UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

FEDERAL TRADE COMMISSION, STATE OF NEW YORK, STATE OF CALIFORNIA, STATE OF OHIO, COMMONWEALTH OF PENNSYLVANIA, STATE OF ILLINOIS, STATE OF NORTH CAROLINA, and COMMONWEALTH OF VIRGINIA, Plaintiffs, -v- VYERA PHARMACEUTICALS, LLC, AND PHOENIXUS AG, MARTIN SHKRELI, individually, as an owner and former director of Phoenixus AG and a former executive of Vyera Pharmaceuticals, LLC, and KEVIN MULLEADY, individually, as an owner and former director of Phoenixus AG and a former executive of Vyera Pharmaceuticals, LLC, Defendants.	20cv00706 (DLC) OPINION AND ORDER

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DENISE COTE, District Judge:

Trial in this antitrust action is scheduled to begin on December 14, 2021. This Opinion addresses the motion brought by the United States Federal Trade Commission and seven States (collectively, "Plaintiffs") to exclude expert testimony offered by Sheldon Bradshaw on behalf of defendants Vyera Pharmaceuticals, LLC, its parent company Phoenixus AG (together, "Vyera"), Martin Shkreli, and Kevin Mulleady (collectively, "Defendants"). For the following reasons, the Plaintiffs' motion to exclude Bradshaw's testimony is largely granted.

Background

At this trial, the Plaintiffs seek to prove that the Defendants orchestrated a scheme to impede generic competition with the branded pharmaceutical Daraprim. The Plaintiffs allege

that the Defendants entered restrictive contracts with U.S. drug distributers and the most viable suppliers of pyrimethamine, the active pharmaceutical ingredient ("API") in Daraprim, to impede generic drug manufacturers in their efforts to obtain Food and Drug Administration ("FDA") approval for a generic competitor to Daraprim. The FDA's regulations regarding Abbreviated New Drug Applications ("ANDAs"), as well as the FDA's practices with respect to a reference listed drug[1] ("RLD") and API supply requirements, are relevant to the issues in dispute at this trial.

I. Summary of Bradshaw's Testimony

The Defendants offer Bradshaw's expert opinions purportedly to rebut testimony by the Plaintiffs' expert witness C. Scott Hemphill.[2] Bradshaw is an FDA regulatory expert. He served as Chief Counsel of the FDA between 2005 and 2007, and is currently

[1] RLD refers to the brand name drug that the FDA has already approved. In this case, the brand name drug Daraprim is the relevant RLD.

[2] Hemphill is testifying at trial about, inter alia, his calculations of the excess net profits Vyera made from its allegedly anticompetitive practices. Bradshaw is principally offered to undermine some of the assumptions on which Hemphill relied in making those calculations, including two dates by which generic suppliers of FDA-approved pyrimethamine may have entered the market. While Bradshaw's affidavit indicates that he is rebutting as well testimony provided by Plaintiffs' experts James Bruno and Edward Conroy, in opposing this motion to exclude the Defendants no longer contend that Bradshaw's testimony is relevant to the testimony offered by these latter two witnesses.

a partner at the law firm King & Spalding LLP, where he practices in the FDA & Life Science Practice Group. He explains that he has based his opinions on his experience with the FDA's regulations and practices regarding the ANDA process, as well as his knowledge of the pharmaceutical industry and review of documents and testimony entered in this case.

Bradshaw offers his opinions in a 60-page affidavit that constitutes his direct testimony. In the first pages of the affidavit, Bradshaw testifies that he has formed twenty-five separate opinions, which he then lists.[3]

Ten of the twenty-five opinions relate to FDA procedures in the review and approval of ANDAs. These opinions emphasize the complexity and time-consuming nature of the process (the "FDA Opinions").[4] Among other things, Bradshaw explains that the FDA exempts API suppliers from Import Alerts[5] only where there is a

[3] The Plaintiffs' motion addressed Bradshaw's expert report of June 4, 2021. Because the motion was filed on the same date that Bradshaw's affidavit was served, only the opposition and reply briefs directly address the affidavit. Bradshaw's report and his affidavit have some significant differences. This Opinion construes the Plaintiffs' motion as seeking to strike those paragraphs identified in the Plaintiffs' reply brief.

