

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

In re: FLONASE ANTITRUST LITIGATION	:	CIVIL ACTION
	:	
	:	No. 08-3149
	:	No. 08-3301
	:	No. 09-1638
THIS DOCUMENT RELATES TO:	:	
All Actions	:	

July 23, 2012

Anita B. Brody, J.

MEMORANDUM

I. Background

Direct and Indirect Purchasers of a steroid nasal spray containing the active ingredient fluticasone propionate (“FP”), along with Roxane Laboratories, Inc. (“Roxane”), a generic FP manufacturer, have brought actions against Defendant SmithKline Beecham Corporation, doing business as GlaxoSmithKline PLC (“GSK”), the manufacturer of the branded version of FP (“Flonase”), alleging various violations arising from GSK’s conduct delaying market entry of generic FP. In its defense, GSK asserts, *inter alia*, that its conduct—particularly the filing of citizen petitions with the Federal Drug Administration (“FDA”) regarding issues related to Roxane’s Abbreviated New Drug Application (“ANDA”)—is protected from antitrust liability under the First Amendment and the *Noerr-Pennington* doctrine, and, additionally, is not the actual cause of generic delay into the market.¹

¹A more detailed discussion of the parties’ arguments, and applicable legal standards, regarding causation and *Noerr-Pennington* is provided in my opinions denying GSK’s motions

Under the *Noerr-Pennington* doctrine, a party that exercises its First Amendment right to “petition[] the government for redress generally is immune from antitrust liability.” *Cheminor Drugs, Ltd v. Ethyl Corp.*, 168 F.3d 119, 122 (3d Cir. 1999) (citing *E. R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961); *United Mine Workers of Am. v. Pennington*, 381 U.S. 657 (1965)). However, one exception to the *Noerr-Pennington* doctrine is when the conduct “is a mere sham to cover . . . an attempt to interfere directly with the business relationships of a competitor” *Noerr*, 365 U.S. at 144. The Supreme Court has established a two-pronged test to determine whether a party’s conduct is a sham and therefore not entitled to *Noerr-Pennington* immunity. See *Prof’l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.* [hereinafter “*PRE*”], 508 U.S. 49 (1993). Under the first prong, known as the objective prong, plaintiffs must show that “a reasonable petitioner could not realistically expect that the petition will succeed on its merits.” *In re Flonase Antitrust Litig.*, 795 F. Supp. 2d 300, 311 (E.D. Pa. 2011) (citing *Cheminor*, 168 F.3d at 122–23; *Bryant v. Military Dep’t of Miss.*, 597 F.3d 678, 693 (5th Cir. 2010)). The second prong, labeled the subjective prong, is only reached if the challenged conduct is deemed objectively meritless. It requires the court to examine the defendant’s “subjective motivation” to determine if the conduct “conceals ‘an attempt to interfere directly with the business . . . of a competitor.’” *PRE*, 508 U.S. at 60–61 (quoting *Noerr*, 365 U.S. at 144).

The parties in these three related actions have retained numerous experts to opine on issues relating to liability, including the *Noerr-Pennington* doctrine and causation, as well as

for summary judgment on these grounds. See *In re Flonase Antitrust Litig.*, 795 F. Supp. 2d 300 (E.D. Pa. 2011) (*Noerr-Pennington*); *In re Flonase Antitrust Litig.*, 798 F. Supp. 2d 619 (E.D. Pa. 2011) (causation).

damages. In 2010, the parties filed several motions to exclude the reports and testimony of certain expert witnesses. In June 2011, I denied without prejudice all those motions that did not relate to Indirect Purchaser Plaintiffs' ("Indirect Purchasers") then-pending motion for class certification. In early 2012, the parties re-filed their respective motions to exclude, but then subsequently withdrew the majority of the motions by stipulation.

Before me now are two motions to exclude the reports and testimony of expert witnesses: (1) GSK's Motion to Exclude in Part the Expert Report and Testimony of Leslie Benet and (2) Plaintiffs' Motion to Exclude the Proposed Expert Testimony of Mary Pendergast. These experts are proffered to opine on, *inter alia*, issues related to the objective prong of *PRE* test (i.e., whether a reasonable petitioner could realistically expect that GSK's citizen petitions will succeed on its merits) and causation. Pursuant to the Supreme Court's decisions in Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993) and Kumho Tire Co. v. Carmichael, 526 U.S. 137 (1997), a hearing was held on April 18 and 19, 2012 to determine whether the testimony of Benet and Pendergast is admissible under Federal Rules of Evidence 702 and 703.² For the reasons set forth below, I will deny both of these motions.

II. Legal Standard for Expert Testimony

The party offering an expert must demonstrate, by a preponderance of the evidence, that the expert's qualifications and opinions comply with Federal Rule of Evidence 702. *See Daubert*, 509 U.S. at 592-93 (citation omitted). Rule 702 provides:

²Plaintiffs' expert Rochelle Kimmel also testified during these hearings. However, all plaintiffs later withdrew their designation of Kimmel as an expert in these actions. Therefore, her testimony will not be discussed in this Memorandum, and, in the accompanying Order, I deny GSK's motion to exclude her report and testimony as moot.

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. Rule 702 has “a liberal policy of admissibility.” *Pineda v. Ford Motor Co.*, 520 F.3d 237, 243 (3d Cir. 2008) (citation omitted).

The Third Circuit has explained that to survive a *Daubert* challenge, an expert must satisfy three “restrictions on expert testimony: qualification, reliability, and fit.” *Schneider ex rel. Estate of Schneider v. Fried*, 320 F.3d 396, 404 (3d Cir. 2003) (citations omitted). The qualification inquiry examines whether a witness possesses specialized expertise. The Third Circuit “has interpreted this requirement liberally, holding that a broad range of knowledge, skills, and training qualify an expert.” *Id.* (citing *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 742 (3d Cir. 1994)).

