UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

IN RE RESTASIS (CYCLOSPORINE OPHTHALMIC EMULSION) ANTITRUST LITIGATION	**18-MD-2819 (NG) (LB)**
THIS DOCUMENT APPLIES TO: ALL END-PAYOR PLAINTIFF CLASS CASES	**OPINION AND ORDER ON END-PAYOR PLAINTIFFS' MOTIONS UNDER RULE 702**

GERSHON, United States District Judge:

The End-Payor Plaintiffs ("EPPs" or "plaintiffs") have moved for class certification in this litigation, which alleges that defendant Allergan, Inc. engaged in anticompetitive conduct to retain a monopoly on its dry-eye drug, Restasis.[1] This opinion is one of two issued today. The other certifies a class of EPPs ("Class Certification Opinion"). Here I address EPPs' motions under Federal Rule of Evidence 702 to exclude evidence proffered by two of the three experts defendant offered in opposition to class certification—Kathryn Masselam Hatch, M.D. and Kyriakos (Ken) Mandadakis, O.D. Plaintiffs have also moved to exclude the opinions of defendant's third expert, Dr. James W. Hughes, to the limited extent that he relies on the challenged opinions of Dr. Hatch and Dr. Mandadakis.

Allergan offers the expert reports and testimony of Dr. Hatch and Dr. Mandadakis principally as evidence that doctors would have been reluctant to prescribe generic Restasis in the but-for world and that this "physician resistance" would have caused brand Restasis to retain a significant percentage of the market after generic entry.

[1] Familiarity with the facts and procedural history of this litigation is presumed.

Both Dr. Hatch and Dr. Mandadakis testified at the class certification hearing held on September 26 and 27, 2019. My observations of them at the hearing inform my ultimate conclusions on EPPs' Rule 702 motions.

For the reasons stated below, both motions are granted in full. I note that, even if I had denied these motions in their entirety, my decision to certify an EPP class would not have been affected, as I would have afforded these experts' opinions little weight.

I. LEGAL STANDARD

Rule 702, which governs expert testimony, 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; *see Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 588 (1993). The district court has a "gatekeeping" function under Rule 702 to ensure "that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." *Daubert*, 509 U.S. at 597. The proponent of the evidence bears the burden of establishing that Rule 702's requirements have been met. *Id.* at 592 n.10.

A court's inquiry into Rule 702's requirements is "a flexible one." *Id.* at 594. To determine whether a proffered expert's testimony is relevant, the court should consider the standards of Rule 401—that is, "whether it has any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." *Amorgianos v. Nat'l R.R. Passenger Corp.*, 303 F.3d 256, 265 (2d Cir. 2002) (internal quotation marks and alterations omitted); Fed. R. Evid. 401.

Factors to consider when evaluating Rule 702's reliability requirement include "whether a theory or technique had been and could be tested, whether it had been subjected to peer review, what its error rate was, and whether scientific standards existed to govern the theory or technique's application or operation." *Nimely v. City of N.Y.*, 414 F.3d 381, 398 (2d Cir. 2005) (citing *Daubert,* 509 U.S. at 593–94). Ultimately, the court must "make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999). When the expert opinion is inadequately supported by data, methodology, or studies, "[a] court may conclude that there is simply too great an analytical gap between the data and the opinion proffered" and exclude the expert testimony. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997).

In addition to the questions of relevance and reliability, Rule 702 presents a "threshold question of whether a witness is qualified" to be an "expert." *Nimely*, 414 F.3d at 396 n.11. This question is "important" because an "'expert' witness is permitted substantially more leeway than lay witnesses" as to the scope of his or her testimony. *Id.* (citing Fed. R. Evid. 703 & 705). "To determine whether a witness qualifies as an expert, courts compare the area in which the witness has superior knowledge, education, experience, or skill with the subject matter of the proffered testimony." *United States v. Tin Yat Chin*, 371 F.3d 31, 40 (2d Cir. 2004).

