THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

JAMES MACK, et al.,	*	
Plaintiffs,	*	Civil Action No.: RDB-08-688
v.	*	
AMERISOURCEBERGEN DRUG CORPORATION, et al.,	*	
Defendants.	*	

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MEMORANDUM OPINION

Plaintiffs James and Sylvia Mack, on behalf of their daughter Crystal Mack, have brought the instant products liability suit against Defendants AmerisourceBergen Drug Corporation, Centocor, Inc., and Johnson & Johnson, Inc. (collectively, "Defendants"). Plaintiffs claim that Crystal Mack died after suffering from a cardiac arrhythmia that was caused by her use of Remicade, a medication that is manufactured by Centocor, a subsidiary of Johnson & Johnson, and distributed by AmerisourceBergen.

On May 27, 2009, Defendants filed a Motion for Summary Judgment (Paper No. 50) and a Motion in Limine to Exclude the Testimony of James T. O'Donnell, Dr. Donald H. Marks and Dr. William L. Manion (Paper No. 51). On August 20, 2009, a motions hearing was conducted and this Court partially granted Defendants' Motion in Limine by ruling to exclude the testimony of James T. O'Donnell. On September 15, 2009 a hearing was conducted pursuant to *Daubert v. Merrell Dow Pharmacies, Inc.*, 509 U.S. 579 (1993) concerning the testimony of Dr. Donald H. Marks. After considering the testimony at the hearing and the parties' submissions, this Court rules that Defendants' Motion in Limine to Exclude the Testimony Dr. Donald H. Marks (Paper

No. 51) is DENIED IN PART insofar as the testimony of Dr. Donald H. Marks is deemed admissible.

I. Analysis

Donald M. Marks, M.D., Ph.D., submitted an expert opinion on behalf of the Plaintiffs, in which he has expressed his opinion that Crystal Mack suffered a cardiac arrest and that Remicade caused or contributed to her death. Defendants now move this Court to exclude Dr. Marks' testimony on the basis that it does not comport with the standards for admissibility set forth in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993) and Federal Rule of Evidence 702.

A. Legal Standard for the Admission of Expert Testimony

Federal Rule of Evidence 702, which governs the admissibility of expert testimony, provides that

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702. Trial judges are entrusted with the duty of serving as "gatekeeper" and must "conduct a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (quoting *Daubert*, 509 U.S. at 592-93).

In *Daubert*, the United States Supreme Court prescribed a non-exclusive list of factors that may guide a lower court in weighing the reliability of expert testimony. These factors are

"(1) whether a theory or technique can be or has been tested; (2) whether the theory has been subjected to peer review and publication; (3) whether a technique has a high known or potential rate of error; (4) whether there are standards controlling the technique's operation; and (5) whether the theory or technique enjoys general acceptance within a relevant scientific community." *Holmes v. Wing Enterprises, Inc.*, No. 08-822, 2009 U.S. Dist. LEXIS 53108, at *8 (E.D. Va. June 23, 2009). Courts have also considered additional factors, such as "'whether the expertise was developed for litigation or naturally flowed from the expert's research; whether the proposed expert ruled out other alternative explanations; and whether the proposed expert sufficiently connected the proposed testimony with the facts of the case.'" *Rolwes v. Centocor, Inc.*, No. 4:03-cv-151, 2004 U.S. Dist. LEXIS 30752, at *8 (E.D. Mo. Apr. 15, 2004) (quoting *Lauzon v. Senco Prods., Inc.*, 270 F.3d 681, 686 (8th Cir. 2001)).

The admissibility of an expert's testimony must be established by a preponderance of the evidence. *See Daubert*, 509 U.S. at 592 n.10. Under this standard, the proponent "must present reliable, probative, and substantial evidence of such sufficient quality and quantity that a reasonable [judge] could conclude that the existence of the facts supporting the claim are more probable than their nonexistence." *United States Steel Mining Co., Inc. v. Dir., Office of Workers' Comp. Programs*, 187 F.3d 384, 389 (4th Cir. 1999).

Rule 702 was intended to liberalize the admission of relevant expert evidence. *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999). The Rule "favors admissibility if the testimony will assist the trier of fact . . . [and] [d]oubt regarding whether an expert's testimony will be useful should generally be resolved in favor of admissibility." *Rolwes*, 2004 U.S. Dist. LEXIS 30752, at *6. Nevertheless, because expert witnesses have the potential to "be both powerful and quite misleading," *Daubert*, 509 U.S. at 595 (internal quotation marks omitted),

court should exclude "any proffered evidence that has a greater potential to mislead than to enlighten." *Westberry,* 178 F.3d at 261.