For an expert’s testimony to be reliable, it “must be based on [] methods and procedures . . . rather than subjective belief or speculation.” *In re TMI Litig.*, 193 F.3d 613, 670 (3d Cir. 1999). “[T]he admissibility inquiry thus focuses on principles and methodology, not on the conclusions generated by principles and methodology.” *Id.* at 665. Furthermore, an “expert's testimony must be accompanied by a sufficient factual foundation before it can be submitted to the jury.” *Elcock v. Kmart Corp.*, 233 F.3d 734, 754 (3d Cir. 2000) (citation omitted).

Finally, Rule 702 requires that the expert testimony fit the issues in the case. Testimony “fits” a case when it is “relevant for the purposes of the case and . . . assist[s] the trier of fact.” *Schneider*, 320 F.3d at 404.

III. Discussion

A. Plaintiffs' Expert Leslie Benet

At trial, Plaintiffs intend to introduce the expert testimony of Dr. Leslie Benet, a professor of bioengineering and therapeutic sciences at the University of California at San Francisco in the Schools of Pharmacy and Medicine for the last forty-three years. Benet has also worked as a consultant to numerous generic and brand drug manufacturers and been a member of several FDA advisory committees. *See* Expert Report of Leslie Benet, May 11, 2010 (“Benet Report”) ¶¶ 1-7; *Daubert* Hr’g Tr. 16, April 19, 2012 (“Benet Hr’g Tr.”). Benet is proffered to opine generally on bioequivalence issues and specifically as to the merits of GSK’s citizens petitions. Benet Report ¶ 10.

At the hearing on April 19, 2012, Roxane³ withdrew those portions of Benet’s report and testimony that related to causation and GSK’s intent in filing the citizen petitions. *See* Benet Hr’g Tr. 9. As a result, the parties acknowledged, at the hearing and in subsequent supplemental briefing, that they had reached an agreement on the admissibility or lack of admissibility of nearly all of Benet’s report and testimony. The lone outstanding dispute concerns Benet’s opinion, found in paragraphs 42 to 48 of his expert report, on GSK’s knowledge, awareness, or understanding regarding whether a final guidance from the FDA needed to be issued prior to approval of an Abbreviated New Drug Application (“ANDA”) for generic FP.

Benet opines, *inter alia*, on the merits of GSK’s request to the FDA, in its May 2004

³While Indirect Purchasers joined Roxane’s opposition to GSK’s motion against Benet, at the hearing Direct Purchaser Plaintiffs (“Direct Purchasers”) stated that they took no position on GSK’s motion. *See* Benet Hr’g Trs. 5-7, 67. Roxane was the only plaintiff to file a post-hearing brief opposing GSK’s motion. Therefore, for purposes of brevity, I will only refer to Roxane in the section of this opinion addressing GSK’s motion against Benet.

citizen petition, that a final guidance document be issued before any approval of an ANDA for generic FP. Specifically, he states in his expert report: “It is well understood by participants in the pharmaceutical industry that the FDA may approve an ANDA prior to the issuance of a final guidance, and that the FDA is not precluded from approving ANDAs merely because it has issued a draft guidance that relates to a proposed drug product.” Benet Report ¶ 41. Benet further opined that “there was no reasonable basis to believe that the FDA would grant GSK’s request that it refrain from approving ANDAs for fluticasone propionate pending issuance of a final guidance document relating to nasal suspension products.” *Id.* ¶ 51.

Benet explained that the information forming the basis of this opinion is his “significant experience with both brand name companies and generic companies,” his academic knowledge, and his understanding of applying and utilizing FDA guidance documents. Benet Hr’g Tr. 25. As an additional basis for his opinion, and the subject of the instant dispute, Benet performed a review of certain GSK internal documents produced in this litigation to demonstrate that GSK’s knowledge, awareness, and understanding regarding FDA practice in approving ANDAs with or without final guidance was consistent with his opinion. *See* Benet Report ¶¶ 42-48. For example, Benet cites to a report by a consulting firm retained by GSK that noted that the FDA “routinely approves ANDAs before final Guidances are published” *Id.* ¶ 45. As another example, Benet opines that “GSK further understood that because it used the draft guidances to develop its own products that FDA would expect an ANDA sponsor to use the same draft guidance in developing its products,” and cites to GSK internal documents as support. *Id.* ¶ 46.

Benet, however, has offered differing explanations for how his review of GSK internal documents, in paragraphs 42-48 of his report, fits with his opinion about the reasonableness of

GSK's FDA final guidance request. When asked about this fit at his deposition, Benet stated:

[I]t's just to support my contention that GSK was well aware that this argument that they're making would not be approved and was not what FDA would – the procedures that FDA would follow, both from their own experience and their own products and from general knowledge.

Benet Dep. 155:13-18, June 11, 2010; *see also* Benet H'rg Tr. 31 (“[These are] documents confirming that at least some individuals within GSK held the same opinion that I did, [and] that there was no basis for believing that this final guidance would be necessary before products were approved.”).

At the *Daubert* hearing, Benet explained what he meant by GSK's “awareness” as follows:

[A]ll I'm saying is aware means that there's information that is available to the company in terms of that final guidances are not necessary for approval of an ANDA. And this is well known within the pharmaceutical industry.

Benet Hr'g Tr. 39. Similarly, when he opines that “GSK understood” that the FDA could, and often did, approve ANDAs without a final guidance document, Benet stated that he used “understood” to mean “that there's information that's available within the company that is not secret, and there's a number of individuals [in the company] that understand[] this.” *Id.* at 40; *see also id.* at 41 (stating that when saying “GSK knew” something, he meant “[t]here's information within the company, at high levels within the company, related to Regulatory Affairs with the FDA, [and] that this is information that is consistent with my position” on GSK's final guidance request).

