UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

BAYER HEALTHCARE LLC,
Plaintiff,

v.

JOHNSON & JOHNSON, INC. and JANSSEN BIOTECH, INC.,
Defendants.

26 Civ. 1479 (DEH)

OPINION AND ORDER

DALE E. HO, United States District Judge:

Before the Court is a Motion for a Preliminary Injunction (the "Motion") brought by Plaintiff Bayer Healthcare LLC ("Bayer"), seeking an order prohibiting Defendant Johnson and Johnson Inc. and its wholly-owned subsidiary Janssen Biotech, Inc. (collectively "J&J") from making allegedly false statements regarding a retrospective pharmaceutical comparison study. Both Bayer and J&J are in the market for a drug used in the treatment of metastatic castration-sensitive prostate cancer. In a presentation and a press release, J&J purported to describe the results of a retrospective observational study (the "Study") that purports to show a roughly 50% reduction in the risk of death for patients prescribed its drug, apalutamide (branded as ERLEADA®), compared to Bayer's drug, darolutamide (branded as NUBEQUA®). Bayer alleges that, among other things, severe methodological flaws in the Study render J&J's claims regarding the relative risk of death for patients receiving the two treatments to be literally false or false by necessary implication, in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a)(1), and New York state law.

Upon careful review of the voluminous submissions from the parties, including 22 declarations from medical and statistical experts, and after a two-day hearing at which 13 of those witnesses testified, the Court concludes that Bayer has failed to establish a likelihood of success

on the merits warranting preliminary injunctive relief. As described herein, the Court finds that the record fails to show methodological errors in the Study that are so substantial as to make J&J's representations regarding the Study's findings materially false (or even misleading) in violation of the Lanham Act. The Court also finds that the communications at issue accurately represent the Study's conclusions, and that they adequately disclose the Study's methodologies and their attendant limitations. Accordingly, the Court concludes that Bayer has failed to meet its burden for preliminary injunctive relief. Its Motion is therefore **DENIED**.

PRELIMINARY FINDINGS OF FACT

"On a motion for preliminary injunction, if essential facts are in dispute, there must be a hearing and appropriate findings of fact must be made." *Nat'l Union Fire Ins. Co. of Pittsburgh, PA v. Stucco Sys., LLC*, 289 F. Supp. 3d 457, 463 (S.D.N.Y. 2018).[1] "After the evidentiary hearing is conducted, pursuant to Federal Rules of Civil Procedure 52(a) and 65(d), the Court is required to set forth the findings of fact and conclusions of law which support its order." *Telebrands Corp. v. Guangzhou Alpaca Home Furnishing Co.*, No. 25 Civ. 3646, 2025 WL 1591970, at *2 (S.D.N.Y. June 5, 2025) (citing *Republic of Philippines v. N.Y. Land Co.*, 852 F.2d 33, 37 (2d Cir. 1988)). Based on the hearing testimony, the Complaint, the Application, the Opposition, the Reply, and all declarations and exhibits attached thereto, the Court makes the following preliminary findings of fact.

I. Background

The Court begins with brief background information regarding the treatment of metastatic castration-sensitive prostate cancer (mCSPC), which is a particular category of prostate cancer that

[1] All references to Rules are to the Federal Rules of Civil Procedure. In all quotations from cases, the Court omits citations, alterations, emphases, internal quotation marks, and ellipses, unless otherwise indicated.

is both (1) metastatic and (2) castration-sensitive. When cancer that originates in the prostate gland spreads to other parts of the body, it is considered "metastatic." Andres Decl. ¶ 6, ECF No. 8. Because prostate cancer originates in the prostate, its growth is typically stimulated by exposure to male hormones, particularly testosterone. *Id.* ¶ 7. Thus, reduction of testosterone—otherwise termed as "castration"—helps reduce tumor growth and spread. *Id.* ¶¶ 7-9. However, in advanced stages, prostate cancer can become resistant to castration efforts, such that there is a delineation between "castration-sensitive" and "castration-resistant" prostate cancers. *Id.* ¶ 10. This case concerns mCSPC: metastatic castration-sensitive prostate cancer—i.e., prostate cancer that has spread to other parts of the body but still responds to reductions in testosterone levels.

There are three common therapies prescribed for the treatment of mCSPC: (1) chemotherapy (most commonly, docetaxel), (2) Androgen Deprivation Therapy (ADT), which is hormone therapy used to reduce testosterone in the body, and (3) Androgen Receptor Inhibitors (ARIs), which block androgen receptors on cancer cells, "preventing those cells from connecting to androgen, their food source." *See* Morris Decl. ¶¶ 19-22, ECF No. 47. "Triplet" therapy involves the use of all three treatments; when an ARI and ADT are used without chemotherapy, it is referred to as "doublet" or "couplet" therapy. *Id.* ¶ 23.

Bayer, J&J, and Pfizer are three pharmaceutical manufacturers that compete in the lucrative market for ARIs. Dinello Decl. ¶¶ 5-6, ECF No. 13. Pfizer's XTANDI® (enzalutamide) has the greatest U.S. market share; Bayer's NUBEQA® (darolutamide) has the second largest; and J&J's ERLEADA® (apalutamide) is third. *Id.* Over the last few years, NUBEQA has yielded billions of dollars in global sales for Bayer. Tr. 258:15-23 (Dinello Direct); PX-71 ¶ 10; PX-80 ¶ 4; PX-11. And Bayer offered testimony that ARIs are mutually exclusive alternatives, such that a gain in market share for one drug necessarily results in a loss in market share for a competitor. Tr. 243:5-15 (Dinello Direct); PX-71 ¶¶ 4-5, 11; PX-80 ¶ 10.