Although "[t]he Supreme Court has not definitively ruled on the extent to which a district court must undertake a *Daubert* analysis at the class certification stage," it has "offered limited dicta suggesting that a *Daubert* analysis may be required at least in some circumstances." *In re U.S. Foodservice Inc. Pricing Litig.*, 729 F.3d 108, 129 (2d Cir. 2013) (citing *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 354 (2011)). The Second Circuit has left the question unresolved.

See id. at 129–30. Nonetheless, courts in this Circuit "regularly subject expert testimony to *Daubert*'s rigorous standards insofar as that testimony is relevant to the Rule 23 class certification analysis." *In re Foreign Exch. Benchmark Rates Antitrust Litig.*, 407 F. Supp. 3d 422, 429 (S.D.N.Y. 2019) (internal quotations marks omitted). These courts limit the scope of their *Daubert* analysis to determining "whether or not the expert reports are admissible to establish the requirements of Rule 23." *Chen-Oster v. Goldman, Sachs & Co.*, 114 F. Supp. 3d 110, 115 (S.D.N.Y. 2015), *objections overruled*, 325 F.R.D. 55 (S.D.N.Y. 2018). I will do the same here.

II. ANALYSIS

A. Dr. Mandadakis

Dr. Mandadakis received his Doctor of Optometry degree from the State University of New York College of Optometry in 2001. He currently has his own private practice in Toronto, Canada. He has also worked in academic, consulting, and advisory roles relating to optometry.[2]

As described in the Class Certification Opinion, Teva Pharmaceutical Industries Ltd. ("Teva") launched a generic version of Restasis in Canada in May 2018. This product captured only a low percentage of the market—less than several other ophthalmic drugs in Canada had achieved. Defendant hired Dr. Mandadakis to provide an expert opinion and analysis on Teva's

[2] From 2012 to 2018, Dr. Mandadakis served as a paid consultant for Allergan; his consultancy had ended before Allergan hired him as an expert in this case. Courts generally hold that experts' potential bias goes to the weight, not admissibility, of their testimony. *See, e.g.*, *Disabled in Action v. City of N.Y.*, 360 F. Supp. 3d 240, 251 (S.D.N.Y. 2019); *Kemp v. CSX Transp., Inc.*, 993 F. Supp. 2d 197, 217–18 (N.D.N.Y. 2014); *Tedone v. H.J. Heinz Co.*, 686 F. Supp. 2d 300, 311 (S.D.N.Y. 2009). Dr. Mandadakis' partiality was apparent at the hearing as well as in his report. As noted below, for example, he relied unquestioningly on Allergan's sales representatives and one of its citizen petitions. For this reason, among others described below, I would have afforded his analysis little weight in the class certification opinion even if I had denied plaintiffs' Rule 702 motion.

product, including his experiences treating patients with it, its tolerability and efficacy, and how patients and their eye care providers are responding to the drug.

In his report, Dr. Mandadakis concluded that users of Teva's generic version of Restasis "likely" have "widespread and serious" complaints about its tolerability and efficacy. Expert Report of Kyriaskos (Ken) Mandadakis, O.D. ("Mandadakis Rep.") ¶ 67. He determined that the drug's problems were "likely partially" attributed to the drug's "inferior [dispensation] vehicle and/or manufacturing process," which he claimed affected "globule size and cyclosporine distribution." Mandadakis Rep. ¶ 71. These problems, he opined, are "likely" leading "many Canadian eye-care providers" to "tak[e] steps to prevent pharmacists from switching patients to generic Restasis®, [] at a higher rate than is normal for ophthalmic generic products in Canada." Mandadakis Rep. ¶ 69. Because Canadian pharmacies typically do not substitute Teva's generic for Restasis MultiDose prescriptions, Dr. Mandadakis himself started prescribing Restasis MultiDose to prevent his patients from receiving Teva's product.[3] Mandadakis Rep. ¶ 69. Dr. Mandadakis ultimately concluded that "the poor performance of Teva's product in Canada is likely a significant driver of the overall low rate of prescriptions of Teva's generic Restasis® product in Canada." Mandadakis Rep. ¶ 72.