[4] These ten opinions are contained in subparagraphs 11(a)-(i), (s).

[5] According to Bradshaw, an Import Alert is a public notice to the FDA's field staff that a particular product sought to be imported into the United States violates the FDA's laws and regulations and may be detained before it enters the country.

"potential shortage" of the banned drug or its API and the product or API is "medically necessary for patients in the United States." He opines that references to Drug Master Files ("DMFs") for APIs in ANDAs do not "guarantee" a faster approval of an ANDA or even its eventual approval. He explains that different "review disciplines" within the FDA proceed at their own paces, and an early resolution by one discipline does not "bar" another discipline from moving more slowly. Finally, Bradshaw testifies that the FDA does not consider the high cost of obtaining an RLD when a generic drug manufacturer seeks a waiver of quantity requirements for bioequivalence ("BE") testing.

Fourteen opinions describe actions that non-party generic drug manufacturers should or should not have taken in seeking FDA approval of their ANDAs for generic pyrimethamine (the "Generics Opinions").[6] These actions were undertaken in response to the difficulties the manufacturers experienced in obtaining a sufficient supply of Daraprim for BE testing or obtaining an approved supplier of the API. He offers his opinion that the manufacturers' actions, not Vyera's conduct in restricting the

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In this case, there was an Import Alert in effect for a foreign manufacturer of pyrimethamine.

[6] These opinions are set out in sub-paragraphs 11(j)-(r), (t)-(x).

supply of Daraprim or FDA-approved API manufacturers, created the delays in the approval of their ANDAs. He testifies, for example, that manufacturers "either knew or should have known" that their applications for an exemption from FDA requirements "had essentially no chance of success." He opines repeatedly that manufacturers "should have known" that the FDA would reject their ANDAs or their various requests during the ADNA process. He also opines that certain requests not only had "essentially no chance of being approved" but also "delayed approval of the ANDA." Additionally, comparing the lengthy amount of time that it took for FDA approval of certain manufacturers' ANDAs (six years, more than four years, and nineteen months) to the relatively swift recent approval of a larger company's ANDA (seven months), Bradshaw expresses his opinion that the delay should be attributed to those manufacturers' unwillingness to commit "necessary resources" to meeting the FDA's regulatory requirements and not to Vyera's conduct.

Finally, Bradshaw offers the opinion that the FDA closely monitors compounded drugs (the "Compounded Drugs Opinion").[7] In giving this opinion, Bradshaw states his understanding that several entities were compounding pyrimethamine during the time

[7] According to Bradshaw, pharmacy compounding is a process that tailors a medication to individual patients.

that Vyera marketed Daraprim, and opines that this gave patients access to low-cost versions of the drug.

The body of Bradshaw's affidavit contains roughly ten pages describing the FDA ANDA approval process. Thus, the bulk of the affidavit is his summary of what he understands the generic drug companies did to obtain adequate supplies of Daraprim and pyrimethamine in order to win FDA approval of their generic competitor to Daraprim, and his opinion of what they should have done instead. Only a fraction of Bradshaw's restatement of record facts relates to the specifics of the FDA ANDA process.

In their motion, the Plaintiffs argue that much if not all of Bradshaw's testimony should be excluded. They first contend that Bradshaw is unqualified to give opinions not arising out of his FDA regulatory expertise, in particular opinions about the decision-making by generic drug companies, including their efforts to obtain Daraprim or the API pyrimethamine. They also argue that Bradshaw's testimony usurps the role of the factfinder by improperly summarizing evidence, opining on witness credibility, and opining on the FDA's state of mind. The Plaintiffs seek to exclude essentially all of Bradshaw's FDA Opinions and Generics Opinions as improper summary testimony, most of the Generic Opinions as beyond his expertise and as opinions on witness credibility, and some of the FDA Opinions as improper speculation on the FDA's state of mind. The Plaintiffs

also move to exclude the opinion comparing the times to FDA approval for the ANDAs pursued by generic manufacturers as not timely disclosed.

