NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, Plaintiff, v. BAYER CORPORATION, Defendant.	Civil Action No. 07-01(JLL) **OPINION**

LINARES, District Judge**.**

This matter comes before the Court on a motion by Plaintiff to exclude expert testimony and two motions by Defendant to exclude expert testimony. The Court has considered the parties' submissions and decides this matter without oral argument pursuant to Federal Rule of Civil Procedure 78. For the reasons set forth below, Plaintiff's motion and Defendant's motions are denied.

I. FACTS AND PROCEDURAL HISTORY

Defendant Bayer Corporation ("Bayer") manufactures and sells a variety of products, including vitamins, dietary supplements, and over-the-counter and prescription drugs. Compl. ¶¶ 4-5, ECF No. 1. Bayer HealthCare, LLC, is a subsidiary of Bayer Corporation, and markets and sells One-A-Day brand vitamins and supplements, including One-A-Day WeightSmart, a multivitamin and dietary supplement. *Id.* ¶ 9. Between 2003 and 2007, Bayer advertised its One-A-Day WeightSmart product through television commercials, print advertisements in magazines, and on the Internet. *Id.* ¶ 10.

On January 3, 2007, the Government filed a complaint against Defendant Bayer Corporation, asserting that Bayer improperly advertised and represented its One-A-Day WeightSmart vitamin. Compl. ¶ 12, ECF No. 1. The Government asserted that Bayer made claims regarding the product's benefits, performance, and efficacy "without possessing and relying upon competent and reliable scientific evidence to substantiate the representations." *Id.*

The parties agreed to settle without adjudication of the merits of any issue of fact or law. Seeking to avoid litigation, Defendant agreed to pay a monetary civil penalty of three million, two hundred thousand dollars ($3,200,000). Consent Decree §I.A, ECF No. 2. Bayer was permanently enjoined from ever violating any provision of the Order and from making representations that any of its products:

> [I]ncreases metabolism; enhances metabolism through its . . . content; helps prevent some of the weight gain associated with a decline in metabolism in users over age 30; helps users control their weight by enhancing their metabolism; makes a material contribution to any program or system that promotes weight maintenance; can or will cure, treat, or prevent any disease; or have any effect on the structure or function of the human body.

Consent Decree §III.A-B, ECF No. 2. Bayer was also enjoined from making any general representation regarding the benefits, performance, efficacy, safety or side effects of such product without possessing and relying upon competent and reliable scientific evidence to substantiate the representation. *Id.* Competent and reliable scientific evidence comprises of "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results." *Id.* at 2. This Consent Decree was entered as the final order on January 3, 2007. *Id.* at 10.

In 2008, Bayer began an extensive campaign to advertise for a new probiotic supplement called Phillips' Colon Health (PCH). Def.'s Br. 8. The Food and Drug Administration (FDA) was

notified of each of Bayer's label claims for PCH. *Id.* In 2011, the Federal Trade Commission (FTC) began investigating Bayer's advertising campaign for PCH to ensure that Bayer was in compliance with section VII.B of this Court's 2007 Order, found at the end of the Consent Decree. Consent Decree §VII.B, ECF No. 2 [hereinafter Consent Decree] ("Within thirty (30) days after receipt of a written request by a representative of the Commission, defendant Bayer Corporation . . . shall submit written reports . . . and produce documents with respect to any conduct subject to this Consent Decree."). The primary focus of the Commission's investigation was "Bayer's constipation, diarrhea, and gas and bloating claims; Bayer's purported substantiation for these claims; and product sales." Pl.'s Br. 3. In 2011 and 2012, Bayer disclosed documents, cover letters, and revenue information "as purported evidence for advertising claims relating to constipation, diarrhea, and gas and bloating." *Id.* After the disclosure of these documents, cover letters, and revenue information, the FTC transferred the case to the U.S. Department of Justice for enforcement. Def.'s Br. 8. On September 12, 2014, the Government filed a Motion for an Order to Show Cause as to why Bayer Corporation should not be held in contempt for violating the Consent Decree. *Id.*

On February 27, 2015, Plaintiff moved to exclude the expert testimony of Dr. Andrew Benson, a geneticist and microbiologist, proffered by Defendant in opposition to Plaintiff's Motion for an Order to Show Cause why Defendant should not be held in contempt. On March 30, 2015, Defendant filed motions to exclude the expert testimony of Dr. Loren Laine, a gastroenterologist, and Dr. Frederic Bushman, a microbiologist, who have both been proffered by Plaintiff in support of its Motion for an Order to Show Cause why Defendant should not be held in contempt.