1. Relevance

Plaintiffs first argue that Dr. Mandadakis' opinions must be excluded as irrelevant under Rule 702(a) because anecdotal evidence of brand retention in Canada is unconnected to Restasis' brand retention rate in the United States. On reply, EPPs assert that the irrelevance of Dr. Mandadakis' opinions is further evidenced by Dr. Hughes's assertion, in his surrebuttal report, that

[3] Restasis MultiDose contains the same Restasis formulation in a multi-dose, rather than single-use, vial.

he did not rely on the performance of Teva's generic in Canada to conclude that 14 to 25 percent of prescriptions in the United States would have remained with brand Restasis in the but-for world.

As described in the Class Certification Opinion, the performance of a generic in Canada bears little relevance to how it would perform in the United States. I nevertheless find Dr. Mandadakis' opinions relevant under Rule 702(a), albeit minimally so. Dr. Hughes did not completely disclaim Dr. Mandadakis' analysis. He explained that "[t]he evidence of substantial underperformance" of Teva's generic served as "support" for his conclusion that brand Restasis would retain 14 to 25 percent of the market in the but-for world and also suggested that the brand retention rate might have been even higher. Surrebuttal Expert Report of Professor James W. Hughes, Ph.D. ¶ 47.

I will now address EPPs' alternative arguments that Dr. Mandadakis' data and methodology are unreliable and that he is unqualified to render certain opinions.

2. Teva's Product's Tolerability and Efficacy

Dr. Mandadakis used a sparse, skewed, and unverifiable dataset to support his opinion that Teva's drug has "widespread and serious" efficacy and tolerability problems. He based his opinion primarily on the complaints of "three-quarters" of "several dozen" of his patients whose pharmacies automatically switched them from brand Restasis to Teva's generic. Mandadakis Rep. ¶¶ 9, 23. At his deposition, Dr. Mandadakis clarified that, by "several dozen," he meant two to three dozen. And his conclusion regarding the drug's reduced efficacy appears to be based on testing he did on just one patient (corroborated by statements from Allergan sales representatives about doctors' vague reports regarding a handful of unnamed patients).

Dr. Mandadakis' sample size, which would not survive peer review, is likely reason enough to deem his data unreliable. *See State v. Deutsche Telekom AG*, 419 F. Supp. 3d 783, 789–90

(S.D.N.Y. 2019); *Chen-Oster*, 114 F. Supp. 3d at 124; *but see U.S. Info. Sys., Inc. v. Int'l Bhd. of Elec. Workers Local Union No. 3, AFL-CIO*, 313 F. Supp. 2d 213, 232 (S.D.N.Y. 2004), *objections overruled,* No. 00-cv-4763, Dkt No. 193 (S.D.N.Y. Apr. 6, 2004) ("[S]mall sample size goes to the weight rather than to the reliability (and admissibility) of a study.").

In any event, Dr. Mandadakis' patient sample was not an objective one. No matter its size, any sample must be "representative—that is, it [must not be] selected in a biased manner." *U.S. Info. Sys.*, 313 F. Supp. 2d at 232; *accord Water Pollution Control Auth. of City of Norwalk v. Flowserve US Inc.*, 2018 WL 1525709, at *14 (D. Conn. Mar. 28, 2018), *aff'd,* 782 F. App'x 9 (2d Cir. 2019); *Chen-Oster*, 114 F. Supp. 3d at 124. Dr. Mandadakis, however, concluded that Teva's product had substantial performance problems based on the self-reporting of some of his patients. *See Playtex Prods., Inc. v. Procter & Gamble Co.,* 2003 WL 21242769, at *10 (S.D.N.Y. May 28, 2003), *aff'd on other grounds*, 126 F. App'x 32 (2d Cir. 2005) (excluding doctor's conclusions that were based on "'anecdotal conversations' she has had with some patients, and not on any survey or scientific study"). As he conceded at his deposition, other patients could have been switched to the generic by their pharmacies and not contacted him because they were not experiencing problems. Yet Dr. Mandadakis did not attempt to account for this potential bias, rendering his analysis unreliable. *See Water Pollution Control Auth.*, 782 F. App'x at 13–14; *U.S. Info. Sys.*, 313 F. Supp. 2d at 235.

