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	:	

October 31, 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, brought actions against Defendant SmithKline Beecham Corporation, doing business as GlaxoSmithKline PLC ("GSK"). GSK manufactures Flonase, the branded version of FP. The various Plaintiffs allege antitrust and state consumer violations that they claim arise from GSK delaying market entry of generic FP. In its defense, GSK asserts, among other things, 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]

[1]A 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)). An exception to the *Noerr-Pennington* doctrine occurs when the conduct "is a mere sham to cover what is actually nothing more than 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, therefore denying *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)). If the challenged conduct is deemed objectively meritless, the trier of fact then considers the second prong, known as the subjective prong. The fact-finder must 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

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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 "*Daubert*" motions to exclude the reports and testimony of certain expert witnesses. *See Daubert* v. *Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579. In June 2011, I denied without prejudice all those *Daubert* 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. In July 2012, I denied two motions to exclude parts of the testimony of Plaintiffs' expert Leslie Benet and GSK's expert Mary Pendergast,[2] both of whom will opine on, among other topics, issues related to the objective prong of the *PRE* test and to causation.

Before me now is GSK's *Daubert* Motion to Exclude Expert Testimony of David A. Kessler, M.D., the former Commissioner of the FDA. *See* Def.'s Mot., Sept. 14, 2012, Case No. 08-3149 ECF No. 456 ("GSK Motion"). Direct Purchaser Plaintiffs proffer Kessler to testify about FDA procedures with respect to citizen petitions; specifically to rebut testimony from Pendergast. Kessler discusses what is likely to move the FDA to change policies in accordance with a citizen petition; he then applies that analysis to conclude that GSK could not have reasonably expected its citizen petitions to succeed on the merits. In other words, Plaintiffs plan to use Kessler's opinion to rebut GSK's *Noerr-Pennington* defense.

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*

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[2] *See In re Flonase Antitrust Litig.*, Nos. 08-3149, 08-3301, 09-1638, 2012 WL 3041815 (E.D. Pa. July 23, 2012).

509 U.S. at 592-93 (citation omitted). Rule 702 provides:

> 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

At trial, Plaintiffs intend to introduce Kessler as an expert on FDA procedures with respect to citizen petitions. Kessler earned a medical degree from Harvard Medical School and a law degree from the University of Chicago Law School. *See* Expert Report of David A. Kessler July 10, 2012 ("Kessler Report") ¶1. He worked on food and drug issues for the Labor and Human Resource Committee in the United States Senate during the 1980s. Kessler Report ¶2. In 1990, President George H. W. Bush appointed Kessler Commissioner of the FDA, a position he held until February 1997, serving under both Presidents Bush and Bill Clinton. *Id.* After he left the FDA, he became the Dean of Yale Medical School, where he taught drug regulation, among other topics. Kessler Hr'g Tr. 27:2-12. He also served as Dean of the medical school at the University of California, San Francisco, where he remains a tenured faculty member. Kessler Hr'g Tr. 27:13-28:13. He has consulted for private firms about drug regulation, FDA procedures, and clinical trials. Kessler Hr'g Tr. 28:17-29:3. He has written books about public health and has published dozens of articles about the regulation of drugs and other public health topics. *See* Kessler Report, Appendix A.

Plaintiffs proffer Kessler to describe how a citizen petitioner could influence the FDA to change its policies; to opine on whether GSK could have reasonably expected the FDA to accept the positions it advocated in its own petitions; and to respond to Pendergast's testimony regarding the use of the term "regulatory merit" at the FDA.