II. LEGAL STANDARD

Rule 702 of the Federal Rules of Evidence governs the admissibility of expert testimony. Rule 702 allows a witness qualified as an expert to give testimony if the expert's scientific, technical or specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue if: (i) the testimony is based upon sufficient facts or data, (ii) the testimony is the product of reliable principles and methods, and (iii) the expert witness has applied the principles and methods reliably to the facts of the case. Fed. R. Evid. 702. The United States Court of Appeals for the Third Circuit has explained that Rule 702 "embodies a trilogy of restrictions on expert testimony: qualification, reliability, and fit." *Schneider v. Fried*, 320 F.3d 396, 404 (3d Cir.2003) (citing *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 741–43 (3d Cir.1994)).

The district court is required to act as a gatekeeper, preventing the admission of opinion testimony that does not meet these three requirements. *Id.* (citing *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 592 (1993)). The proponent of the evidence bears the burden of establishing the existence of each factor by a preponderance of the evidence. *Daubert*, 509 U.S. at 592; In re Paoli, 35 F.3d at 743–44. A court's rejection of expert testimony should be the exception rather than the rule. Fed. R. Evid. 702 Advisory Committee Note. As the United States Supreme Court noted in *Daubert*, "vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." 509 U.S. at 595.

An expert's opinion is reliable if it is "based on the 'methods and procedures of science' rather than on 'subjective belief or unsupported speculation'; the expert must have 'good grounds' for his or her belief." *Calhoun v. Yamaha Motor Corp., U.S.A.*, 350 F.3d 316, 321 (3d Cir. 2003) (quoting *Daubert*, 509 U.S. at 589). "*Daubert* suggests several factors that a district court should

take into account in evaluating whether a particular scientific methodology is reliable[.]" *In re Paoli*, 35 F.3d at 742. The factors that *Daubert* and this Court have already declared important include:

> (1) whether a method consists of a testable hypothesis; (2) whether the method has been subject to peer review; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique's operation; (5) whether the method is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the methodology; and (8) the non-judicial uses to which the method has been put.

Id. at 742 n. 8 (citing *United States v. Downing*, 753 F.2d 1224, 1238–41 (3d Cir. 1985)).

The Supreme Court in *Kumho Tire*, however, clearly indicated that this list is non-exclusive and that each factor need not be applied in every case. The Court further explained that:

> [T]he trial judge must have considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable. That is to say, a trial court should consider the specific factors identified in Daubert where they are reasonable measures of the reliability of expert testimony.

Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 152 (1999); *see also Milanowicz v. The Raymond Corp.*, 148 F.Supp.2d 525, 536 (D.N.J.2001) (reconfiguring *Daubert* for application to "technical" or "other specialized" subjects such as engineering and identifying several factors for trial courts to consider in evaluating reliability, including relevant literature, evidence of industry practice, and product design and accident history). As such, "[t]he inquiry envisioned by Rule 702 is ... a flexible one." *Daubert*, 509 U.S. at 594.

III. DISCUSSION

A. Plaintiff's *Daubert* Motion

1. Dr. Andrew Benson

Dr. Andrew Benson is Defendant's proffered expert and is a geneticist and microbiologist. Dr. Benson "has studied the human gut microbiome for nearly two decades. He currently leads the University of Nebraska Gut Function Initiative, an internationally recognized, federally-funded research program in comparative and population genomics of bacterial species." Def. Br. at 2. According to Defendant, Dr. Benson has proffered two opinions: "(1) geneticists and microbiologists do not require randomized, controlled, double-blind, product-specific, population-specific, human clinical trials; and (2) the species of bacteria in Phillips' Colon Health contain a shared genetic core that helps with the digestive symptoms at issue." *Id.* at 1.

Plaintiff argues that this Court should preclude Defendant's expert from testifying at trial, claiming that Defendant's expert does not satisfy the standards required by *Daubert*. Specifically, Plaintiff maintains that: (1) Dr. Benson's ultimate opinion is based on insufficient facts; (2) Dr. Benson's testimony is unreliable; and (3) Dr. Benson's proffered testimony ventures far from his area of expertise. Defendant counters that: (1) Plaintiff has failed to challenge Dr. Benson's actual opinions; (2) Plaintiff applies the incorrect legal standard for excluding testimony; and (3) Dr. Benson is well within his area of expertise, and he is not required to perform the tests for which he testifies about.