Dr. Mandadakis' reliance on his discussions with "several optometrists and ophthalmologists" whose patients "have complained about tolerability and efficacy problems after using Teva's generic product" is similarly flawed. Mandadakis Rep. ¶ 46. As an initial matter, that the doctors' statements are hearsay does not alone prohibit Dr. Mandadakis from considering them. Rule 703 permits an expert to rely on otherwise inadmissible information "[i]f experts in

the particular field would reasonably rely on those kinds of facts or data in forming an opinion on the subject." Fed. R. Evid. 703. This includes doctors relying on the reports of other doctors. *Singh v. Greiner*, 2002 WL 31641608, at *4 n.2 (E.D.N.Y. Nov. 18, 2000) (citing Fed. R. Evid. 703 advisory committee's note).

But Dr. Mandadakis' reliance on other doctors' reports is inadmissible because he did not apply a sound methodology to his analysis. Other than the three colleagues in his practice, Dr. Mandadakis has never asked doctors about their experiences with Teva's product, let alone has he ever conducted a formal survey. Rather, he based his conclusions on doctors' unsolicited remarks to him when he saw them at professional gatherings. As he conceded at the hearing, some doctors may not have felt comfortable approaching him or may not have spoken to him because their patients had not had problems with Teva's drug. Finally, Dr. Mandadakis relied on yet another biased source to draw his conclusion about problems with Teva's drug—Allergan's own sales representatives. Unsurprisingly, these representatives "confirmed" his suspicions about Teva's product. Mandadakis Rep. ¶ 47.

Representations in Dr. Mandadakis' report also cast doubt on his credibility. He omitted crucial information when describing "adverse incident reports" about Teva's generic that had been submitted to Health Canada. It is also undisputed by defendant that Dr. Mandadakis incorrectly summarized the results of a February 2019 survey regarding Allergan's and Teva's products in Canada that he offered to bolster Allergan's claim that many patients were switching from Teva's generic back to brand Restasis. An expert's inability to properly interpret a survey calls into serious question either his credibility or his methodology.

Dr. Mandadakis' methodology also cannot be tested—yet another factor weighing against a finding of reliability. *See Daubert*, 509 U.S. at 593. "In order for a Court to determine the

admissibility of expert opinions, the party offering the expert must disclose the bases for those opinions." *Water Pollution Control Auth.*, 2018 WL 1525709, at *17. Here, Dr. Mandadakis provided the medical records of only one of his patients. He deemed a search of his patient database to review all of his records—or even those of the 24 to 36 patients on which his conclusions primarily relied—too time consuming. Dr. Mandadakis' "failure to follow proper protocols" because it "would have required more time than he had available" is an "unacceptable" excuse under *Daubert*. *See Wessmann v. Gittens*, 160 F.3d 790, 805 (1st Cir. 1998); *accord United States v. Tuzman*, 2017 WL 6527261, at *16 (S.D.N.Y. Dec. 18, 2017). Dr. Mandadakis also did not offer the names of most of the doctors with whom he spoke.[4] Finally, he referenced "several incident reports" that he claimed to have filed with Health Canada concerning his patients' reactions to Teva's product, but he provided none, saying that he had not kept copies. Mandadakis Rep. ¶ 41.

Defendant asserts that "courts routinely permit doctors to testify about what reasonable doctors do in particular circumstances." Allergan, Inc.'s Opposition to End Payor Plaintiffs' Motions to Exclude Testimony of Doctors Kathryn Masselam Hatch and Kyriakos (Ken) Mandadakis at 11. It cites cases in which doctors were permitted to testify about the standard of care in a medical malpractice action. *See Carroll v. Morgan*, 17 F.3d 787, 789–90 (5th Cir. 1994); *Stelman v. United States*, 2016 WL 5315196, at *9–10 (S.D.N.Y. Sept. 21, 2016); *K.R. ex rel. Perez v. United States*, 843 F. Supp. 2d 343, 355 (E.D.N.Y. 2012); *see also United States v. Wexler*, 522 F.3d 194, 203–04 (2d Cir. 2008). But a physician's use of his or her relevant experience in a specialized area of medicine to express an opinion about the standard of care for a particular patient

[4] At his deposition, Dr. Mandadakis named only two of the doctors; both had served as consultants for Allergan—another potentially biased sample.

is not the same as a doctor using his limited, cherry-picked experience with a drug to opine on the drug's overall effectiveness or tolerability.