Doctors often rely on the results of clinical studies in making treatment decisions for their patients. *See* ECF No. 42 ¶¶ 35, 43-44. As far as the Court is aware, there have been no randomized clinical trials comparing the efficacy of darolutamide and apalutamide for the treatment of mCSPC in doublet form—that is, without chemotherapy. As a result, J&J undertook a retrospective, observational study comparing patients prescribed each drug in the doublet therapy context, and the resulting treatment outcomes. Tr. 365:16-366:11 (Morrow Direct); DX-156A at 3. While the full Study has not yet been publicly released, J&J presented the results of the Study at a conference for prostate cancer specialists in Vail, Colorado earlier this year—the International Prostate Cancer Update ("IPCU")—as well as in a press release. DX-155 at 10; ECF No. 51 ¶¶ 48-52; Tr. 51:8-52:5 (Andres Cross); DX-154 ¶ 52; DX-156; DX-158.[2]

The topline conclusion of the Study is striking. According to J&J, the Study showed a 51% relative risk reduction in death over a two-year period for J&J's apalutamide compared to Bayer's darolutamide when used in doublet form to treat mCSPC. ECF No. 51 ¶¶ 42-43; DX-156A at 5. Bayer immediately objected to J&J's use of the results in any communications and issued a press release of its own, claiming the Study was "flawed." DX-4; DX-9; DX-10; DX-11; Tr. 285:18-288:1 (Dinello Cross). When attempts to reconcile their differences of opinion on the validity of the Study's results failed, Bayer brought suit in this Court, alleging that J&J made false statements in violation of the Lanham Act. *See* Compl., ECF No. 1.

Given the relevant legal framework, the Court must characterize both the statements made and the alleged underlying methodological flaws. The parties agree that J&J made statements concerning the Study results in at least three forms: (1) the presentation at the IPCU conference in

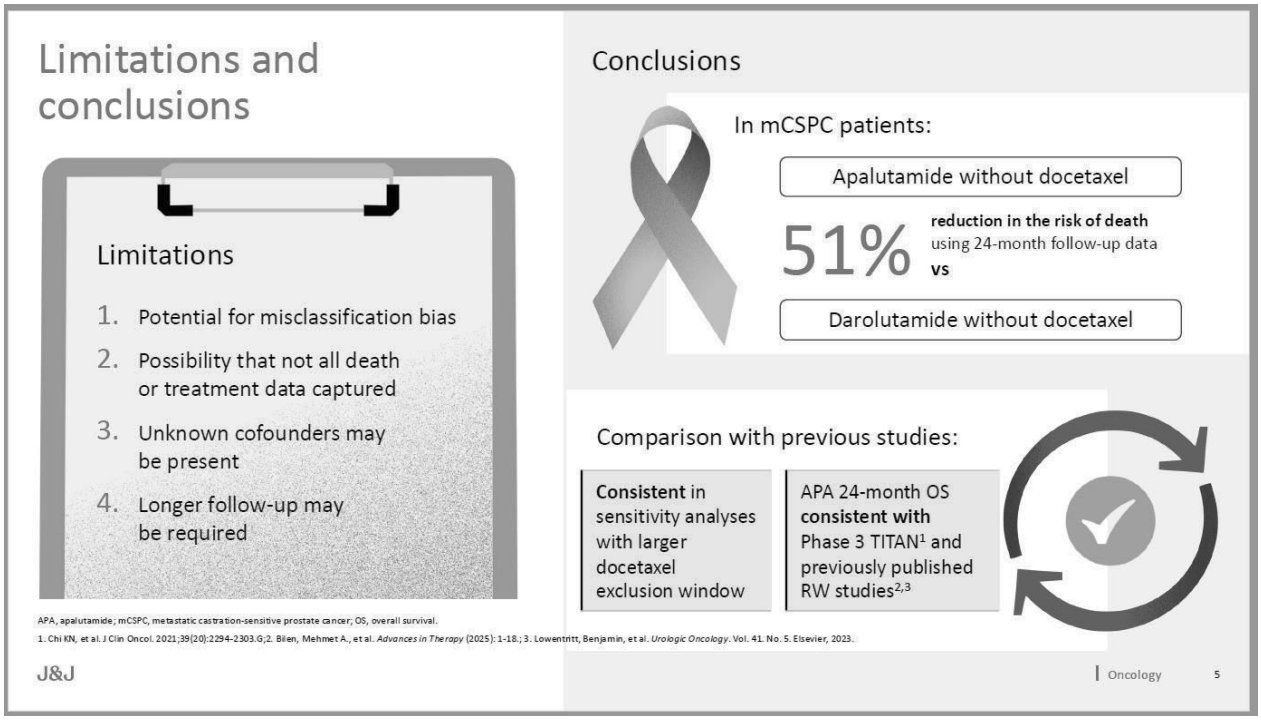
[2] Bayer also alleges that J&J has used the Study's results in advertisements targeted at prescribing doctors across the country, but those communications are not directly at issue on the merits of this Motion.

Vail, including a set of PowerPoint slides; (2) the placement of the presentation on J&J's Medical Connect website, including an "overview" slide; and (3) a press release in PR Newswire, a commercial wire distribution (collectively, the "challenged communications"). DX-156A; DX-157A; ECF No. 45 ¶¶ 3-10. The presentation included an abstract of the unpublished Study and a set of PowerPoint slides describing the results. A recording of the actual presentation is also available online, so long as an individual checks a box indicating they are a doctor or payer. PX-19; Tr. 248:9-249:16 (Dinello Direct); Tr. 201:21-202:16 (Morris Cross); Tr. 402:17-404:25, 405:24-406:20 (Morrow Cross).

The Presentation includes six PowerPoint slides as well as an overview slide. Bayer alleges that the PowerPoint made the following representations about the Study:

1. The Data Analysis looked at two groups of patients with mCSPC: an apalutamide cohort and a darolutamide cohort. Characteristics about the patients were identified through two databases: the Precision Point Specialty Analytics Database and the Komodo Research Claims Database.
2. After some patients were excluded based on three selected exclusion criteria, the apalutamide cohort totaled 1,460 patients, and the darolutamide cohort totaled 287 patients. 456 patients in the apalutamide cohort and 87 patients in the darolutamide cohort remained at risk at 24 months.
3. The "Results" of the Data Analysis showed that, "Through 24 months: Apalutamide demonstrated ↓ 51% reduction in risk of death."
4. The Data Analysis concluded that mCSPC patients taking apalutamide without docetaxel have a 51% reduction in the risk of death using 24-month follow-up data relative to mCSPC patients taking darolutamide without docetaxel.
5. One of the Data Analysis "Limitations" was that "[u]nknown cofounders [sic] may be present."
6. The "Study Period" was "01/01/2016-06/30/2025," but the earliest date patients were first prescribed treatment was August 5, 2022.

Mem. of Law in Supp. of Mot. for Prelim. Inj. at 10-11 ("Mot."), ECF No 7. The PowerPoint also included a "limitations and conclusions" slide, shown below.