Plaintiff has failed to convince this Court that Dr. Benson's opinions are unreliable, are based on insufficient facts or venture far from his area of expertise, as they are based on widely accepted scientific methods and procedures. *See Altana Pharma AG v. Teva Pharms. USA, Inc.*, 2013 U.S. Dist. LEXIS 74211 at *8 (2013) ("The proponent of expert testimony need not prove

that its expert is correct, but that the expert's 'opinion is based on valid reasoning and a reliable methodology'") (citing *Oddi v. Ford Motor Co.*, 234 F.3d 136, 145 (3d Cir. 2000)). Indeed, not only does Dr. Benson have extensive experience working as a microbiologist and geneticist, he used peer-reviewed articles, his own peer-reviewed publications, many randomized controlled trials on a variety of digestive health end points," "several well-conducted meta-analyses," and "the recent consensus scientific report in the prestigious journal *Nature Reviews Gastroenterology*" in utilizing his methodology and conducting his analysis. Plaintiff also fails to demonstrate how Dr. Benson neglected to apply the principles and methods reliably to the facts of this case. Plaintiff's criticisms of Dr. Benson's methodology, and the reliability, relevancy and "certainty" of his opinions, are, at their core, targeted to weight and credibility, not admissibility. That is, Plaintiff opposes Dr. Benson's factual conclusions, not his credentials or methods. *See Oddi*, 234 F.3d at 145–46 ("The test of admissibility is not whether a particular scientific opinion has the best foundation or is demonstrably correct. Rather, the test is whether the particular opinion is based on valid reasoning and reliable methodology."). The alleged weaknesses of Dr. Benson's opinions are best left to consideration by this Court once Dr. Benson has been cross-examined at the show cause hearing. *Kannankeril v. Terminix International, Inc.*, 128 F.3d 802, 806 (3d Cir. 1997) ("The analysis of the conclusions themselves is for the trier of fact when the expert is subjected to cross-examination.").

Accordingly, the Court finds that Dr. Benson's testimony meets the requirements of Fed. R. Evid. 702.

A. Defendant's *Daubert* Motions

1. Dr. Loren Laine

Dr. Loren Laine is a gastroenterologist "with over 25 years of experience in clinical research and clinical practice." Pl. Opp'n Br. at 2. He currently is a Professor of Medicine and Director of Clinical Research at the Yale University School of Medicine in the Section of Digestive Diseases. Dr. Laine maintains a clinical practice, providing care to patients at the Yale-affiliated V.A. Connecticut Healthcare System. He is the immediate past Chair of the American Gastroenterological Association. Prior to joining Yale, he was a Professor of Medicine and Associate Chair of the Department of Medicine at the University of Southern California School of Medicine, as well as Chief of the Section of Gastroenterology. He also served as Chief of Staff at the L.A. County & U.S.C. Healthcare Network. Currently, he serves on the Scientific Advisory Board for the AGA's Center for Gut Microbiome Research and Education. Dr. Laine has authored over 200 articles which were published in peer-reviewed journals. He has also served as an Associate Editor on at least two major gastroenterology journals, as well as on a major gastroenterology textbook. He opines that "a product- and population-specific [randomized, controlled, human clinical trial] is required to substantiate Bayer's specific claims." Pl. Opp'n Br. at 7.

Defendant argues that Dr. Laine's testimony should be precluded under *Daubert* because: (1) Dr. Laine is not an expert in probiotics; (2) Dr. Laine's testimony cannot assist the trier of fact because it is inconsistent with federal law; and (3) Dr. Laine's testimony should be excluded because his declarations contradict one another.

Plaintiff maintains that Dr. Laine is an expert in his field and his opinion is well founded in the facts of the case and in his own experience. Plaintiff also contends that "his testimony will

assist the Court in assessing whether Bayer did, in fact, possess and rely upon competent and reliable scientific evidence since 2008 when making specific claims that PCH is efficacious specifically for constipation, diarrhea, and gas and bloating." Pl. Opp'n Br. at 3.

Defendant neglects to articulate why Dr. Laine's testimony does not meet the flexible standards set forth in *Daubert*. *Daubert*, 509 U.S. at 594 ("the inquiry envisioned by Rule 702 is ... a flexible one ... the focus must be solely on principles and methodology, not on the conclusions they generate"). While Defendant argues that the Government's expert should be excluded in this case because he is not an expert in probiotics, the Court finds that this is not a case simply about probiotics and as such, Dr. Laine is not required to be a probiotics expert to be useful to the Court. This case is about whether Bayer was in possession of "competent and reliable scientific evidence" to substantiate its claims about PCH. The issue to be decided by this Court is whether Defendant possessed or relied upon "competent and reliable scientific evidence" to support its claims that PCH "defends against occasional constipation, diarrhea, and gas and bloating, or that [PCH] prevents, cures or treats those symptoms." Clearly, a gastroenterologist with extensive experience in testing the effectiveness of proposed treatments for gastrointestinal issues has an expertise in an area relevant and useful to the Court's determination.