In sum, for the reasons expressed above, there is "simply too great an analytical gap between the data and" Dr. Mandadakis' opinion on the efficacy and tolerability of Teva's generic drug in Canada. *See Gen. Elec. Co.*, 522 U.S. at 146. It must be excluded.

3. Drug Manufacturing and Generic Penetration

I agree with EPPs that Dr. Mandadakis is entirely unqualified to render the other two opinions in his report—that manufacturing problems caused Teva's generic to be an inadequate replica of brand Restasis and that the generic's "poor performance" is "likely a significant driver of the overall low rate of prescriptions of Teva's generic Restasis® product in Canada."[5] Mandadakis Rep. ¶¶ 71–72.

Dr. Mandadakis himself admitted at the hearing that he lacks experience with pharmaceutical manufacturing and that he knows nothing about how Teva manufactures its generic. *See Malletier v. Dooney & Bourke, Inc.,* 525 F. Supp. 2d 558, 642 (S.D.N.Y. 2007). Moreover, even if he were qualified, Dr. Mandadakis' opinion on manufacturing is nonetheless inadmissible. He cites almost exclusively to one of Allergan's citizen petitions to the Food and Drug Administration ("FDA")—an advocacy document—to describe Restasis' manufacturing process.[6] "Such heavy reliance on [Allergan's] subjective view, without analysis of the basis for that party's conclusion, is wholly insufficient to survive a *Daubert* motion." *Playtex Prods.*, 2003

[5] EPPs ask me to preclude Dr. Mandadakis' opinion on generic penetration rates in the United States, but he never opined on that subject.

[6] Dr. Mandadakis' only other sources are warning letters the FDA sent to another generic manufacturer for violations of manufacturing processes unrelated to Restasis. These are irrelevant to his assertion that Teva's generic drug was manufactured improperly.

WL 21242769, at *10; *accord Paguirigan v. Prompt Nursing Emp't Agency LLC*, 2019 WL 4647648, at *11 (E.D.N.Y. Sept. 24, 2019); *Arista Records LLC v. Usenet.com, Inc.*, 608 F. Supp. 2d 409, 429 (S.D.N.Y. 2009).

Dr. Mandadakis also has no expertise in the factors that drive generic penetration in Canada—making him unqualified to offer his opinion as to why Teva's generic has not sold well. Even if he were qualified, his opinion is too unreliable to be admitted. He did not cite a single source showing that a generic's side effects or inferior performance can significantly affect its penetration rates, and he did even attempt to rule out other factors that may have affected Teva's product's penetration rate. *See* Fed. R. Evid. 703 (an expert's testimony must be based on information of a type reasonably relied upon by experts in the particular field in forming opinions upon the subject). Dr. Mandadakis merely wrote, in a conclusory fashion, that he had "considered whether other factors have contributed to the low rate of adoption of Teva generic Restasis® in Canada," including Allergan's discounting of Restasis, and that, in "[his] opinion," "the frequent and widespread tolerability and efficacy problems with Teva's generic product were likely a substantial and contributing factor for switching." Mandadakis Rep. ¶ 60. His "failure to give reasonable explanations for discounting or dismissing these alternative possibilities . . . undermines the reliability of his opinions." *In re Mirena IUD Prods. Liab. Litig.*, 169 F. Supp. 3d 396, 437 (S.D.N.Y. 2016) (internal quotation marks and alteration omitted).

In conclusion, EPPs' motion to exclude evidence proffered by Dr. Mandadakis in support of Allergan's class certification opposition is granted.