Morrow Decl. Ex. 2 at 6, ECF No. 51-2; PX-2. The left-hand side of the limitations and conclusions slide identified four potential limitations of the Study:

1. the "[p]otential for misclassification bias";

2. the "[p]ossibility that not all death or treatment data [were] captured" in the databases;

3. the possibility that "[u]nknown confounders" not controlled for "may be present";

4. and the possibility that "[l]onger follow-up may be required."

PX-2 at 5.

Separate from the PowerPoint, the presentation also included an "overview" slide, which is similarly published online. That slide posed a series of questions, answers, and broader claims including:

1. What do these results mean for individuals with metastatic castration-sensitive prostate cancer (mCSPC)?

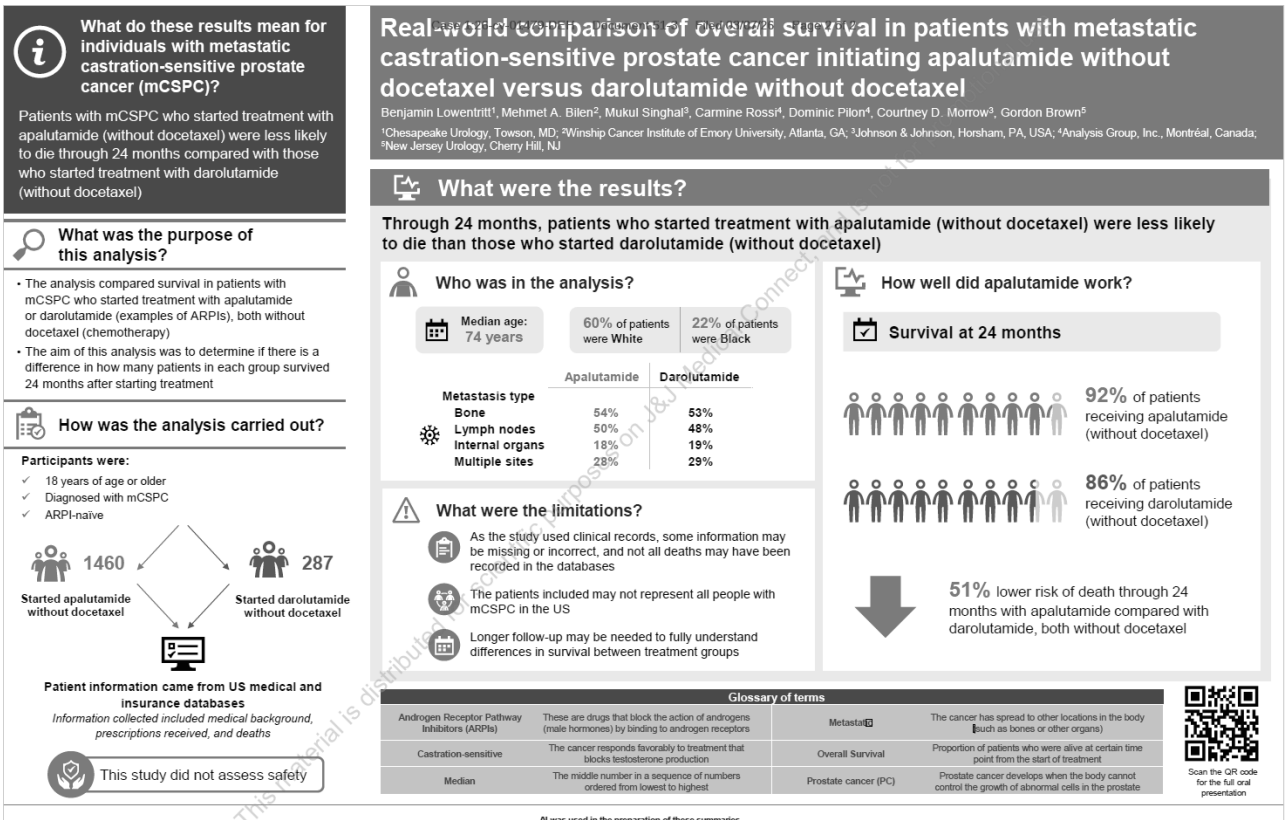
> Patients with mCSPC who started treatment with apalutamide (without docetaxel) were less likely to die through 24 months compared with those who started treatment with darolutamide (without docetaxel).

2. The aim of this analysis was to determine if there is a difference in how many patients in each group survived 24 months after starting treatment.

3. How well did apalutamide work?

> With a large red downward arrow, 51% lower risk of death through 24 months with apalutamide compared with darolutamide, both without docetaxel.

Mot. at 11; Mem. of Law in Opp. to Mot. for Prelim. Inj. ("Opp.") at 8, ECF No. 40; PX-3. The full slide is shown below.



Morrow Decl. Ex. 3, ECF No. 51-3; PX-3. The center column of the overview slide notes three limitations of the Study:

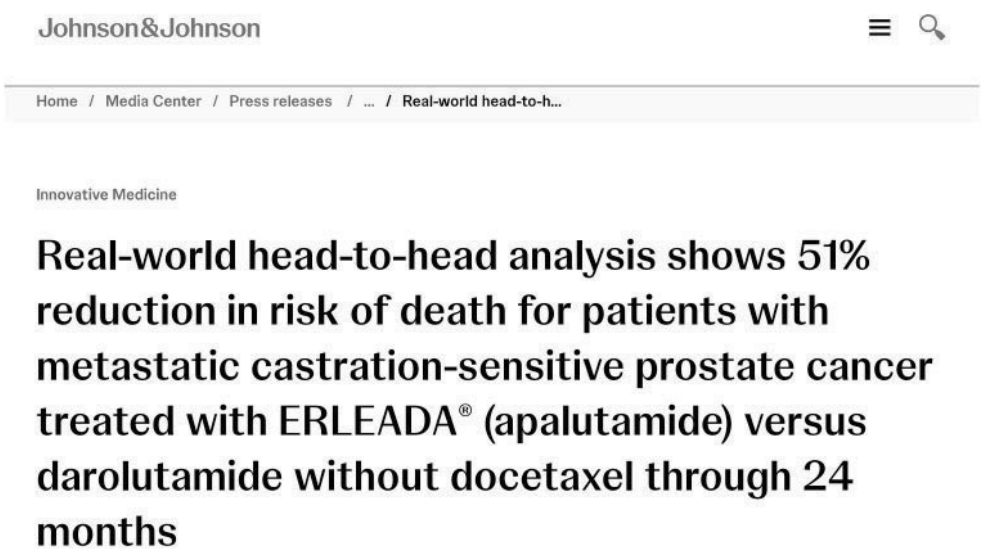
> As the study used clinical records, some information may be missing or incorrect, and not all deaths may have been recorded in the databases

The patients included may not represent all people with mCSPC in the US

Longer follow-up may be needed to fully understand differences in survival between treatment groups

PX-3.