B. Dr. Marks' Qualifications

As an initial matter, this Court finds that Dr. Marks has the requisite education, training and experience to qualify as an expert in the present case. Dr. Marks has earned both a doctorate in microbiology and a medical degree. He is a board-certified practitioner in the field of internal medicine, and he currently serves as the Director of the Hepatitis Clinic at Cooper Green Hospital in Birmingham, Alabama. He has significant experience in the pharmaceutical industry, including work as the Director of Clinical Research at Connaught Pasteur Merieu (currently Sanofi Pasteur), and as the Associate Director of Clinical Research at Hoffmann-La Roche. His experience with the Food and Drug Administration includes the creation and presentation of annual reports and protocol presentations for institutions such as the National Institute of Health and the National Cancer Institute. He has performed outside inspections on Investigational New Drug Applications (IND's) and New Drug Applications (NDA's) for corporate partners. Finally, he has written numerous peer-reviewed articles in the field of clinical toxicology, medical causation, and drug safety. Although he has never prescribed Remicade, he has clinical familiarity with the drug. Dr. Marks' clinic gives weekly infusions of Remicade and he is responsible for handling any adverse effects resulting from its administration. Dr. Marks states that he is familiar with Remicade's adverse effects profile and with the class of drugs in which Remicade belongs.

C. Dr. Marks' Methodology

Defendants challenge the methodology underlying Dr. Marks' expert opinion on several grounds. First they claim that Dr. Marks has pointed to no proof of general causation, "an

essential prerequisite to proving specific causation." *Foster v. Legal Sea Foods, Inc.*, 2008 WL 2945561 (D. Md. July 25, 2008). Second, they contend that he has not reliably grounded his opinion as to specific causation due to flaws in his differential diagnosis. Finally, Defendants claim that Dr. Marks was merely a "mouthpiece" for plaintiffs' counsel, as his testimony was largely shaped by Plaintiffs' counsel.

1. Dr. Marks' Opinion as to General Causation

In support of his opinion on general causation, Dr. Marks cited a 2008 article summarizing a study led by Pietro Enea Lazzerini, entitled "Arrhythmic risk during acute infusion on infliximab: a prospective, single-blind, placebo-controlled, crossover study in patients with chronic arthritis." This placebo-controlled study evaluated the presence of cardiac rhythm disorders in patients with chronic arthritis during acute infusions of Remicade. The study found that patients receiving Remicade experienced an 8% incidence of new-onset ventricular tachyarrhythmias, in contrast to the patients receiving the placebo, who only experienced a 2.7% incidence of arrhythmias. The study also found that the Remicade patients with arrhythmias experienced more severe symptoms than their counterparts that received the placebo.

Dr. Marks opined that the Lazzerini study evidenced a link between Remicade and the occurrence of arrhythmias, although he acknowledged that its findings were not statistically significant because the study did not concern a large enough sample size. He added that while Crystal Mack did not exhibit any clinical signs of an arrhythmia at infusion, she did experience palpitations, which can be indicative of an arrhythmia. (Marks Dep. 116:5-9.) Finally, he noted that Centocor and Johnson & Johnson had convened a review meeting of its Cardiovascular Safety Group in order to consider the results of the Lazzerini study and that the companies would

be conducting further analyses concerning the relationship between Remicade and cardiac events.

Dr. Marks also discussed the findings of case reports and letters to the editor that evidenced a link between cardiac events and Remicade. Because they are not peer-reviewed articles, these case reports are of limited evidentiary significance. Nevertheless, combined with the results of the Lazzerini study, this Court finds that Dr. Marks' opinion as to general causation is based upon a sufficient evidentiary basis.

2. Dr. Marks' Opinion as to Specific Causation

In reaching his opinion that Remicade caused or contributed to the death of Crystal Mack, Dr. Marks employed a differential diagnosis, which is defined as "a standard scientific technique of identifying the cause of a medical problem by eliminating the likely causes until the most probable one is isolated." *Westberry*, 178 F.3d at 262 (citing *Baker v. Dalkon Shield Claimants Trust*, 156 F.3d 248, 252-53 (1st Cir. 1998)). It is well-established that an expert opinion on causation may be based upon a differential diagnosis. *See Westberry*, 178 F.3d at 263 (noting that the "overwhelming majority of courts of appeals . . . have held that a medical opinion on causation based upon a reliable differential diagnosis is sufficiently valid").

Defendants challenge the reliability of Dr. Marks' differential diagnosis that relates to his opinion on specific causation. Towards this end, they first contend that Remicade was not in Crystal Mack's body at the time of her death. Defendants claim that "it takes five half-lives for the active ingredients of a medicine to be eliminated from a patient's body." Defs.' Mot. in Limine at 27. However, Dr. Marks testified that Defendants' calculation was inapplicable to cases involving antibodies, which exhibit two half lives. (Marks Dep. 42:8-17.) He added that further complications may affect the half-lives of antibodies such that they could still be present

in the body up to eight weeks after infusion. (Marks Dep. at 44:1-13.) Based upon these facts, and an internal memo produced by Defendants stating that biological agents such as Remicade can be toxic at low levels, Dr. Marks concluded that Remicade was still in Crystal Mack's body at the time of her death in an amount that was potentially dangerous.