A hearing was held on October 15, 2012. Kessler testified that the FDA is a data-driven organization and offered his opinion that a citizen petitioner can move the FDA to adopt new policies by presenting scientific and medical data that is "clinically meaningful." Kessler explained that "clinically meaningful" data is more than just statistically significant data; it is

data that relates to a drug's clinical safety and effectiveness. Hearing Tr. 38:3-18, October 15, 2012, ("Kessler Hr'g"). Applying this principle—that only clinically meaningful data would move the FDA to adopt positions advocated in a citizen petition—Kessler concluded that there was no reasonable possibility that the FDA would have granted GSK's requests to refrain from approving new FP generics until the Agency had finalized "guidances" on standards and policies.[3] *Id.* at 51:9-17. Kessler testified that, in forming his opinions, he reviewed GSK's citizen petitions and the FDA responses to them, additional FDA documents, congressional testimony relating to FDA's review of ANDAs between 2001 and 2005, and the Hatch-Waxman Act that set forth ANDA procedures. Kessler Hr'g Tr. 89:4-92:16. GSK objects to Kessler's testimony on all three prongs of the *Daubert* inquiry: qualification, reliability, and fit.

A. Qualifications

On the question of his qualifications, GSK argues that Kessler's determination whether GSK's petitions lacked clinically meaningful data reflect an opinion on the scientific merit of the petitions, which GSK argues he lacks the expertise to offer. *See* GSK Motion, at *8-12. GSK argues that Kessler never personally reviewed any ANDAs, and that he lacks first-hand experience conducting research in the area of bioequivalence. Without such expertise, GSK argues, Kessler is not qualified to offer opinions regarding the FDA's ANDA approval process.

These arguments fall flat. As a former Commissioner of the FDA charged with overseeing the agency's response to all citizen petitions, Kessler is qualified to opine on what moves the FDA to adopt positions espoused in a citizen petition. Kessler testified that regulations

[3] My *Noerr-Pennington* decision contains a more detailed description of the requests in GSK's citizen petitions. 795 F.Supp.2d 300, 305-08.

surrounding ANDAs were "front burner at the Agency when I got there," and that the approval of generic drugs occupied "a considerable amount of attention." Kessler Hr'g 19:10-14. Indeed, Kessler signed the extensive FDA regulations implementing the Hatch-Waxman Act, which revised the procedures for the approval of generic drugs; these regulations specifically covered citizen petitions as well. *See* Abbreviated New Drug Application Regulations, 57 FR 17950 (April 28, 1992) (codified at 21 C.F.R. pts. 2, 5, 10, 310, 314, 320, 433); *see also* Kessler Hr'g 10:12-17. Kessler testified that while he did not write the Agency's responses to each individual ANDA, he "influenced" the responses by setting FDA policy. Kessler Hr'g 23:8. He testified that he was more than a mere "figurehead" at the Agency; he was substantively trained in the science and was actively involved in setting FDA policy. Kessler Hr'g Tr. 23:15-18. He was particularly involved in the review of citizen petitions relating to the regulation of tobacco, personally signing the FDA's response that changed the Agency's treatment of tobacco and started the process of regulating cigarettes as a drug for the first time.

Kessler's lifelong experience in the field of food and drug regulation demonstrates that he is well-equipped to discuss the FDA's processes for responding to citizen petitions, and that he is qualified to opine on whether a sophisticated petitioner like GSK could have reasonably expected to succeed in changing FDA policy with its petitions.

B. Reliability

As to reliability, GSK makes three main objections: (1) Kessler's opinions about the citizen petition review process at the FDA are based on neither independent analysis nor reliable methodology. Rather, GSK argues, Kessler merely parrots the FDA's responses to GSK's petitions. (2) Kessler's definition of "regulatory merit" is unreliable because Kessler himself

admitted he was not familiar with the term. (3) Kessler's opinions on causation are unreliable because they are too generalized and outside the scope of GSK's specific petitions. *See* GSK Motion, at *13-22. Like GSK's arguments regarding Kessler's qualifications, I find its arguments about the reliability of Kessler's opinions unavailing.

On the basis of his personal experience at the FDA, along with his academic and advisory experience in the years after he left the Agency, Kessler intends to testify that the FDA is a scientifically-based organization, and that only petitions that include "clinically relevant" data—meaning data that goes to a drug's efficacy or safety—would be likely to move the FDA to alter its policies. Kessler applies that analysis to GSK petitions, which asked the Agency, among other things, to delay approving any ANDAs for generic FP until the agency had issued final guidance. Kessler opines that a sophisticated petitioner like GSK had no reasonable expectation of success because its petitions lacked the clinically relevant data that would persuade the FDA.