Turning to the press release, in what Bayer calls "big bold letters," J&J titled the release, "Real-world head-to-head analysis shows 51% reduction in risk of death for patients with metastatic castration-sensitive prostate cancer treated with ERLEADA® (apalutamide) versus darolutamide without docetaxel through 24 months." Neuner Decl. Ex. A, ECF No. 17. The headline is shown below:



PX-1. Within the release, J&J made several other claims regarding the Study, including:

1. The Data Analysis was the "first ever head-to-head analysis [that] compares overall survival outcomes of ERLEADA® versus darolutamide."

2. The Data Analysis "demonstrat[es] that patients with [mCSPC] initiating ERLEADA® without docetaxel experienced a statistically significant 51 percent reduction in the risk of death compared to those who initiated on darolutamide without docetaxel through 24-months of follow up . . . ."

3. The Data Analysis "provid[ed] comparative effectiveness evidence."

4. "These real-world data show the survival benefit of apalutamide versus darolutamide in patients with mCSPC" and were the result of "using rigorous methodology to support clinical decision-making."

5. The "methodological safeguards [of the Data Analysis] deliver robust, reproducible insights" and the "real-world findings" from the Data Analysis "adhere to the rigorous standards set by the U.S. FDA."

6. The methodology used in the Data Analysis "remov[ed] bias from measured confounders and replicat[ed] the conditions of a randomized clinical trial."

Mot. at 9-10.

Bayer argues that various statements made in the challenged communications, including that apalutamide patients had a 51% lower death rate than darolutamide patients, are literally false or false by necessary implication. Mot. at 16. Bayer's arguments fall into two categories.

First, Bayer contends that J&J's statements that there was a lower risk of death for patients taking apalutamide are false due to several alleged methodological flaws in the Study. These purported flaws, explained in greater detail below, include: (1) possible differences in the treatment cohorts, stemming from the fact that the use of darolutamide in doublet form was "off-label" for much of the Study period; (2) the inadequacy of the statistical controls employed by J&J to account for differences between the treatment cohorts; (3) the low quality of the data sources on which the Study was based; and (4) the inaccuracy of J&J's method of calculating the relative risk of death among the treatment cohorts (the "hazard ratio").

Second, Bayer also claims that the challenged communications misrepresent the Study's methodology and results in various ways, including by: (1) overstating the Study's findings regarding the relative risk of death between the two treatment cohorts, by describing the Study's results as showing a 51% difference in the risk of death; (2) using the word "reduces" to ascribe a causal relationship between the drugs in question and the observed differences in death rates between the two treatment cohorts, when the Study could not provide actual evidence of causation;

(3) falsely claiming that the Study involved a period of "24 months" total of follow-up for all patients, when many patients in the Study were actually followed for a shorter time period; and (4) falsely describing the Study as "replicating" the conditions of a clinical trial, when it could not do so.

As expected, J&J disagrees on each of the above points. The parties presented expert testimony and declarations regarding each of the asserted methodological flaws in the Study and alleged misrepresentations in the communications, as described below.

II. Alleged Methodological Flaws in the Study

Bayer presented testimony that attempted to show that the Study suffered from severe methodological flaws and was based on unreliable or erroneous data. Rather than going witness by witness, the Court summarizes the testimony on both sides relating to each critique. As explained below, after carefully considering the testimony in the current record, the Court ultimately finds that Bayer has failed to show that J&J's study is methodologically flawed.

A. Possible Sources of Bias

Bayer first notes that, until June 2025—that is, just before the conclusion of the Study—darolutamide had been approved for use only in the context of triplet therapy. Tr. 29:21-30:4 (Andres Direct); PX-71 ¶¶ 5-6; PX-77 ¶ 13. This means that, for 97% of the data analysis period, darolutamide had not yet been approved specifically for use in the context of doublet therapy—meaning that its use in that context was considered "off-label." Tr. 200:13-16 (Morris Cross); Tr. 413:13-414:8 (Morrow Cross); PX-69 ¶ 9. Thus, for the vast majority of the time period of the Study, the comparison was between *on-label* apalutamide and *off-label* darolutamide, potentially inserting a source of bias in the Study's results. DX-40 at 1, 7.

Bayer offered two reasons why a doublet therapy patient might have received darolutamide off-label. First, various witnesses testified that doctors would generally prescribe a drug off-label

only when patient-specific issues warranted avoidance of the on-label options already on the market. Tr. 37:4-18, 83:12-84:1 (Andres Redirect); Tr. 334:7-16, 342:23-24 (Vassilev Direct); Tr. 88:2-10 (Constantinovici Direct); Tr. 116:22-117:6 (Constantinovici Cross); Tr. 174:14-23, 176:3-8 (Morris Direct); Tr. 193:5-195:2 (Morris Cross). They testified that doctors would likely have prescribed off-label darolutamide as opposed to on-label apalutamide when patients presented with conditions such as seizure history, fall and fracture risk, independent treatment with anticoagulants, general frailty, or other comorbidities. *See, e.g.*, Tr. 193:5-21 (Morris Cross); Tr. 499:16-500:3 (Drake Direct). This is because apalutamide's common side effects are associated with worsening these conditions, while darolutamide does not have such effects, making the benefits of reduced side effects for patients predisposed to these conditions worth the uncertainty associated with taking darolutamide off-label. Tr. 37:4-18 (Andres Direct); Tr. 83:12-84:1 (Andres Cross); Tr. 334:7-16, 342:23-24 (Vassilev Direct); Tr. 88:2-10 (Constantinovici Direct); Tr. 116:22-117:6 (Constantinovici Cross); Tr. 174:14-23, 176:3-8 (Morris Direct); Tr. 193:5-195:2 (Morris Cross). In Bayer's view, each of these conditions is associated with a higher risk of death, creating a bias in the respective study populations, which predisposed the darolutamide cohort to higher mortality.