The Court is similarly unpersuaded by Defendant's other arguments. An expert opinion need only be reliable; there is no requirement that it be consistent with federal law. Fed. R. Evid. 702. Nonetheless, it is clear that in forming his opinion, Dr. Laine defined the scope of the legal standard set forth in the 2007 Order. Finally, Defendant's argument regarding contradictions in Dr. Laine's testimony is classic impeachment material and not an appropriate challenge under *Daubert*. *Daubert*, 509 U.S. at 595 ("vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means

of attacking shaky but admissible evidence"). Any alleged deficiencies or contradictions in Dr. Laine's testimony is best left to the Court's determination as to the appropriate weight to be afforded Dr. Laine's opinion upon cross-examination at the show cause hearing.

Defendant has failed to provide any sufficient reason why this Court should exclude Dr. Laine's testimony. Therefore, this Court finds that Dr. Laine's expert opinion meets the requirements of Fed. R. Evid. 702.

2. Dr. Frederic Bushman

Dr. Frederic Bushman received his "Ph.D. in cellular and developmental biology from Harvard University in 1988 and has been a Professor of Microbiology at the Perelman School of Medicine at the University of Pennsylvania since 2003." Pl. Opp'n Br. at 3. He is a member of the American Academy of Microbiology and the American Association for the Advancement of Science, as well as the co-director of the Microbiome Program of the University of Pennsylvania and Children's Hospital of Philadelphia. *Id.* Currently, his research includes "host/microbe interactions, with specific projects focusing on the human microbiome, HIV pathogenesis, and human gene therapy." *Id.* Dr. Bushman has also published over 235 scientific papers and two books in the fields of microbiology and microbial genetics. *Id.* at 4. He has also "performed extensive studies monitoring the presence of [B]ifidobacteria and [L]actobacillus in gut bacterial communities by taking stool samples and determining the presence of different kinds of bacteria based on DNA sequencing, including such monitoring to evaluate the effects of diet in healthy people, and performed a similar analysis of stool samples of macaques who had been administered a probiotic intervention." *Id.* After considering the documents Bayer provided to the FTC, reading extensive scientific literature on the relevant issues and considering some of the papers relied upon by Defendant's expert, "Dr. Bushman concluded that Bayer lacked competent and reliable

scientific evidence for the specific claims at issue, and that Bayer's 'core genome' hypothesis was unfounded." *Id.* at 5.

Defendant argues that Dr. Bushman's testimony should be precluded under *Daubert* because: (1) he lacks expertise or experience in any area the government might claim is relevant to the dispute; (2) he does not apply the legal standard in the consent decree and the FTC's guidance; and (3) his declaration and testimony are not credible on their face. Specifically, Defendant notes that there are multiple inconsistencies between Dr. Bushman's declaration, and his deposition testimony.

Plaintiff contends that Dr. Bushman's opinion concerns matters within his area of expertise, is reliable and will assist this Court in evaluating Bayer's response to the order to show cause. Plaintiff further argues that Dr. Bushman's scientific opinion based on the facts of this case does not require legal knowledge. Finally, Plaintiff maintains that witness credibility is not a basis for exclusion of testimony.

For the same reasons stated above with respect to Dr. Laine, Defendant's motion to exclude Dr. Bushman's testimony must also be denied. Dr. Bushman, possessing a Ph.D. in cellular and developmental biology, as well as extensive knowledge, skill and experience, meets the requirements for providing expert testimony in the relevant field of microbiology and microbial genetics. In addition, Dr. Bushman's opinion is not a legal opinion because that is not what is required of an expert. Rather, he has provided an expert, scientific opinion tailored to the facts of this case after consideration of the appropriate legal standard in this case, *i.e.*, what is "competent and reliable scientific evidence." Furthermore, Defendant's attempt to exclude Dr. Bushman's testimony on the basis of credibility is equally unavailing as credibility is not a basis for excluding

an expert who otherwise meets the requirements of Fed. R. Evid.702. Accordingly, this Court finds that Dr. Bushman's testimony meets the requirements of Fed. R. Evid. 702.

IV. CONCLUSION

For the reasons set forth above, Plaintiff's motion and Defendant's motions to exclude expert testimony are denied. An appropriate Order accompanies this Opinion.

DATED: April 29, 2015

s/ Jose L. Linares
JOSE L. LINARES
U.S. DISTRICT JUDGE