Discussion

Federal Rule of Evidence 702 governs the admissibility of expert testimony. The proponent of expert testimony carries the burden of establishing its admissibility by a preponderance of the evidence. United States v. Williams, 506 F.3d 151, 160 (2d Cir. 2007). The trial judge must first address "the threshold question of whether a witness is qualified as an expert by knowledge, skill, experience, training, or education to render his or her opinions." Nimely v. City of New York, 414 F.3d 381, 396 n.11 (2d Cir. 2005) (citation omitted). "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).

Even when an expert is qualified, it is the role of a district court to perform a "gatekeeping function" by ensuring that "an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." In re Mirena IUS Levonorgestrel-Related Prod. Liab. Litig. (No. II), 982 F.3d 113, 122–23 (2d Cir. 2020) (quoting Daubert v. Merrell Dow

Pharm., Inc., 509 U.S. 579, 597 (1993)). An expert's opinion must have "a reliable basis in the knowledge and experience of his discipline." Daubert, 509 U.S. at 592. Although Daubert set forth factors comprising indicia of reliability in some cases,[8] there is no "definitive checklist or test" for reliability, as there are "there are many different kinds of experts, and many different kinds of expertise." United States v. Romano, 794 F.3d 317, 330 (2d Cir. 2015) (quoting Kumho Tire Co. v. Carmichael, 526 U.S. 137, 150 (1999)). Accordingly, a district court has "broad discretion in determining what method is appropriate for evaluating reliability under the circumstances of each case." Amorgianos v. Nat'l R.R. Passenger Corp., 303 F.3d 256, 265 (2d Cir. 2002). A witness tendered on the basis of their experience "must show how his or her experience . . . led to his conclusion or provided a basis for his opinion." SR Int'l Bus. Ins. Co. v. World Trade Ctr. Properties, LLC, 467 F.3d 107, 132 (2d Cir. 2006).

Reliability alone, however, is not enough. An expert's opinion is relevant if it will "help the trier of fact to

[8] These factors are "(1) whether a theory or technique has been or can be tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) the technique's known or potential rate of error; (4) the existence and maintenance of standards controlling the technique's operation, and (5) whether the technique is generally accepted in the relevant scientific community." United States v. Jones, 965 F.3d 149, 159 (2d Cir. 2020) (citation omitted).

understand the evidence or to determine a fact in issue." Fed. R. Evid. 702; see Daubert, 509 U.S. at 591. "The role of an expert is not to displace the [trier of fact] but rather to provide the groundwork to enable the [trier of fact] to make its own informed determination." In re Methyl Tertiary Butyl Ether (MTBE) Products Liab. Litig., 725 F.3d 65, 114 (2d Cir. 2013) (citation omitted). Expert testimony assists the trier of fact "when it sheds light on activities not within the common knowledge of the average juror." United States v. Wexler, 522 F.3d 194, 204 (2d Cir. 2008) (citation omitted).

"Expert testimony that usurps the role of the factfinder or that serves principally to advance legal arguments should be excluded." Choi v. Tower Rsch. Cap. LLC, 2 F.4th 10, 20 (2d Cir. 2021). As a result, "expert opinions that constitute evaluations of witness credibility, even when such evaluations are rooted in scientific or technical expertise, are inadmissible under Rule 702." Nimely, 414 F.3d at 398. Similarly, it is not the role of an expert to advise the factfinder on the law, including law embodied in government regulations. United States v. Stewart, 433 F.3d 273, 311 (2d Cir. 2006). "An opinion that purports to explain the law to the [factfinder] trespasses on the trial judge's exclusive territory." Id. "[A]lthough an expert may opine on an issue of fact within the [factfinder's] province, he may not give

testimony stating ultimate legal conclusions based on those facts." United States v. Bilzerian, 926 F.2d 1285, 1294 (2d Cir. 1991).

The Plaintiffs make several arguments for excluding all or most of Bradshaw's testimony. Many of these arguments are interrelated and overlap. Thus, many passages in the affidavit are subject to more than one of these arguments.