Defendants also contend that Dr. Marks did not sufficiently rule out alternative explanations for arrhythmia. As a result of his differential diagnosis, Dr. Marks ruled out pulmonary embolism, massive intestinal hemorrhage, congestive heart failure, anemia and electrolyte imbalances as potential causes of death. While Dr. Marks did not rule out all of the alternative explanations for Crystal Mack's arrhythmia, it is clear that "'[a] medical expert's causation conclusion should not be excluded because he or she has failed to rule out every possible alternative cause of a plaintiff's illness.'" *Westberry*, 178 F.3d at 265 (quoting *Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 156 (3d Cir. 1999)). Consequently, the admissibility of Dr. Marks' testimony is not affected by the existence of alternative causes or any other claimed defects concerning his differential diagnosis. Instead these matters implicate only the weight of his testimony and they may be explored by Defendants through cross-examination. *See Westberry*, 178 F.3d at 265 (citing *McCullock v. H.B. Fuller Co.*, 61 F.3d 1038, 1044 (2d Cir. 1995)).

3. Dr. Marks as a "Mouthpiece" for Plaintiffs' Counsel

Dr. Marks admitted that the content of his expert report was mostly drafted by Plaintiffs' counsel and that counsel selected the supporting exhibits. Plaintiffs counter that Dr. Marks still played an important role in the drafting process by providing edits and feedback concerning the report's conclusions. However, the degree of attention and care that Dr. Marks applied in developing the report appears to be minimal. Indeed, Dr. Marks testified that he actually

disagreed with a section in the report entitled "Medical Necessity Not Established," but that he did not catch the error when he initially reviewed counsel's draft. He admitted that he typically prepares the entirety of his expert reports, and that this was the first time that he had testified in a *Daubert* hearing after submitting a report mostly drafted by counsel.[1]

This Court has previously held that "it is not improper for an attorney to assist a retained expert in developing opinion testimony for trial." *Musselman v. Philips*, 176 F.R.D. 194, 201 (D. Md. 1997). *See also Elm Grove Coal Co. v. Dir., Office of Workers' Comp. Programs*, 480 F.3d 278, 301 n.23 (4th Cir. 2007) ("The fact that a lawyer has participated in the preparation of his testifying expert's report does not bar the use of the expert's opinion, or necessarily even impeach the expert's reliability."). Nevertheless, even when it is deemed admissible, expert testimony that has been influenced by a hiring attorney is often afforded less deference by a fact-finder. *See, e.g.*, *Musselman*, 176 F.R.D. at 200 ("[T]he fact that an attorney has interjected him or herself into the process by which a testifying expert forms the opinions to be testified to at trial affects the weight which the expert's testimony deserves."); *Occulto v. Adamar of New Jersey*, 125 F.R.D. 611, 616 (D.N.J. 1989) ("[A]n expert who can be shown to have adopted the attorney's opinion as his own stands less tall before the jury than an expert who has engaged in painstaking inquiry and analysis before arriving at an opinion.").

Opposing attorneys rely upon cross-examination to expose the influence that a hiring attorney has upon an expert's testimony. *See Elm Grove Coal Co.*, 480 F.3d at 301 n.23 ("The interplay between testifying experts and the lawyers who retained them . . . [is] fair game for cross-examination."). Their efforts are aided by Federal Rule of Civil Procedure 26, which requires expert witnesses to disclose their opinions and "the data or other information considered

[1] In response to this Court's questions, Dr. Marks stated that in approximately ninety-eight percent of the cases in which he has been hired as an expert he has personally drafted his expert reports.

by the witness in forming the opinions." Fed. R. Civ. P. 26(a)(2)(B). Even attorney work product that is provided to and considered by an expert witness is discoverable. *Musselman*, 176 F.R.D. at 202. Thus cross-examination is the principle means of ensuring that the truth finding process at trial is preserved in the present circumstances—that is, when an attorney plays a proactive role in shaping an expert's testimony. *See, e.g.*, *id.* at 201; *Lamonds v. General Motors Corp.*, 180 F.R.D. 302, 306 (W.D. Va. 1998) (noting that even where an expert is qualified under *Daubert*, "[i]t can be important for the trier of fact to know whether the expert arrived at his opinions after an independent review of all relevant facts or whether he relied on 'facts' chosen and presented by an attorney advocating a particular position"); *Karn v. Rand*, 168 F.R.D. 633, 639 (N.D. Ind. 1996) ("[T]he impact of expert witnesses on modern-day litigation cannot be overstated; yet, to some, they are nothing more than willing musical instruments upon which manipulative counsel can play whatever tune desired . . . Thus, full, effective cross examination is critical to the integrity of the truth-finding process." (citations omitted)).

In this case, the record reflects that plaintiffs' counsel substantially shaped the content of Dr. Marks' expert opinion. While this influence does not undermine the admissibility of his testimony, it may undermine its weight and credibility—matters that may be revealed by Defendants through cross-examination.

CONCLUSION

For the foregoing reasons, Defendants' Motion in Limine to Exclude the Testimony of Dr. Donald H. Marks (Paper No. 51) is DENIED IN PART insofar as the testimony of Dr. Donald H. Marks is deemed admissible. A separate Order follows.

Dated: September 29, 2009

/s/
Richard D. Bennett
United States District Judge