In seeking to exclude Benet's opinion—using GSK internal documents—on GSK's knowledge or awareness regarding FDA practice in approving ANDAs without final guidance,

GSK makes two arguments: (1) this opinion is irrelevant to the jury's inquiry on whether the petition is entitled to *Noerr-Pennington* immunity, and (2) Benet's interpretation of GSK's state of mind via GSK's internal documents is not appropriate expert testimony. In response, Roxane contends that: (1) Benet's opinion is relevant to the objective prong of the *PRE* test, and (2) Benet does not opine on GSK's state of mind, but on information and knowledge available to GSK.

The objective prong of the *PRE* test requires plaintiffs to show that "a reasonable petitioner could not realistically expect that the petition will succeed on its merits." *In re Flonase Antitrust Litig.*, 795 F. Supp. 2d 300, 311 (E.D. Pa. 2011) (citations omitted). "If an objective [party] could conclude that the [petition] is reasonably calculated to elicit a favorable outcome, the [petition] is immunized under *Noerr*, and an antitrust claim premised on the sham exception must fail." *Id.* (citing *PRE*, 508 U.S. at 60).

Both parties offer competing definitions of, or least limitations for, the "reasonable petitioner." GSK contends that a reasonable petitioner's knowledge or understanding cannot include GSK's knowledge or understanding, which, instead, is more appropriately directed toward the subjective prong of the *PRE* test.⁴ Roxane, meanwhile, claims that "whether a reasonable petitioner in GSK's situation would have expected success on the merits is circumscribed by what information and knowledge was available to GSK." Roxane's Post-Hr'g Mem. 2. It further asserts that "[w]hat other pharmaceutical companies knew at the time is not

⁴During the course of this litigation, I have explained that expert testimony on GSK's intent in filing its citizen petitions would be inadmissible. *See, e.g.*, Tr. of Telephone Conference 6, 9-10, April 12, 2012; *see also In re Diet Drugs Prods. Liab. Litig.*, MDL No. 1203, 2000 WL 876900, at *9 (E.D. Pa. June 20, 2000) ("[T]he question of intent is a classic jury question and not one for experts.").

relevant to the [objective prong] inquiry,” but that GSK’s knowledge and available information “at the time is crucial to an understanding of whether a reasonable petitioner in GSK’s shoes would have had a reasonable expectation of success on the merits.” *Id.* at 4 n.3.

The information and knowledge available and possessed by GSK at the time of its filing the citizen petitions can be relevant to the determination of the objective prong, not because GSK is the defendant in this matter, but because GSK is an active and important player in the pharmaceutical industry. GSK’s knowledge and understanding can inform an opinion as to the state of knowledge in the pharmaceutical industry as a whole, which is relevant in determining whether a reasonable petitioner could realistically expect that GSK’s citizen petitions will succeed on their merits. In that same light, though, what other pharmaceutical companies knew at the time of GSK’s petitioning activity is also relevant to the objective prong inquiry. Therefore, Roxane’s argument is also flawed, as it attempts to narrow the “reasonable petitioner” standard to such a degree that it merges with the subjective prong inquiry.

As such, Benet will be permitted to opine, relying on internal GSK documents, on the information that was available to GSK regarding FDA practice and policy for approving ANDAs without final guidance documents, as set forth in paragraphs 42 - 48 of his report.⁵ To the extent that GSK disagrees with Benet’s opinion on GSK’s knowledge and awareness to show the state of knowledge in the pharmaceutical industry, the appropriate method for challenging such

⁵GSK argues that Benet’s use of GSK internal documents is inappropriate expert testimony because the jury will be fully capable of reading and comprehending the documents themselves. Although the jury can certainly read the documents for themselves, Benet’s opinions, utilizing the documents, will be helpful to the jury in assessing whether a reasonable petitioner would realistically expect that GSK citizen petitions would succeed on their merits. This is so especially considering Benet’s qualifications and the complexities surrounding the ANDA approval and citizen petition response processes at the FDA.

testimony is through cross-examination or the introduction of its own expert testimony.

GSK argues that this opinion will be Benet's interpretation of GSK's "state of mind" and, therefore, is inappropriate expert testimony. Benet's testimony in his report does not speak to the intent, motive, or state of mind of GSK in filing its citizen petitions. I understand GSK's concern, however, given Benet's statement at his deposition regarding his use of these GSK internal documents: "[I]t's just to support my contention that GSK was well aware that this argument that they're making would not be approved." Benet Dep. 155:13-18. Such a statement goes beyond opining on the information and knowledge available to a key entity in the pharmaceutical industry (GSK) regarding the necessity of final guidances prior to ANDA approval, and instead evidence by which GSK's state of mind in filing the May 2004 citizen petition may be inferred. This is impermissible, and should Benet offer such testimony at trial, GSK can object at that time. *See In re Rosuvastatin Calcium Patent Litig.*, No. 07-805, 2009 WL 4800702, at *8 (D. Del. Dec. 11, 2009) ("Generally, expert witnesses are not permitted to testify regarding 'intent, motive, or state of mind, or evidence by which such state of mind may be inferred'") (citing *Oxford Gene Tech., Ltd. v. Mergen, Ltd.*, 345 F. Supp. 2d 431, 443 (D. Del. 2004)); *In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 547 (S.D.N.Y. 2004) ("Inferences about the intent or motive of parties or others lie outside the bounds of expert testimony.")⁶

B. GSK's Expert Mary Pendergast

GSK proffers Mary Pendergast, an expert in the field of pharmaceutical regulation, to opine on three issues: (1) "the merit, from a FDA regulatory perspective, of the issues raised" in GSK's citizen petitions; (2) "the date on which FDA was prepared to approve" Roxane's generic

⁶Instructions to the jury to clarify this may be necessary.