A. Beyond His Expertise: Bradshaw's Opinions on RLD Sourcing and API Procurement

The Plaintiffs seek to exclude a significant portion of Bradshaw's testimony on the ground that he is unqualified to offer the opinions he tenders.[9] He is not an expert on the pharmaceutical business or that industry's business decisions but offers many opinions on those topics. Those opinions include judgments about the decisions the generic drug manufacturers made as they attempted to obtain samples of Daraprim and to find an API supplier, what they would have done if they had faced fewer obstacles in those efforts, and the reasons an API manufacturer had for declining to supply the API to those manufacturers.

[9] The testimony that the Plaintiffs seek to exclude is summarized in paragraphs 11(n), 11(o), 11(t), 11(u), and 11(x), and contained in paragraphs 38-41, 56-72, 76-81, 91-99, 102-111, and 115-131.

The Plaintiffs are correct that Bradshaw, an FDA regulation expert, is unqualified to offer opinions on the business decisions made by the generic drug manufacturers in pursuit of their ANDAs or by API suppliers. For example, Bradshaw's testimony ventures beyond his expertise when he opines that a manufacturer "wasted time and resources petitioning the FDA to reconsider its decision to require new BE testing, and that it did so because it did not want to incur the costs necessary to purchase new RLD and conduct new BE testing." As another example, he opines that that same manufacturer "could have purchased all five bottles of Daraprim RLD from [a certain supplier] and then immediately commenced BE testing, rather than ordering only three bottles and waiting eight months for FDA to act on its request to use a reduced number of RLD tablets in BE testing."

Because he has no expertise to support much of his testimony, his affidavit functions "as little more than a legal brief." See Choi, 2 F.4th at 20. His arguments should be advanced through cross-examination of witnesses or in counsel's summation.

The Defendants agree that Bradshaw is not an expert on the pharmaceutical industry. They argue, however, that he is offering opinions about the decisions made by the generic drug manufacturers from an FDA regulatory perspective. That framing

of his testimony does not save it. The above-described testimony does not arise from his expertise. His expertise is in the FDA regulatory process; it does not stem from the management of a generic drug company.

Bradshaw's affidavit describes a process in which the FDA staff reviews written submissions and requests in support of an ANDA. He describes himself as an expert in that process. To the extent that his affidavit offers opinions regarding the FDA's options in treating or reacting to a specific request to the FDA, that may be a proper subject of his expert testimony. For example, Bradshaw is qualified to opine on the factors that the FDA considers when granting exemptions to an Import Alert. Beyond that, his testimony must be stricken.

The Defendants next assert that two paragraphs in the identified testimony -- paragraphs 120 and 121 -- are admissible because Bradshaw is just expressing his criticism of another expert's testimony. These paragraphs contain the Defendants' attack on assumptions that underlie Hemphill's calculation of Vyera's excess profits. These arguments may be made by defense counsel. They are not admissible expert testimony from Bradshaw.

B. Bradshaw's Judgments on the Credibility, Motives, and State of Mind of Witnesses Associated with Generic Manufacturers

The Plaintiffs seek to exclude Bradshaw's testimony associated with the Generics Opinions on the ground that he improperly offers his evaluation of witness credibility, motives and state of mind.[10] Bradshaw's testimony in the challenged passages is replete with conclusory opinions, sweeping characterizations of the hidden motives of the businesses he discusses, judgments about the truthfulness of their representations, assertions of what they knew and should have known, and extensive recitation of the record urging a particular interpretation of the actions of these businesses.

This prong of the Plaintiffs' motion must also be granted. It is the role of the finder of fact to assess the credibility of witnesses and make findings, where relevant, regarding their motives and state of mind.

The Defendants do not disagree that their expert's testimony must be stricken to the extent it opines on these issues. Instead, they argue that Bradshaw is only offering his opinion about the effects on the FDA of decisions made by the ANDA applicants. This argument ignores much of the testimony

[10] The testimony sought to be excluded is summarized in paragraphs 11(k), 11(n), 11(o), 11(p), 11(s), and corresponds to paragraphs 56, 61, 70-71, 116-118, 123, 127, and 130.

offered by Bradshaw in the passages identified by the Plaintiffs. Again, to the extent Bradshaw offers opinions about the FDA's options in reacting to a specific request to the FDA, that testimony would be within his area of expertise and likely admissible.