B. Dr. Hatch

Dr. Hatch, an ophthalmologist, is the Site Director of the Waltham, Massachusetts branch of Massachusetts Eye and Ear hospital, and an Assistant Professor of Ophthalmology at Harvard

Medical School. She has treated thousands of patients with dry-eye disease. She also is a peer review editor for many academic journals in the field of ophthalmology and is an active fellow of the American Academy of Ophthalmology and a diplomate of the American Board of Ophthalmology. Dr. Hatch also previously served as a Scientific Advisory Board member for Allergan regarding Restasis.

Dr. Hatch expressed four opinions in her report. Plaintiffs do not challenge the first—that Restasis, an oil-in-water emulsion, is a complex product. The following three opinions are the subject of EPPs' motion: that generic Restasis would have captured less of the market than a typical ophthalmic product in the United States; that eye care providers are generally skeptical of generic ophthalmic drugs, especially complex ones; and that approval of generic Restasis would result in increased costs for patients and insurance companies.

1. Generic Penetration in the But-For World

EPPs contend that Dr. Hatch is unqualified to offer an opinion on Restasis' generic penetration rate in the but-for world. Dr. Hatch conceded that she is not an expert, and has never conducted studies, on the subject. Rather than arguing that Dr. Hatch is qualified, Allergan asserts that she did not offer an opinion on generic penetration. This is inaccurate. While defendant correctly notes that Dr. Hatch did not predict the precise penetration rate generic Restasis would have achieved in the but-for world, she did opine on the central dispute in this case—that she "would expect patient usage levels for generic Restasis® to be significantly lower than it was for other ophthalmic drugs such as generic latanoprost compared to branded Xalatan®."[7] Expert Report of Kathryn Masselam Hatch, M.D. ("Hatch Rep.") ¶ 60. She also predicted that, "[i]f a

[7] Latanoprost is the generic form of Xalatan.

generic version of Restasis® is launched in the United States, there are several reasons why the proportion of patients who would continue to take the branded version of Restasis would likely be substantially higher than a typical ophthalmic product due to efforts by eye care providers to keep patients on the brand, for example, by denoting 'dispensed as written' on prescriptions for Restasis®." Hatch Rep. ¶ 15; *see also* Hatch Rep. ¶ 68.

Notably, in its opposition to class certification, Allergan cited Dr. Hatch's report as support for the proposition on which it now claims she did not opine: that eye care providers' "distrust" of generic drugs, particularly complex ones, would "greatly increase the number of brand loyalists[.]" Allergan's Memorandum of Law in Opposition to End-Payor Plaintiffs' Motion for Class Certification at 20; *accord id.* at 24. I therefore conclude that Dr. Hatch did offer an opinion on Restasis' but-for generic penetration rate, that she was unqualified to do so, and that her opinion should be excluded under *Daubert* for this reason.

Were Dr. Hatch qualified to render her opinion, her analysis would nonetheless be inadmissible as unreliable. First, her opinion is largely dependent on Dr. Mandadakis' inadmissible opinions, making it inadmissible as well.[8] *See Rink v. Cheminova, Inc.,* 400 F.3d 1286, 1294 (11th Cir. 2005). To the extent Dr. Hatch determined on her own that generic Restasis would have performed worse than the brand, her hearing testimony revealed that her conclusion was based largely on incorrect assumptions about the FDA's bioequivalence requirements for generic Restasis.

Dr. Hatch also based her opinion regarding generic penetration rates on eye care providers' "historical skepticism towards generic complex ophthalmic drug products." Hatch Rep. ¶ 59. But

[8] The section of Dr. Hatch's report in which she discusses generic penetration is titled "Recent Evidence From Canada Confirms the Veracity of Physician Concerns and the Likelihood that U.S. Patients Will Not Be Substituted to Generic Restasis®."

she cited no studies linking physician resistance or drug complexity to generic penetration rates. Indeed, during her own testimony, she described the powerful mechanisms in the pharmaceutical industry that often compel doctors to prescribe generic drugs, including that a consumer's insurance will not cover the brand drug or that the brand drug will be much more expensive.