FP for marketing; and (3) “the effect, if any” of the citizen petitions and supplements filed by GSK and two law firms on behalf of two generic manufacturers⁷ “on the consideration and timing of approval by FDA of Roxane’s ANDA for fluticasone.” Expert Report of Mary K. Pendergast, August 13, 2010 (“Pendergast Report”) 3.

In forming her opinions, Pendergast relied on the citizen petitions filed by GSK and two generic drug manufacturers, and the comments and supplements to those petitions; FDA’s response to the petitions; documents produced in discovery by several generic companies seeking approval for generic FP; FDA statutes, regulations, and regulatory documents; deposition transcripts; documents produced by FDA in discovery; and certain publicly available documents. Pendergast Report 3. In addition, she relied on her professional background, which I briefly review below.

As for her background, Pendergast has worked in the field of pharmaceutical regulation for over thirty years. Pendergast Rep. 1. From 1979 to 1997, she worked for the FDA. *Id.* at 1-2; Decl. of Mary K. Pendergast, December 9, 2010 (“Pendergast Decl.”) ¶ 3. During her first eleven years at the FDA, she worked at the FDA’s Office of General Counsel, where she was an Associate Chief Counsel for Enforcement. Pendergast Report 1. In that capacity, Pendergast became familiar with the Drug Price Competition and Patent Term Restoration Act of 1984 (the “Hatch-Waxman Amendments”), as she was part of a small team that reviewed the legislation while pending in Congress, interpreted the law for the FDA, and examined FDA statements

⁷Specifically, the petitions filed by the law firm Bell Boyd & Lloyd on behalf of the generic drug manufacturer, Watson Pharmaceuticals, Inc. on May 1, 2004, and by the law firm Frommer Lawrence & Haug LLP on behalf of the generic drug manufacturer, Dey, L.P. on July 26, 2004 (including the June 16, 2005 supplement). *See* Expert Report of Mary K. Pendergast, August 13, 2010, 3.

about the law. *Id.*; *see also Daubert* Hr’g Tr. 11, April 18, 2012 (“Pendergast Hr’g Tr.”). She also assisted in the development of regulations, guidance documents, litigation, and FDA interpretations pertaining to the Hatch-Waxman Amendments. Pendergast Rep. 1; Pendergast Hr’g Tr. 12-13. During this process, Pendergast supported the Office of Generic Drugs (“OGD”)⁸ in developing ANDA regulations and guidance documents—for example, establishing the similarities and differences between ANDAs and New Drug Applications. Pendergast Hr’g Tr. 13.

In 1988 and 1989, while in the Office of General Counsel, Pendergast was part of a “cleanup” team that addressed significant problems at the OGD, as certain employees were benefitting some generic drug companies in the timing and substance of their ANDA reviews. Pendergast Hr’g Tr. 14. During this process, she assisted OGD—both senior management and the substantive experts in the various fields (i.e., bioequivalence, chemistry)—in developing policies, practices, procedures, and standards to prevent such behavior from occurring again. *Id.* at 14-15. Specifically, for example, her team developed systems and standards to help ANDA reviewers manage their large workloads by creating an amendment system that helped differentiate ANDA amendments that could be addressed immediately from those that would require placing an applicant “to the back of the line for consideration.” *Id.* at 15-16; *see also* Pendergast Decl. ¶ 3(c).

From 1990 to 1997, Pendergast was the Deputy Commissioner of the FDA, the most senior, non-political official within FDA. Pendergast Report 1. In this capacity, she “provided

⁸The OGD is a department within the Center for Drug Evaluation and Research (“CDER”) at the FDA. Pendergast Decl. ¶ 3(c). It is responsible for evaluating and approving ANDAs. *Id.*

leadership across [FDA] on a wide variety of issues, including issues pertaining to generic drugs. . . .” *Id.* at 1. During this time, she continued to work with OGD to ensure that fair procedures were in place to review ANDAs. *Id.*; Pendergast Decl. ¶ 4(a).

Pendergast was also involved with citizen petitions while at the FDA. At the hearing on April 18, 2012, she explained that, while she was there, “the Office of General Counsel, generally speaking, quarter-backed the citizen[] petitions.”⁹ Pendergast Hr’g Tr. 19. The lawyers and general counsel would work with the substantive experts around FDA to develop a proper answer to a petition, i.e. whether it required a substantive answer, a simple one-sentence answer (for petitions with little merit), or no action at all. *Id.* at 20. During this time she “authored what was later adopted as the [FDA’s] standard 180-day response letter to citizen petitions.” Pendergast Decl. ¶ 3(b). She further explained that she has been involved with “dozens, if not more,” citizens petition responses. Pendergast Hr’g Tr. 20.

Initially, Pendergast noted, “FDA tried to treat every citizen petition in the same way and give it all the same amount of time and energy.” *Id.* To conserve agency resources, she worked with others at the FDA to develop “a way of thinking through citizen petitions and a way of answering some of them briefly or abruptly where it didn’t obligate the agency to spend any time on the citizen petition.” *Id.* at 20-21. When asked how the importance of a citizen petition was determined, Pendergast explained:

It’s measured by the agency’s mission, and by its policies and practices and what it

⁹Presently, the Office of Regulatory Policy (“ORP”) is the department within CDER that is generally responsible for preparing answers to citizen petitions. Pendergast explained that the ORP did not exist during the time she worked in the Office of General Counsel; as a result, she “served in . . . multiple different roles,” including being involved with citizen petition responses. Pendergast Hr’g Tr. 150.

needed to do, what it needed to think about when it was working on something . . . when the citizen petition came in and it was important and relevant to a decision that the FDA had to make, that was substantively relevant, and that it was something that the agency needed to grapple with to make a decision, it got a lot of attention.