Second, testimony in the record also indicated that doctors prescribed darolutamide to patients who were seen as possibly needing chemotherapy at some point—but that some such patients ultimately did not undergo chemotherapy for some reason and therefore remained classified as "doublet" patients. Because darolutamide is considered by at least some doctors to be the better treatment option for patients receiving docetaxel, patients who doctors thought might need chemotherapy at some point down the road were more likely to be put on darolutamide. *See* Tr. 195:1-2, 196:13-22 (Morris Cross). Bayer argued that such patients were likely to be suffering

from a more advanced disease or otherwise more frail, thus introducing further bias in the respective study populations. Tr. 538:16-539:9 (Bayer Summation).

J&J's experts countered this testimony in several ways. For example, J&J put on evidence that darolutamide, although off-label for doublet therapy during much of the Study period, was prescribed on a widespread basis in doublet form during that time. Tr. 171:8-173:1 (Morris Direct); *compare* DX-270 at 29-30 *with* DX-160 at 29-30 (showing same prescribing recommendation for darolutamide for doublet use before and after FDA approval). Indeed, Bayer's own publications described darolutamide as being used "ubiquitously" in both doublet and triplet therapy, despite its off-label status in the former context at the time. DX-40. J&J also provided evidence that the fact that a doctor prescribed a patient darolutamide based on the possibility of chemotherapy down the road did *not* necessarily suggest that the patient was sicker or more frail because, generally speaking, patients must have a baseline level of health to receive chemotherapy. *See* Tr. 213:1-19 (Morris Redirect); 532:5-13 (Drake Redirect). As Dr. Morris explained, the physical toll of a docetaxel regimen can only be survived by patients of sufficient strength. Tr. 213:1-19 (Morris Redirect). In other words, the fact that a patient was marked for the possibility of chemotherapy, and then received darolutamide as a consequence, did not necessarily suggest that the patient was older or otherwise less healthy. *See id.*

J&J also presented testimony that their statistical controls, explained in more detail below, adequately accounted for any potential bias from differences in the treatment cohorts, by controlling for age and other comorbidities. Tr. 384:2-385:6 (Morrow Direct); Tr. 445:25-446:22 (Gibbons Direct). And Bayer's experts admitted that their criticisms regarding the treatment cohorts were essentially hypothetical, because they had no empirical data showing that off-label darolutamide doublet patients were sicker, more frail, or more likely to have non-cancer co-morbidities than on-label apalutamide patients. *See, e.g.*, Tr. 228:4-229:5 (Sullivan Cross).

The Court finds that, at least at this stage, Bayer has failed to show that among mCSPC patients in doublet therapy, those receiving off-label darolutamide were sicker in some unmeasured way than those receiving apalutamide on-label. The Court credits the testimony that darolutamide was often prescribed throughout the Study period in doublet form despite its off-label status at that time. While Bayer's experts presented a plausible hypothesis that, during the Study period, mCSPC doublet therapy patients receiving darolutamide off-label were likely to have more underlying comorbidities than those who received apalutamide on-label, Bayer failed to present any empirical data supporting its supposition in this regard. And while Bayer's experts also presented evidence that chemotherapy may be associated with more severe mCSPC, J&J presented evidence from several experts that individuals who are candidates for triplet therapy are not necessarily sicker or more frail. As with Bayer's other hypothesis about differences between the treatment cohorts, there is no empirical evidence in the record to support its supposition that the potential use of chemotherapy would signal that a patient was more likely to die during the Study period.

Based on the above, the Court finds that Bayer has failed to establish that the cohorts receiving the different ARIs in the Study differed in such a way that the results would be biased.

B. Alleged Inadequacy of Statistical Controls

Separate from potential sources of bias in the respective cohorts, Bayer also challenges the methodology used by the Study to control for population imbalances, known as Inverse Probability of Treatment Weighting (IPTW). Gibbons Decl. ¶ 14, ECF No. 49. IPTW seeks to control for imbalances in cohorts by applying statistical weighting of individuals within cohorts to balance populations. Tr. 382:12-18, 386:22-389:10 (Morrow Direct); Tr. 439:1-5 (Gibbons Direct); Tr. 470:25-472:6 (Malone Direct). Bayer's witnesses testified that, in the context of this study, IPTW was insufficient to capture potential confounders between the respective cohorts. Tr. 219:19-

220:21 (Sullivan Direct); Tr. 100:10-103:3 (Constantinovici Direct); Tr. 44:15-45:3 (Andres Direct); Tr. 336:14-338:3, 343:15-344:19 (Vassilev Direct).

Bayer first critiqued the use of Quan-Charlson Comorbidity Index (Quan-CCI) scores to capture potential comorbidities in the respective treatment populations. Tr. 219:19-220:21 (Sullivan Direct); Tr. 100:10-103:3 (Constantinovici Direct); Tr. 44:15-45:3 (Andres Direct); Tr. 336:14-338:3, 343:15-344:19 (Vassilev Direct). Quan-CCI scores assign points for certain medical conditions that are associated with a likelihood of death in the coming year, e.g., a score of 2 for prostate cancer and a score of 6 for metastatic cancer. Tr. 101:14-22 (Constantinovici Direct). Bayer's witnesses testified that these scores offer only limited ability to control for comorbidities across study populations. For example, Quan-CCI scores award points only in binary fashion for various measured medical conditions based on whether a particular condition is present or absent. Tr. 101:5-7 (Constantinovici Direct). In Bayer's view, while such scores may identity the presence of certain underlying conditions, they do not account for the *severity* of such conditions, and therefore insufficiently control for potential population comorbidities. Tr. 102:12-14 (Constantinovici Direct). Bayer's witnesses also noted that, here, the Quan-CCI scores across the two cohorts after weighting measured, on average, more than 10 points, which, in Bayer's view, suggested that the population receiving darolutamide was inherently sicker. Tr. 119:3-16 (Constantinovici Cross). Bayer's witnesses also emphasized that these scores could only account for measured comorbidities, leaving unmeasured potential confounders uncontrolled for. Tr. 219:2-3 (Sullivan Direct). Lastly, Bayer also put on testimony that critiqued the use of different sized population cohorts. When cohort sizes are imbalanced—here, 1,460 in the apalutamide cohort as compared to only 287 in the darolutamide cohort (a 5:1 ratio)—IPTW must assign

extreme weights to match the smaller cohort to the larger, which can compound distortions if there are unmeasured confounding variables.[3] Tr. 319:7-25 (Ennis Cross).