2. Eye Care Providers' General Skepticism of Generic Drugs

EPPs also challenge Dr. Hatch's opinion that eye care providers generally view generic versions of ophthalmic products, particularly complex ones, "with skepticism and concern for their safety, efficacy, and/or tolerability." Hatch Rep. ¶ 14. Plaintiffs argue that Allergan offers Dr. Hatch's testimony on the eye care provider community only to support her and Allergan's claims about generic penetration rates. They therefore assert that, if I exclude Dr. Hatch's testimony on generic penetration (which I have done), her testimony on eye care providers' resistance to generic drugs should be excluded as irrelevant. Alternatively, they argue that the opinion is unreliable because it is based on anecdotal, unscientific, and potentially biased evidence.

The relevance of Dr. Hatch's opinion is, at best, extremely limited. Generic Xalatan's successful penetration of the market shows that any general skepticism Dr. Hatch claims eye care providers have towards generic drugs does not reduce their penetration rates. Xalatan is a solution, not a complex drug, and the generic version of the drug penetrated, on average, nearly 95 percent of the market after nearly three years. Thus, Dr. Hatch's opinion is relevant to Allergan's class certification opposition only if she can show that eye care providers are especially skeptical of complex drugs (like Restasis) and if Allergan can link that skepticism to generic penetration rates. As noted in the Class Certification Opinion, however, defendant has failed to make that link. "[I]t has not bridged the gap between eye care providers' preferences and generic penetration rates." Class Cert. Op. at 29.

Even if defendant had linked physician resistance to generic penetration rates, Dr. Hatch's opinion regarding eye care providers' particular skepticism of complex generic ophthalmic drugs falls far short of Rule 702's demands. Dr. Hatch and defendant emphasize that her years of experience as an eye care provider was the principal basis for her opinion. But the doctor's description of her own skepticism of complex generic drugs does not appear to be grounded in reality. At the hearing, Dr. Hatch seemed convinced that generic Restasis would not just be inferior to brand Restasis, but that it would not work at all or make her patients feel worse. Class Cert. Hr'g Tr. at 97 ("It just creates a bigger problem if you give [a patient] something that's not going to help them."); *id*. at 137 (". . . I think the patients are already suffering from these symptoms and then you put them on a therapy that can make them feel worse, and then they get very upset."); *id.* at 134. Based on these assumptions, she testified that she might not prescribe any drug at all to her patients if generic Restasis were the only option—despite the serious suffering she said dry-eye disease causes. Dr. Hatch's underlying assumption that an FDA-approved version of generic Restasis would offer no benefit to her patients does not survive *Daubert*'s rigorous analysis. *See Zerega Ave. Realty Corp. v. Hornbeck Offshore Transp., LLC,* 571 F.3d 206, 213–14 (2d Cir. 2009) ("[A] trial judge should exclude expert testimony if it is speculative or conjectural or based on assumptions that are so unrealistic and contradictory as to suggest bad faith." (internal quotation marks omitted)). Rather, it reveals a bias either against generic drugs or in favor of Restasis that renders her analysis untrustworthy.[9]

[9] Cases cited by defendant in which courts have allowed treating physicians to testify as experts based on their experience caring for a particular patient, *Figueroa v. Bos. Sci. Corp.*, 254 F. Supp. 2d 361, 368 (S.D.N.Y. 2003); *Reyes v. Delta Dallas Alpha Corp.*, 2000 WL 526851, at *2 (S.D.N.Y. May 2, 2000), do not support the proposition that Dr. Hatch's experience alone qualifies her as an expert on the prescribing practices of ophthalmologists generally. Indeed, as one of those courts made clear, "an expert basing his opinion solely on experience must do more than aver

Additionally, one of Dr. Hatch's main sources, a December 2018 article in *Ophthalmology Times* called *Branded vs. Generics: You Make the* Call,[10] undermines the distinction she makes between doctors' skepticism of complex and non-complex ophthalmic products. The article addressed in detail doctors' concerns about the inferiority of generic Xalatan—a non-complex drug.[11] Indeed, at her deposition, Dr. Hatch agreed that Xalatan is "another good example" of why doctors "have to be wary of just substituting generics for branded medications in ophthalmology." Hatch Deposition at 146.