When it was something within the agency's purview that [] was of less public health importance, or it was something that really wasn't gonna be important for another 10 or 20 years, then we gave it much more short shrift and just said thank you, we don't have the resources to deal with it, or some other short answer.

Id. at 21-22. During her time as Deputy Commissioner, a citizen petition backlog occurred, and she worked on a policy to help the citizen petition system operate more effectively. *Id.* at 23; Pendergast Decl. ¶ 4(b).

From 1997 to 2003, Pendergast worked for Elan Pharmaceuticals as the Executive Vice President for Government Affairs. Pendergast Report 2. In this position, she worked on generic drug issues, "as well as on the applications for the approval of new drugs for several diseases." *Id.* at 2. She continued to intermittently deal with the FDA, for instance, "when an Elan [generic drug] application was stuck . . . at the Office of Generic Drugs because of some scientific or policy question." Pendergast Hr'g Tr. 24. Since 2003, Pendergast has operated as an individual consultant and written citizen petitions, as well as comments on other citizen petitions, for various clients. Pendergast Report 2; Pendergast Decl. ¶ 1.

Direct Purchasers¹⁰ seek to exclude Pendergast's report and testimony, both as to the

¹⁰Direct Purchasers and Roxane re-filed motions to exclude Pendergast's report and testimony in January 2012. Indirect Purchasers re-filed their motion for joinder and adoption of Direct Purchasers' motion at the same time.

At the April 18, 2012 hearing, counsel for Direct Purchasers cross-examined Pendergast and represented Roxane and Indirect Purchasers in so doing. *See* Pendergast Hr'g Tr. 83. In addition, only Direct Purchasers filed a post-hearing brief in support of the motion against Pendergast. Therefore, for purposes of brevity, I will only refer to Direct Purchasers in the section of this opinion addressing Plaintiffs' motions against Pendergast.

merit of GSK’s citizen petitions from a regulatory perspective—which relates to the objective prong of the *PRE* test—and as to the effect of GSK’s citizen petitions on Roxane’s ANDA approval—which relates to causation.

1. Opinions Relating to the Objective Prong of the *PRE* Test

Direct Purchasers contend that Pendergast’s testimony on the merits of GSK’s citizen petitions should be excluded on the following grounds: (1) her opinion that GSK’s citizen petitions have “regulatory merit” and are “appropriate” will not assist, but instead confuse, the jury in assessing the objective prong of the *PRE* test; and (2) she is unqualified to use language suggesting a statement of scientific merit, and such suggestive language will confuse the jury. I will address each of these arguments in turn.

i. *Relevance of “Appropriate” and “Regulatory Merit” Opinions to Objective Prong of PRE*

GSK intends to introduce Pendergast at trial to opine on the merits of GSK’s citizen petitions from a regulatory perspective. In her report and testimony, Pendergast opines generally that the issues raised in GSK’s citizen petitions, from an FDA policy and regulatory perspective, are “appropriate” and have “regulatory merit.” *See, e.g.*, Pendergast Report 4 (“GSK’s May and November Citizen Petitions had regulatory merit and were an appropriate use of the Citizen Petition process . . .”). Much of the parties’ dispute regarding Pendergast’s testimony and report centers on the definition, and effect, of these words.

At the April 19, 2012 hearing, Pendergast explained her meaning of “appropriate”:

Appropriate . . . means anything that is properly considered in the citizen’s petition, in a citizen’s petition so it’s got to be within the FDA’s jurisdiction. [The petitions are not] used to ask the FDA to take specific enforcement action, but [they are] within the regulatory framework [of the FDA].

Pendergast Hr'g Tr. 153. At her deposition, she explained that “appropriate,” in the context of a citizen petition, means that the subject matter was “well within the ballpark of the kinds of things that the Citizen Petition process should be used for.” Pendergast Dep. 48:2-5, September 22, 2010. She also explained that “appropriate” could mean that a petition raises questions “that may be of interest to the FDA” and addresses matters “that could benefit from FDA consideration.” *Id.* at 44:22-25.

By comparison, Pendergast testified at the hearing that in opining on the citizen petitions, her use of the word “appropriate” evoked a “broader” concept than the words “regulatory merit.” Pendergast H'rg Tr. 152-3. She explained that by “regulatory merit” she meant:

What I'm saying is that . . . it's a question that was raised by GSK that is relevant because the FDA has to make a regulatory decision. It's relevant to that decision. It's necessary for the FDA to resolve the matter before it makes a decision, and that the FDA should come to a conclusion on that [question].

Id. During cross-examination, she explained the term further: “When I said that a position had regulatory merit, that is a summary way of saying that it was quite possible, in fact more than possible, a qualitatively good idea for the FDA to accept that petition – accept that position when it was reviewing ANDAs.” *Id.* at 107; *see also id.* at 106 (“What I was trying to convey when I said things had regulatory merit was that it was a position that the FDA could well have adopted.”).

Direct Purchasers assert that Pendergast’s opinion that the petitions were “appropriate” and possessed “regulatory merit” eviscerates the legal standard under *PRE*, will not assist the trier of fact in assessing the objective prong of *PRE*, and will confuse the jury. To buttress these assertions, Direct Purchasers claim that Pendergast’s entire opinion “amounts to nothing more

than a statement that the issues raised in the petition[s] are the kind of matters covered by an ANDA review and are within the purview of the FDA.” Direct Purchasers’ Post-Hr’g Mem. 3. As a result, “Pendergast opines that petitions have ‘regulatory merit’ and are entitled to [*Noerr-Pennington*] immunity regardless of whether they meet the standard set by *PRE*, i.e. regardless of whether the petitioner was likely to succeed on the merits.” *Id.* at 5.

