA data is **EXCLUDED** under Rule 702. Dr. Abramson may not opine that Defendant has a "duty" or "obligation" to take specific action; such testimony is **EXCLUDED** under Rule 403. The motion is otherwise **DENIED**.

AND IT IS SO ORDERED.

Richard Mark Gergel
United States District Court Judge

May 6, 2016
Charleston, South Carolina