Finally, the reliability of Dr. Hatch's analysis is further called into question by her citation to the comments of four doctors in support of Allergan's citizen petitions, all of whom had received substantial payments from Allergan during the relevant time period.

3. Increased Medical Costs

EPPs lastly challenge Dr. Hatch's claim that the introduction of a generic version of Restasis would result in additional costs for patients and their insurance companies because patients would visit their doctors more frequently. As these additional medical costs are not only

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conclusorily that his experience led to his opinion." *Figueroa*, 254 F. Supp. 2d at 365–66 (internal quotation marks omitted).

[10] *Available at* www.ophthalmologytimes.com/article/branded-vs-generics-you-make-call.

[11] EPPs have also submitted evidence that some of the doctors quoted in this article received significant payments from Allergan. Furthermore, while the article references a study of Medicare Part D data finding that in 2013 eye care providers prescribed more brand medication than all other medical providers, Dr. Hatch admitted that she did not read this underlying study, raising doubt about the rigor of her work. In addition, as noted in the Class Certification Opinion at 28 n.26, this study reported that brand medications' "[h]igh costs result in less frequent medication purchases and lead to lower medication adherence," deeming it "likely critically important to prescribe less expensive [generic] medications as first-line therapies to help decrease the risk of cost-related medication nonadherence." Dr. Paula A. Newman-Casey, et al., *Brand Medications and Medicare Part D: How Eye Care Providers' Prescribing Patterns Influence Costs*, 125 Ophthalmology 332 (2018), www.ncbi.nlm.nih.gov./pmc/articles/PMC5732892.

speculative but irrelevant to the calculation of overcharges paid by class members, *see* Class Cert. Op. at 44, Dr. Hatch's opinion is legally irrelevant on class certification and therefore will be excluded. *See In re Delta/AirTran Baggage Fee Antitrust Litig.*, 317 F.R.D. 675, 690 (N.D. Ga. 2016).

C. Dr. Hughes' Reliance on Dr. Hatch and Dr. Mandadakis

Plaintiffs ask that I exclude the portions of Dr. Hughes' report that are derivative of the excluded opinions of Dr. Hatch and Dr. Mandadakis. To the extent Dr. Hughes relied on the opinions that I have excluded above, that request is granted. *See, e.g.*, *Rink*, 400 F.3d at 1294; *Malletier,* 525 F. Supp. 2d at 664.

D. Defendant's Alternative Argument Under Rule 701

Finally, I deny defendant's alternative argument that I allow Dr. Hatch and Dr. Mandadakis to testify as lay witnesses under Rule 701. A lay witness cannot purport to base his or her testimony "on scientific, technical, or other specialized knowledge within the scope of Rule 702." Fed. R. Evid. 701(c). "The purpose of Rule 701(c) is 'to eliminate the risk that the reliability requirements set forth in Rule 702 will be evaded through the simple expedient of proffering an expert in lay witness clothing.'" *Bank of China, N.Y. Branch v. NBM LLC*, 359 F.3d 171, 181 (2d Cir. 2004) (quoting Fed. R. Evid. 701 advisory committee's note). Here, Dr. Hatch and Dr. Mandadakis were quintessential expert witnesses. They were retained by defendant solely to support its position in this litigation, and they cited their "experience and specialized knowledge" in medicine as the basis for their conclusions. *See id.*; *United States v. Garcia*, 413 F.3d 201, 215 (2d Cir. 2005).

III. CONCLUSION

Plaintiffs' motions to exclude evidence proffered by Dr. Mandadakis and Dr. Hatch, and the derivative evidence of Dr. Hughes, are granted.

SO ORDERED.

Dated: May 5, 2020
Brooklyn, New York

/S/
NINA GERSHON
United States District Judge