Although Pendergast's labeling the petitions "appropriate"—or within the FDA's jurisdiction—is of little assistance in establishing whether the petitions were likely to succeed on the merits, at trial, Pendergast will be permitted to explain that the petitions were "within the FDA's jurisdiction," or raised topics properly considered in the citizen petition process, as a predicate to the rest of her opinions on each citizen petition. I am concerned, though, that Pendergast's labeling the citizen petitions "appropriate," considering her definition(s) of the word, could confuse the jury in its consideration of the *PRE* objective test. As such, she will not be permitted to use this word to describe the citizen petitions at trial.

Direct Purchasers Plaintiffs mischaracterize the remaining scope of Pendergast’s opinion by conflating her definitions of “appropriate” and “regulatory merit.” The scope of Pendergast’s opinion, as Plaintiffs even concede, goes beyond simply opining that the petitions raised issues within the FDA’s purview. *See, e.g.*, Direct Purchasers Post-H’rg Mem. 9-10 (quoting testimony from Pendergast calling the questions raised in GSK’s citizen petitions “serious,” “substantive,” and “important for the FDA to consider”). For example, in discussing GSK’s November 2004 Petition, Pendergast stated in her report: “In my judgment, GSK’s request for FDA to impose equivalent quality standards [for brand and generic drugs] was meritorious, and FDA should have granted that part of GSK’s Citizen Petition, since it actually followed GSK’s request and required

Roxane to set manufacturing quality specifications on [droplet size distribution] and [spray pattern].”). At the April 18 hearing, Pendergast explained that, in using the term “regulatory merit”, she meant that GSK’s citizen petitions asserted policy positions which “the FDA could well have adopted.” Pendergast Hr’g Tr. 106. Pendergast also opines that GSK’s citizen petitions actually influenced the FDA’s ANDA standards. *See* Pendergast Rep. at 29 (“[T]he Citizen Petitions caused FDA to consider, and then change, its standards for approval of fluticasone nasal spray generics.”); *id.* at 43 (“GSK’s November Citizen Petition changed OGD’s behavior [and GSK got some of the relief it requested]).¹¹

As such, I do not think her opinion as to the “regulatory merit” of GSK’s petitions is entirely divorced from the objective prong determination of *PRE*, i.e. whether a reasonable petitioner could realistically expect a petition to succeed on its merits. In detailing the parameters of *Noerr-Pennington* immunity, the *PRE* Court explained that the sham exception did not apply to “a valid effort to influence government action.” *PRE*, 508 U.S. at 58 (citing *Allied Tube & Conduit Corp v. Indian Head, Inc.*, 486 U.S. 492, 500 n.4 (1988)); *see also In re Wellbutrin XL Antitrust Litig.*, No. 08-2431, 2012 WL 1657734, at *25 (E.D. Pa. May 11, 2012) (“*PRE* does not define success in the context of a citizen petition, but it does state that the petition must be calculated to ‘elicit’ a favorable outcome or to ‘influence’ government action.”) (citing *PRE*, 508 U.S. at 58, 60). Policy considerations, therefore, are not irrelevant in assessing the applicability of the *Noerr-Pennington* doctrine. *See In re Gabapentin Patent Litig.*, 649 F. Supp. 2d 340, 360-61 (D. N.J. 2009) (“The *Noerr-Pennington* doctrine protects activities by

¹¹I recognize that plaintiffs dispute Pendergast’s characterization of the requests made in GSK’s citizen petitions. However, what the petitions were requesting is a question of fact that the parties will have to establish, and the jury will have to decide, at trial.

parties to influence government *policy* or legislation from antitrust claims.” (emphasis added) (citations omitted)); *see also In re Prograf Antitrust Litig.*, No. 11-md-2242, 2012 WL 293850, at (D. Mass. Feb. 1, 2012) (same).

The petitions at issue were addressed and responded to by the FDA, a regulatory body. FDA decisions are informed not only by science, but also by FDA policy, procedure, and practice. Therefore, as even Plaintiffs have noted, the objective prong determination can be informed by predicate factual questions *beyond* just the strength and weaknesses of GSK’s scientific positions in its petitions. Direct Purchasers’ Memorandum in Support of Their Mot. to Exclude the Proposed Expert Testimony of Def’s. Expert Mary K. Pendergast 11 (“The predicate factual questions are whether an objective filer, knowing the applicable *law and regulations* of ANDA approvals, *FDA practices*, and the objective strengths and weaknesses of the scientific preconditions for ANDA approval urged by GSK, could conclude that the petitions . . . were calculated to elicit a favorable outcome for GSK”) (emphasis added).

Pendergast’s background underscores this reality. As a lawyer in the Office of General Counsel, she was involved in reviewing and responding to numerous citizen petitions, as well as developing systems and standards to more efficiently respond to citizen petitions based on their importance to FDA policy and practice. *See generally* Pendergast Hr’g Tr. 19-22. Relying on her substantial FDA and related experience, Pendergast opines on how the FDA grappled with certain policy questions raised in GSK’s petitions and was, in certain instances, subsequently influenced by these positions. Such regulatory policy and practice cannot simply be ignored in the consideration of whether an objective party could conclude that GSK’s citizen petitions were reasonably calculated to elicit a favorable outcome.