At the hearing, Kessler explained that final guidance on generic drugs is not required, and that there are guidances going back several decades that are still in draft form. Kessler Hr'g 39:23-25. He testified that sufficiently relevant data could lead the FDA to "stop the approval process the Agency is mandated to conduct under the statute" to await issuing final guidance on the standards for the generic drug. Kessler Hr'g Tr. 40:9-41:6. However, halting the ANDA process requires "a relatively high showing" that would include "provid[ing] scientific or medical data, that shows therapeutically or clinically meaningful result[s]." Kessler Hr'g Tr. 40:21-41:2. "I believe, again, if there's a scientific reason it's shown that has potential clinical importance to patients, then I think it's okay for the Agency to take a time out . . . and go finalize a guidance and stop the approval process." Kessler Hr'g Tr. 41:2-6.

Kessler concludes that GSK did not meet this "high showing" in its petitions: "GSK did not provide scientific or medical data that were therapeutically or clincially meaningful to support GSK's position." Kessler Report ¶58; *see also* Kessler Hr'g Tr. 51:11-17 ("Q: [D]o you have an opinion as to whether GSK presented scientific and medical data that were therapeutically or clinically meaningful to support its petitions? A: I do. Q: And what is your opinion? A: They did not."). Importantly, Kessler is not offering an opinion whether GSK's data was "correct," something that GSK insists Kessler is unqualified to do. Kessler Hr'g Tr. 52:2-4. Rather, he concludes only that the data GSK presented was not *relevant* to the FDA—that GSK's petitions did not present information that spoke to the drug's safety or efficacy that might lead the FDA to change its policies.

Although Kessler's opinions comport with the FDA's own analysis, he is not merely "parrot[ing]" back the FDA's conclusions. *See* GSK Motion at *2. His opinions satisfy *Daubert*'s reliability prong because they are based on his own analysis of GSK's petitions and the Agency's responses, founded on the principle that only clinically meaningful data moves the FDA to change is policies. In other words, Kessler is analyzing *how* the FDA made its determinations, to demonstrate that a reasonable petitioner could not have reasonably expected the FDA to grant its petition.

Finally, GSK argues that Kessler's opinion about the definition of "regulatory merit" should be excluded as unreliable. In her expert report and during her *Daubert* hearing, GSK expert Mary Pendergast, a former FDA employee and expert in the field of pharmaceutical regulation, testified that GSK's petitions were "appropriate" and had "regulatory merit." *See In re Flonase Antitrust Litig.*, Nos. 08-3149, 08-3301, 09-1638, 2012 WL 3041815, *8. (E.D. Pa. July

23, 2012). She explained that a petition with "regulatory merit" referred to a "position that the FDA could well have adopted." *Id*. at *9. A petition with regulatory merit, she testified, meant 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*.

In his report, Kessler countered Pendergast's testimony: "To my knowledge, the term 'regulatory merit' is not used in FDA statutes or regulations. The absence of the term from FDA's statutory and regulatory framework means that it is not a concept that has any common or formal application at the agency." Kessler Report ¶43. At the hearing, Kessler testified that he could find only one FDA document that had used the term. Kessler H'rg Tr. 61:21-62:5. He testified that he interpreted Pendergast's use of the term "regulatory merit" to mean "something that would move the Agency." *Id.* at 64:1-2. He emphasized that he was not offering a competing definition of the term, only that the term itself does not have common or formal use at the FDA. *Id.*

In its motion, GSK argues that Kessler's opinion about "regulatory merit" should be excluded because he has no familiarity with the term. GSK Motion at *21. But his lack of familiarity—his testimony that the term is *not* part of regular FDA parlance—is itself relevant information that rebuts Pendergast's testimony. More importantly, Pendergast used the term when describing what was likely to move the FDA to adopt a position in a citizen petition. Kessler's testimony is similarly focused: He presents his own opinion as to what moves the Agency. In his view, the touchstone is not "regulatory merit," but "clinically meaningful data." Kessler's statement that "regulatory merit" is not a term of art at the FDA is inextricably linked to his larger opinion about what *does* move the Agency to adopt citizen petitions, an opinion I

have already determined that he is qualified to make, and one that is founded upon reliable principles.