J&J countered this testimony in several ways. It first noted that Bayer had put on no evidence that any potential confounding variable existed, and Bayer's witnesses admitted that they were essentially hypothesizing that such a methodological problem *might* have biased the results. *See, e.g.*, Tr. 67:15-68:5 (Andres Cross); Tr. 110:24-115:18 (Constantinovici Cross); Tr. 228:13-229:8 (Sullivan Cross); ECF No. 8 ¶ 15 (patients in the NUBEQA® cohort "could have had issues" with competitor drugs); ECF No. 16 ¶ 9 (uncontrolled differences "can" impact results). J&J also presented evidence concerning the informative value of the Quan-CCI score in terms of predicting mortality. While J&J's experts acknowledged that "it is impossible" to control for unmeasured confounders without a randomized control trial, Tr. 385:7-14 (Morrow Direct)—and indeed, the conclusions slide of the PowerPoint acknowledged the possibility of unknown confounders, *see* PX-2 at 5—J&J's experts explained the effectiveness of IPTW in balancing the cohorts across nearly every measured variable.[4] Tr. 386:5-389:10 (Morrow Direct). While the Quan-CCI score treats the presence of a particular condition in binary fashion (i.e., present or absent), it assigns different point values to different conditions. Tr. 450:19-451:8 (Gibbons Direct). J&J also obtained admissions that Bayer's experts themselves had used IPTW with Quan-CCI scores in their past retrospective studies to control for possible confounding differences among treatment

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[3] Bayer also contends that the imbalance in cohort sizes was an independent methodological flaw but provided no evidence or argument for why the size of the cohorts alone would bias results beyond the additional weight given to individuals in the smaller cohort.

[4] J&J also explained that researchers used 95%-trimming to ensure that extreme outliers on any particular variable did not bias results. Tr. 452:5-11 (Gibbons Direct) ("Q: So it's literally impossible that the criticism of outlier patients affecting the final results, that's mathematically impossible here, that's your opinion? A: To the extent that the 95th percentile is not an outlier, and of course it isn't. It is nowhere near what could be a truly extreme value of a propensity score that either goes to 0 or 1.").

cohorts, undermining the credibility of the stated critiques. *See, e.g.*, Tr. 70:10-71:14 (Andres Cross). J&J further noted that the Study controlled for many variables beyond Quan-CCI—such as Gleason score, Prostate-Specific Antigen (PSA) level, type of metastasis, and ADT use—that are all "measured indicators, valid indicators of the severity of their illness" that closely correlate with patient health status. Tr. 445:9-24 (Gibbons Direct).

Lastly, J&J put on unrebutted statistical testimony that demonstrated the unlikelihood that an unmeasured confounder exists here. One of their experts, Dr. Gibbons,[5] presented an E-value analysis, which indicated the necessary magnitude of an unmeasured confounder "to explain away the [51%] observed difference found in the study." Tr. 447:5-8 (Gibbons Direct). The E-value here of 3.5 here is "enormous," meaning that, for any unmeasured confounder (or set of such confounders) to "explain away" the observed difference across cohorts, it would have to *simultaneously* make a patient 350% more likely to receive darolutamide *and* 350% more likely to die. Tr. 447:20-448:3 (Gibbons Direct); Gibbons Decl. ¶ 34, ECF No. 49. To illustrate the point, Dr. Gibbons testified that the E-value here is significantly larger than that for heart disease and smoking. In his essentially unchallenged opinion, this makes it implausible that unmeasured confounders alone account for the resulting associated benefit of apalutamide relative to darolutamide. Tr. 448:12-16 (Gibbons Direct).

The Court credits the testimony of J&J's experts, including Dr. Gibbons, and preliminarily finds that the balancing methods used by researchers in the Study were properly executed and unlikely to have biased results through the failure to capture unmeasured confounders. Bayer's

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[5] Dr. Gibbons is a professor of biostatistics and medicine at the University of Chicago who has taught and published in biostatistics for over 40 years. Tr. 438:9-25 (Gibbons Direct). He has published extensively in the Journal of American Medical Association (JAMA) and other leading journals using propensity score and IPTW methodology and has served on FDA advisory committees. *Id.*; Tr. 452:11-12 (Gibbons Direct).

experts failed to demonstrate that the use of IPTW or Quan-CCI scores would not account for possible bias in the underlying results of the Study. Furthermore, Bayer's use of the same methodology for its own retrospective studies undermines the credibility of its experts who lodged this criticism.[6] The Court also finds Bayer's failure to even attempt to rebut Dr. Gibbons' E-value analysis to weigh heavily in favor of the validity of the Study's overall conclusion as to a lower risk of death among apalutamide patients. Accordingly, the Court affords little weight to Bayer's critiques of J&J's weighting methods.

C. Data Limitations (PPS, Komodo, and Manual Verification)

As a next attack, Bayer criticized the underlying data sources used in the Study. Here, J&J linked two sources of data: PPS (Precision Point Specialty), a clinical urology database that pulls electronic medical records from clinical practices, and the Komodo research database, which was described by Bayer as "a verified, adjudicated, and de-identified administrative claims dataset covering >140 million individuals from >150 US private insurance providers," and "contain[ing] mortality data from several sources, including claims or other mortality data sources, with 92% matching the death data reported by the Centers for Disease Control and Prevention in the year following 2017." Morris Decl. ¶ 97; DX-156A at 4; Tr. 372:11-373:6 (Morrow Direct).

Bayer's experts explained that the PPS data contain significant errors. For example, in one Bayer study, as many as 40% of patients that initially appeared to be eligible to be included in the study based on PPS data were, in reality, ineligible once researchers examined the patients' underlying charts. Tr. 93:23-95:9 (Constantinovici Direct). Bayer argued that chart verification

[6] This includes Dr. Richard Andres, who had no explanation for why this methodology was appropriate in a study he co-authored for Bayer but was supposedly unreliable in the Study here, *see* Tr. 66:20-67:14 (Andres Cross), as well as Dr. Zdravko Vassilev, who similarly used the same methods that he critiques in this case, *see* Tr. 347:12-348:9 (Vassilev Cross).

is therefore necessary for the reliable use of PPS data. Bayer also attacked J&J's use of the Komodo research database to perform a similar method of data verification as insufficient, as an insurance claims database might not include all of the relevant patient treatment information, particularly information on whether patients received docetaxel (and thus, were in triplet rather than doublet therapy, and consequently should not have been included in the Study). *See* Tr. 221:8-10 (Sullivan Direct) (noting that Komodo contains "very limited clinical information").