Therefore, I find that Pendergast’s testimony on the merit of GSK’s citizen petitions in the context of FDA regulatory policy and practice is relevant and helpful to the trier of fact in assessing the objective prong of the *PRE* test.¹² Whether it is as relevant as GSK claims—which plaintiffs strongly dispute—is not a question to decide in the context of a *Daubert* motion.¹³

ii. *Unqualified to Address Scientific Positions in GSK’s Citizen Petitions*

Direct Purchasers have continually asserted that Pendergast is unqualified to opine on the scientific positions set forth in GSK’s citizen petitions. Neither GSK nor Pendergast dispute this assertion. *See, e.g.*, Pendergast Hr’g Tr. 90-91, 98, 105 (acknowledging that she is not holding herself out as an expert in biostatistics, bioequivalence standards, or *in vivo* studies that assess

¹²It should be noted that another federal district court, in addressing a post-trial motion for judgement as a matter of law, found that sufficient evidence existed to support a jury verdict that a citizen petition filed with the FDA was not objectively baseless under *PRE*. *See La. Wholesale Drug Co., Inc. v. Sanofi-Aventis*, No. 07-cv-7343, 2009 WL 2708110 (S.D.N.Y. Aug. 28, 2009). In so finding, the court repeatedly cited to the testimony of Pendergast, who opined on the issues raised in a citizen petition considering FDA policy, practice, and regulations. *Id.* at *5. Although plaintiff in that case did not lodge a *Daubert* challenge to Pendergast, the ruling in *Louisiana Wholesale* provides additional support for my finding Pendergast’s report and testimony relevant to the objective prong of *PRE*.

¹³In the alternative, Direct Purchasers argue that because of Pendergast’s using the term “regulatory merit,” the jury will confuse her opinions with the objective standard under *PRE*. However, Pendergast’s opinion should not be excluded simply because she used one word—merit—that is also located in a legal standard. Plaintiffs’ own expert, James Morrison, has used the word “merit” in his own opinions. *See, e.g.*, Morrison Dep. 106:15-25, July 1, 2010 (stating, regarding one of GSK’s citizen petitions, that it had “no merit, meaning that it doesn’t even wildly pertain to anything that would possibly be related to a review”). Pendergast explained at the hearing that by “regulatory merit” she meant that GSK’s citizen petitions asserted policy positions which “the FDA could well have adopted” and which were “qualitatively good idea[s] for the FDA to accept.” Pendergast Hr’g Tr. 106-7. The best route for Plaintiffs to rectify any confusion—between “regulatory merit” and “succeed on the merits”—is through cross-examination at trial.

bioequivalence); Pendergast Dep. 52:16-53:11 (“I do not give an opinion as to whether or not one scientific standard or another scientific standard should be adopted by the FDA.”). Direct Purchasers claim that, despite these admissions, “Pendergast opines about the merits of GSK’s positions that require a scientific understanding or technical knowledge that she does not possess.” Direct Purchasers’ Post-Hr’g Mem. 8. As an example, they cite to the following exchange during the hearing on April 19:

Q: Okay. And what overall opinion did you reach as to the May petition?

A: My overall conclusion was that it was a good citizen’s petition that had regulatory merit, which means that it was raising questions that the FDA had to consider that were substantive and that should be addressed by the agency.

Q: And was your opinion that that would be the view of the agency or that would be just sort of your view?

A: No, I was putting myself in the shoes of the agency. Because the citizen petition is going to the agency before the agency has to make a decision. So if you focus on it from the agency’s point of view, was it important for the FDA to consider these issues, think about them, and come to a conclusion before it took the step of approving products.

Id. at 9 (citing Pendergast Hr’g Tr. 54).

Direct Purchasers argue that opining that the petitions asked questions that “the FDA had to consider,” were “important for the FDA to consider,” and were “serious” or “substantive” requires an understanding of the scientific merit of GSK’s positions. Direct Purchasers’ position is unfounded for two reasons. First, to formulate this position, they again misconstrue the scope of Pendergast’s opinion. *See* Direct Purchasers’ Post-Hr’g Mem. 9 (“Pendergast’s opinion that the petition asked ‘questions the FDA had to consider’ . . . or were ‘serious’ . . . go well beyond her opinion that the topic of GSK’s requests were within the FDA’s jurisdiction.”); *supra* Section III.B.1.i (discussing how Direct Purchasers mistakenly conflate Pendergast’s definition of “appropriate” and “regulatory merit” in an attempt to confine the scope of her opinion).

Second, Pendergast's use of words like "important," "substantive," "good," or "serious" does not automatically transform her opinion into a scientific one. Pendergast has consistently acknowledged that she is not opining on the *scientific* merits of GSK's citizen petitions. *See, e.g.,* Pendergast Dep. at 53:17-21 ("I am not giving an opinion, for example, take this case, whether or not the right scientific standard for the statistical analysis of in vitro studies is population bioequivalence or geometric mean."); Pendergast Hr'g Tr. 108 ("I'm not qualified to talk about the science. I'm only qualified to talk about the regulatory process and procedure that is part and parcel of FDA coming to a scientific conclusion."). Pendergast distinguished her regulatory, policy-focused opinion from a scientific opinion during her deposition:

I do not give an opinion as to whether or not one scientific standard or another scientific standard should be adopted by the FDA. That's not . . . something I'm doing. I'm only addressing the question of whether . . . there should be a scientific standard and whether the scientific standard should be addressed before [ANDAs] are assessed. That's what I'm discussing. So it's not science per se. It is the manner and timing of asking the question about the science.