An examination of an expert's reliability focuses on the methodology behind his opinion. Kessler relied on his own direct experience at the FDA to formulate his opinions about what moves the Agency to act. For these reasons, Kessler's testimony satisfies the "reliability" prong of *Daubert*.

C. Fit

On the question of "fit," GSK argues that Kessler's opinions regarding how the FDA handles citizen petitions fail the fit requirement because they are detached from the specific issues of the case, and encourage the jury to improperly rely on Kessler's impressive resume. *See* GSK Motion at *3.

The question fo fit examines how relevant the expert's testimony is to the issues at trial and how helpful it will be to the trier of fact. Despite GSK's objections, Kessler's testimony has a tight "fit" in this case. As explained above, GSK claims that its petitions are protected under the First Amendment and thus cannot form the basis of antitrust liability. To get around this immunity, Plaintiffs will have the burden of proving that the petitions were "shams," which requires showing that they were both objectively and subjectively baseless. Kessler's testimony is directly relevant to the question of objective baselessness. By opining on what moves the FDA to adopt policies from a citizen petition, Kessler's testimony will assist the jury in determining whether GSK could reasonably expect to succeed in its petitions.

GSK also complains that Kessler improperly offers an opinion on causation when he described a "culture at the Agency to respond in a detailed and exhaustive fashion to citizen

petitions." Kessler Report ¶69. Kessler explained that the FDA considered a response to a citizen petition "to be a 'final agency action,'" which required detailed responses, "regardless of whether the issues and information raised by the petition changed or could realistically change agency policy." Kessler Report ¶70. He stated that the process of responding to petitions about generic drug approvals was "time consuming," Kessler Report ¶73, and that the responses "took time and resources from the generic drug approval process due to an environment that was particularly constrained and limited by resources." Kessler Report ¶75. GSK claims that these opinions are "generalized and superficial" and thus both lack reliability and fail to meet the "fit" requirement. GSK Motion at *23. GSK asserts that Kessler is too unfamiliar with the petition review process to testify about whether it slows down the Agency's other work, and objects that there is no basis to apply Kessler's generalized opinions to GSK's petitions in particular.

GSK overstates the opinions Kessler is presenting. As he emphasized in his testimony, he does not intend to opine on whether GSK's petitions specifically caused Roxane's delayed entry into the market. Kessler Hr'g Tr. 68:13-18. His testimony concerned general FDA procedures, which provides context for his opinions about the citizen petition review process. At the hearing, he provided further foundation for his opinions about how the FDA responds to citizen petitions. He pointed to the FDA commentary to the proposed regulation on citizen petitions, which explained that final agency actions require the FDA "to create a comprehensive administrative record." Kessler Hr'g Tr. 67:5-23 (citing 57 FR 17950). Because he is not offering an opinion on what actually caused the delay of Roxane's generic FP onto the market, I find that his general opinions on the the process of responding to citizen petitions is well-founded, reliable, and admissible.

For these reasons, there can be no legitimate dispute that Kessler's testimony is directly relevant to the central questions at issue in this trial, and therefore satisfies *Daubert*'s "fit" requirement.

III. Conclusion

"The Rules of Evidence embody a strong and undeniable preference for admitting any evidence which has the potential for assisting the trier of fact." *Kannankeril v. Terminix Inter., Inc.*, 128 F.3d 802, 806 (3d. Cir. 1997). Rule 702 extends this liberal policy to expert witnesses. Kessler's testimony will assist the jury in understanding federal regulations relating to ANDAs and how the FDA implemented those regulations to deal with ANDA-related citizen petitions. His testimony is directly related to the question of sham petitioning, and squarely rebuts expert testimony presented by GSK. He is a credible witness with an indisputably impressive background. Kessler's expert testimony satisfies *Daubert*'s requirements and is admissible under Rule 702. I will therefore deny GSK's Motion to Exclude Expert Testimony of David A Kessler.

s/Anita B. Brody

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ANITA B. BRODY, J.