C. Bradshaw's Opinions on the FDA's Hypothetical Conduct

The Plaintiffs seek to exclude portions of Bradshaw's testimony as improperly opining on the FDA's state of mind.[11] The Plaintiffs contend that any testimony offering an opinion on the FDA's hypothetical conduct in a counterfactual world (that is, a world without Vyera's challenged conduct) usurps the role of the factfinder and must be stricken as inadmissible speculation.

The Plaintiffs' motion on this ground is granted in part. At least some of Bradshaw's testimony on the FDA's conduct in the but-for world is admissible, however, since it arises from his area of expertise. He may, for example, testify that

> [T]he FDA approval process for generic drugs is complicated with many requirements that must be satisfied. Many variables impact the fact and timing of FDA approval and there is no reason to believe that either FDA's response to a pending application or the timing of such a response would have been the same if the applicant had used API from a different supplier.

[11] The Plaintiffs seek to exclude opinions summarized in paragraphs 11(a), 11(b), 11(s), 11(y), and that corresponds to paragraphs 18, 19, 104, 113, and 119.

Opinion testimony at this level of generality may not be terribly enlightening, but it is not inadmissible for that reason.

In some of the identified passages, however, Bradshaw presents an argument or opinion he is not qualified to offer (e.g. paragraphs 11(s) and 11(y), 104, 113, and 119), rather than an opinion he is qualified to offer. Thus, some of the material identified in this prong of the Plaintiffs' motion must also be stricken.

D. Bradshaw's Summary of the Record

The Plaintiffs seek to exclude the majority of Bradshaw's testimony as improper summary testimony.[12] Much of Bradshaw's testimony merely recounts facts in support of his views on matters beyond his expertise, or in support of an argument more appropriately made by counsel. For example, in order to criticize the manufacturer's strategic choices, Bradshaw narrates communications between the FDA and a generic manufacturer in its effort to obtain an Import Alert exemption.

The Plaintiffs' objection on this ground is granted. To the extent that Bradshaw offers an opinion that he is qualified

[12] The Plaintiffs' reply brief did not specify which paragraphs of Bradshaw's affidavit correspond to the passages in the June 4 report challenged in their motion. It appears that through this prong of their motion the Plaintiffs seek to exclude paragraphs 11(a)-(x) and corresponding paragraphs 38-102.

to make, explaining the record facts on which he relied to arrive at that opinion may provide necessary context and may also be admissible. But where the challenged passages purport to support opinions that must be excluded for the reasons explained above -- or support no opinion at all -- they must be excluded. In other words, Bradshaw's construction of a narrative of events untethered to any admissible opinion must be excluded.

The Defendants contend that Bradshaw's summary of facts is admissible since he is simply reciting "objective" facts. Objective or not, that is not the role of the expert. A naked recitation of facts usurps the role of the finder of fact.

E. Bradshaw's Opinion Comparing the FDA Approval Times of Generic Manufacturers' ANDAs

Finally, the Plaintiffs contend in their reply that paragraphs 11(w), 104, and 116 of Bradshaw's affidavit offer new opinions that were not included in his expert report. Supplements to expert reports must be disclosed during the discovery period. Fed. R. Civ. P. 26(e)(1)(A). Even if the cited paragraphs would otherwise be admissible, they may not be offered if not timely disclosed pursuant to Rule 26.

In sum, very little of Bradshaw's affidavit survives this motion. This is particularly true for subparagraphs 11(j) through (y) and the material from paragraph 37 to the end of the

affidavit. Even when a paragraph may have a kernel of an admissible opinion, that kernel is often embedded in material that must be stricken.

Conclusion

The Plaintiffs' motion is granted in part. A fraction of Bradshaw's affidavit survives this motion. The Defendants shall strike inadmissible material from Bradshaw's October 20 affidavit and conform it to these rulings. They shall provide the Plaintiffs by November 29, 2021, at noon with a copy of the redacted affidavit. The parties shall thereafter confer and bring any remaining dispute to the Court's attention by December 3 at noon.

Dated: New York, New York
November 16, 2021

DENISE COTE
United States District Judge