Pendergast Dep. 52:22-53:11. In its post-hearing brief, GSK points to several different opinions of Pendergast's to further highlight this distinction. For example, in examining GSK's request in its May 2004 citizen petition that generic ANDAs include data for the most difficult to treat condition Pendergast opines that GSK's request was consistent with prior FDA *policy* based on her review of previous citizen petitions and the FDA's response to GSK's citizen petition. Pendergast Rep. 35-36, 73-75. As another example, Pendergast opined that GSK's citizen petitions raised "important" questions for the FDA because, based on her experience with citizen petitions, the FDA rarely issues such a lengthy response to the petitions (twenty-four single-spaced pages) signed by the Associate Commissioner for Policy and Planning (instead of the

Director of CDER) unless “it’s important to the [FDA].” Pendergast Hr’g Tr. 57-59. Neither of these opinions, based on her review of previous FDA policy statements and her knowledge of FDA practices and regulations, requires Pendergast to opine on the merits of the scientific issues raised in the petitions.

I am satisfied that Pendergast is offering opinions from an FDA regulatory and policy perspective, and not delving into the merits of any scientific position in GSK’s citizen petitions. However, I do understand plaintiffs’ concern. If Pendergast should cross this line, and opine on scientific merit, I will inform the jury that this witness is not qualified to testify as to the scientific merits of GSK’s citizen petitions. By way of example of when this line will be crossed—and the lone example pointed out by Direct Purchasers—Pendergast’s using the phrase “strongest science,” as she did in her report, will not be permitted. *See* Pendergast Report 44.¹⁴

For the foregoing reasons, I will not exclude Pendergast’s opinions regarding the merits of GSK’s citizen petitions from a regulatory and FDA policy perspective, as set forth in her report and testimony.

2. Opinions as to Causation

Daubert motions against Pendergast were originally filed in October 2010. In those motions, Plaintiffs sought to exclude Pendergast’s report and testimony relating to causation issues because they were contrary to law and FDA practice, and because she was unqualified to

¹⁴Direct Purchasers additionally contend that the jury will confuse Pendergast’s regulatory and policy-based testimony with testimony on the scientific merits of the issues in GSK’s citizen petitions. In doing so, they repeat many of the same arguments I have previously rejected. As detailed above, Pendergast has not hidden the fact that she is not a scientific expert and is not opining on the merits of any scientific positions. Rigorous cross-examination, combined with my above-mentioned admonition, should alleviate any concerns regarding jury confusion.

offer such opinions. Plaintiffs re-filed these same motions and accompanying memoranda in January 2012. On April 18, 2012, a *Daubert* hearing was held regarding the admissibility of Pendergast's report and testimony. At that all-day hearing, Direct Purchasers did not ask Pendergast any questions concerning her causation-related opinions. *See* Pendergast Hr'g Tr. 147 ("I do not intend to ask any questions [concerning causation] direct [sic], although I would appreciate an opportunity to address our causation argument in argument or a post hearing submission."). Moreover, in post-hearing briefing, Direct Purchasers failed to mention her opinions regarding causation.

Considering this silence from Plaintiffs and Pendergast's FDA and related experience involving citizen petition consideration and response, as well the development of methods for ANDA approval with OGD, I will not exclude Pendergast's opinions related to causation as set forth in her report and testimony.

IV. Conclusion

The Federal Rules of Evidence clearly illustrate a preference for admitting any evidence which might assist the trier of fact and indicate that this policy extends to the admissibility of expert testimony. *See Kannankeril v. Terminix Intern., Inc.*, 128 F.3d 802, 806 (3d Cir. 1997). In determining the reliability of expert testimony, the standard is lower than one of correctness, and need not be right, only based on good grounds. *See Schieber v. City of Philadelphia*, No. CIV.A. 98-5648, 2000 WL 1670888, at *2 (E.D. Pa. November 7, 2000). I am satisfied that both Plaintiffs and GSK have demonstrated that their respective expert's qualifications and opinions comply with Federal Rule of Evidence 702, subject to the limitations noted above. Therefore, I will deny GSK's Motion to Exclude in Part the Expert Report and Testimony of Leslie Benet,

and deny Plaintiffs' Motion to Exclude the Proposed Expert Testimony of Mary Pendergast.

s/Anita B. Brody

ANITA B. BRODY, J.

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**IN THE UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF PENNSYLVANIA**

In re FLONASE ANTITRUST LITIGATION :
: CIVIL ACTIONS
THIS DOCUMENT RELATES TO :
: No. 08-CV-3149
All Actions : No. 08-CV-3301
: No. 09-CV-1638
:
:

ORDER

AND NOW, this ___23rd___ day of _July___ 2012, for the reasons set forth in the accompanying memorandum of this same date, it is **ORDERED** that:

- GSK’s Motion to Exclude in Part the Expert Report and Testimony of Leslie Benet (No. 08-3149, ECF No. 288; No. 08-3301, ECF No. 350; No. 09-1638, ECF No. 183) is **DENIED**.
- Plaintiffs’ Motion to Exclude the Proposed Testimony of Mary K. Pendergast (No. 08-3149, ECF No. 291; No. 08-3301, ECF No. 346¹; No. 09-1638, ECF No. 180) is **DENIED**.
- GSK’s Motion to Exclude the Expert Report and Testimony of Rochelle Kimmel (No. 08-3149, ECF No. 290; No. 08-3301, ECF No. 351; No. 09-1638, ECF No. 184) is **DENIED** as moot.²

The motions are denied subject to the limitations noted in the accompanying memorandum of this same date.

¹This motion, filed by Indirect Purchaser Plaintiffs, contains two parts, as it was a motion for joinder of Direct Purchaser Plaintiffs’ motions to exclude Mary Pendergast and GSK Expert Gunther Hochhaus. That portion of the motion relating to Dr. Hochhaus was previously withdrawn by stipulation. *See* No. 08-3301, ECF No. 427.

²The plaintiffs have withdrawn their designation of Rochelle Kimmel as an expert in each of the above-captioned actions. *See* No. 08-3149, ECF No. 337; No. 08-3301, ECF No. 410; No. 09-1638, ECF No. 209.

s/Anita B. Brody

ANITA B. BRODY, J.

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