To rebut Bayer's attacks on the underlying data verification, J&J again noted that Bayer has used the same datasets in the same way in their own retrospective studies on multiple occasions. *See* DX-40 at 3 (PPS); DX-41 at 2 (PPS); DX-48 at 3 (Komodo); DX-52 at 2 (Komodo); DX-57 at 3 (Komodo). In any event, both the conclusions slide of the PowerPoint and the overview slide acknowledged the possibility of data errors, *see* PX-2 at 5 (acknowledging possible "misclassification bias" and "that not all death or treatment data [were] captured]), PX-3 (acknowledging that, because "the study used clinical records, some information may be missing or incorrect"). But J&J's witnesses testified that linking the Komodo research database to PPS data is not only an acceptable practice but encouraged under relevant research guidelines. Tr. 472:15-473:2 (Malone Direct). Moreover, J&J's experts explained that the errors in PPS data that impacted Bayer's study would not have the same effect here. That is because PPS data records contain an affirmative code that a patient's cancer is metastatic, but no code that it is non-metastatic. Tr. 185:16-186:1 (Morris Direct). In Bayer's study, researchers found errors where doctors had failed to affirmatively code metastatic patients in PPS data, such that relying on the absence of that code to identify non-metastatic patients for Bayer's study would have resulted in the erroneous inclusion of certain patients as "non-metastatic" who were, in fact metastatic. But because the "metastatic" code must be affirmatively selected, anyone whose cancer was coded as metastatic in PPS records would be expected to have metastatic cancer, and thus would meet this

Study's selection criteria. Tr. 186:3-24 (Morris Direct). The erroneous inclusion problem from Bayer's study would therefore not present an issue here.[7]

The Court finds that Bayer failed to demonstrate the inadequacy of the data validation method used in the Study. Bayer's use of the same method in its own research is again an indictment of its criticism here. And while Bayer hypothesized that the Komodo research database might be insufficient to address underlying flaws in the PPS data, it presented no empirical evidence that this was the case, such as research demonstrating that the Komodo database was less accurate than are patient charts for purposes of validating the PPS data. Tr. 541:5-542:5 (Bayer Summation). Bayer also failed to rebut J&J's explanation for why PPS data entry errors were unlikely to prevent accurate identification of metastatic patients for inclusion in the Study. Accordingly, the Court again finds that Bayer's assertions of flaws in the Study data associated with using the PPS and Komodo research databases are unsupported by the record.

D. Results Reporting (Hazard Ratios)

As a final attack, Bayer alleges that the reporting of an overall hazard ratio for the entire Study period was likely to provide an inaccurate picture of the underlying association between drug treatment and mortality. A hazard ratio is generally accepted as the standard method of reporting comparative survival results for oncology studies. Tr. 441:12-14 (Gibbons Direct). The measured ratio here is 0.49, meaning a patient being treated with apalutamide was 0.49x as likely to die during the observed period as a patient receiving darolutamide. Tr. 441:6-8 (Gibbons

[7] This does, however, raise the potential question whether some patients were erroneously *excluded* from the Study. That is—if some metastatic patients are not affirmatively coded as such in the PPS data, they may have been erroneously excluded from the Study (assuming that validation through the Komodo database was not successful in identifying such patients for inclusion). In any event, J&J did not argue, let alone put on evidence, that the erroneous exclusion of some metastatic patients might have actually biased the Study's results, and so the Court does not consider this question.

Direct). Thus, the Study's top line result stated a 51% reduction in the risk of death between the cohorts, "another way of saying the same thing." Tr. 441:3-8 (Gibbons Direct).

Bayer does not contest the use of hazard ratios generally; rather, it argues that the use of a hazard ratio here, as calculated over the 24-month Study period, is inappropriate. Because a hazard ratio presents a single measurement for the entire period, where outcomes may differ over time, a hazard ratio may over- or understate the likelihood of an event at a given moment. Ennis Aff. ¶ 9, ECF No. 14 ("*[i]f* hazards vary substantially at different stages … then a single summary hazard ratio *may* obscure meaningful differences"). Bayer theorized that sicker, close to death patients received darolutamide and then died fairly quickly, resulting in a long-term hazard ratio that overstates the difference in outcomes. Tr. 98:20-99:10 (Constantinovici Direct); Tr. 338:4-339:10 (Vassilev Direct).

The Court finds that the use of an overall hazard ratio here is a generally-accepted method for reporting retrospective comparative study, and further notes the fact that Bayer has used the same reporting methodology in its own research. *See, e.g.*, DX-41. More specifically here, the Court finds that Bayer failed to present any evidence that the hazard ratio improperly stated the difference in associated risk of death between the two drugs. As Bayer's experts admitted, they performed no statistical analysis to estimate varying hazard ratios using different time periods. Tr. 115:11-15 (Constantinovici Cross). As Dr. Gibbons aptly put it, "there was just a lot of speculation, there was this may happen, that could happen . . . [No one showed] those things actually impacted the study." Tr. 440:3-9 (Gibbons Direct).

* * *

As one of Bayer's experts acknowledged, "[i]t's the nature of [pharmaceutical research]" to "disagree." Tr. 236:23-24 (Sullivan Cross). But mere disagreement with the methodological choices employed or data sources used is insufficient. Absent evidence that the methods employed

were not reliable, that the data were inaccurate, or that the limitations of the methods and/or data actually biased the Study's results, the Court cannot conclude that the Study's results were invalid. And here, the Court cannot, on the current record, find that the methodology underlying the Study is so problematic as to render its results unreliable. Indeed, this is not a particularly close call. While all experts in this case agree that an observational study cannot establish causation with the same degree of certitude as a randomized control test, the Court credits the testimony of J&J's experts that the data sources and statistical methodological choices made in the Study are widely-accepted and commonly-used scientific methods for conducting retrospective observational studies in pharmacologic research, and that they are reliable. While Bayer's experts hypothesized that mCSPC patients receiving doublet therapy who were taking darolutamide off-label were sicker or more frail than those taking apalutamide on-label, there is no empirical data in the record to support that supposition. And even if there were such evidence in the record, the Court credits the testimony of J&J's witnesses that the statistical controls used to balance the cohorts adequately captured potential bias stemming from differences in the treatment populations. Accordingly, the Court cannot, on the current record, conclude that the Study's results are unreliable.

III. The Accuracy of the Relevant Communications in Describing the Study

Having preliminarily found that the Study was conducted using a reliable and valid methodology, the Court turns to Bayer's arguments that J&J's statements in the challenged communications misrepresent the Study's methodology and results.[8] As explained below, the

[8] While the Complaint appears to challenge J&J's presentation of the Study's results at the IPCU conference, at oral argument counsel explained that Bayer was challenging J&J's communications about the Study only to the extent they went beyond the presentation at the IPCU conference and the scientific community in attendance, to reach the general public. Tr. 546 (Bayer Summation).

Court concludes that the challenged communications, taken as a whole, accurately represent the Study's methods and conclusions.

A. Target Audience

As noted, the communications at issue are a presentation regarding the Study's results given at a medical conference and posted on a J&J website, and a press release about the Study and its results. There are no, for example, consumer-facing advertisements at issue in this case. Nevertheless, Bayer argues that the relevant target audience for the communications at issue is the general public rather than more sophisticated experts like doctors. PX-80 ¶¶ 5-9; Tr. 248:2-18, 259:23-260:4 (Dinello Direct); Tr. 304:3-9 (Dinello Redirect); Tr. 141:15-142:4 (Dean Direct). To support that point, Bayer produced evidence of search engine and AI-generated results that point to the superiority of apalutamide for mCSPC based wholly on the press release and the presentation's statements. PX-5; PX-21–PX-25; Tr. 249:18-250:11 (Dinello Direct). Further, Bayer provided evidence that patients can often influence prescribing decisions. DX-210; Tr. 269:19-271:17 (Dinello Cross). In essence, Bayer argues that the communications at issue are intended to trickle out to patients, and will lead lay individuals to choose apalutamide over darolutamide based on a misplaced belief in the superiority of apalutamide. While Bayer acknowledged the presence of disclaimers in the various communications, Tr. 479:24-480:13 (Troy Direct); DX-156A; DX-157A; ECF No. 45 ¶¶ 3-10; ECF No. 51 ¶ 66, and notwithstanding that its claim sounds in literal falsity rather than in misleading or deceptive practices, Bayer argues that the disclaimers are insufficient to prevent a consumer from being misled by the topline "51% reduction" result.

J&J, however, put on evidence suggesting that only doctors, not patients, were the target audience for the challenged communications. Two treating physicians testified at the hearing, and both testified that they were not aware of a single instance of a patient identifying either

darolutamide or apalutamide (or the brand names NUBEQA and ERLEADA) during an appointment. Tr. 168:5-24 (Morris Direct); Tr. 503:20-504:7 (Drake Direct). In fact, many witnesses testified that, in the context of mCSPC treatment, it is highly unlikely that a patient would be driving a treatment decision. For example, Bayer's experts conceded that the evidentiary basis for their assertion that patients sometimes drive prescription decisions is from research regarding painkillers prescribed by general practitioners, where direct-to-consumer advertising might have more impact. Tr. 79:19-80:12 (Andres Cross). In contrast, the doctors who testified before the Court stated that, in their experience, it is the physician, not the patient, who identifies the treatment course for mCSPC.

The Court credits the testimony from the testifying physicians that patients do not drive treatment decisions for mCSPC. Therefore, the Court finds that the relevant audience for the communications at issue consists of prescribing physicians, and therefore analyzes the statements with that sophisticated audience in mind.

B. The Accuracy of the Challenged Statements about the Study's Methodology and Results

The parties also presented evidence regarding the alleged falsity of several statements contained within the presentation and/or press release. The Court discusses the evidence presented statement-by-statement (rather than publication-by-publication). Because the Court has already preliminarily found that the Study methodology was sound, it focuses its analysis in this section on whether the statements in the communications at issue misrepresent the Study's results.

1. 51% Statement

Bayer first argues that the statement of a 51% reduction in the risk of death inaccurately portrays the Study's conclusions. The Study purports to show that, during the 24-month Study period, doublet therapy patients receiving Bayer's darolutamide had a roughly 86% survival rate,

while those receiving J&J's apalutamide had a roughly 92% survival rate—statistics that are disclosed in the overview slide. *See* PX-3. Given that the vast majority of mCSPC patients survived during the Study period regardless of which ARI they took, Bayer argued during the hearing that the use of the 51% relative risk figure in the press release and the PowerPoint without more context is misleading to the general public. *See* Tr 13:14-24 (Bayer Opening). That is, Bayer argues that the public seeing "92.1 percent for Erleada and a '51 percent reduction in risk of death' for Erleada vs. Nubeqa would plausibly infer Nubeqa has a survival rate of approximately 60 percent when in fact it was 86 percent." *Id*. at 13:18-24 (Bayer Opening). Bayer appears to contend that the relevant communications should have included the Study's finding that darolutamide had an 86% survival rate.

The Court finds that the failure to include the 86% absolute survival measure does not misrepresent the Study's results. As J&J's witnesses explained, a relative comparison in the form of a hazard ratio is a standard method for reporting comparative observational study results. *See, e.g.*, Tr. 440:17-441:19 (Gibbons Direct). Further, the Court finds that, contrary to Bayer's contention, the communications adequately disclosed the absolute difference in outcomes through disclaimers. DX-156A at 5; DX-157A at 2; DX-158 at 3; Tr. 391:6-18 (Morrow Direct); Tr. 205:9-16 (Morris Cross). It would be obvious to any medical practitioner that a hazard ratio reflects a relative, rather than absolute, difference. DX-156A at 5; DX-158 at 3; Tr. 440:17-441:19 (Gibbons Direct). That is, the 51% figure is not literally false, because it is based on basic arithmetic comparing the relative survival rates of patients receiving the two ARIs; and the survival rate for darolutamide patients in the Study is calculable based on the information in the communications at issue.

2. "Reduces"

Bayer's second criticism revolves around word choice: that the press release claims that apalutamide "reduces" mortality risk rather than merely being "associated with" decreased mortality. Bayer's critique here is somewhat stronger; as Bayer's witnesses testified, the use of "associated with a reduction in X" would be a more apt description of the results of a retrospective, observational study like the one here. Tr. 222:10-20 (Sullivan Direct); Tr. 457:19-458:16, 459:11-460:9 (Gibbons Cross); Tr. 76:24-77:10 (Andres Cross); Tr. 83:4-8 (Andres Redirect); Tr. 99:6-10 (Constantinovici Direct); PX-79 ¶ 46; PX-76 ¶ 8. In contrast, using the word "reduces" may be interpreted to imply causation, which generally can be shown only through a randomized trial. PX-76 ¶ 8.

Ultimately, however, the Court declines to find the use of the word "reduces" in the communications to be literally false, particularly given the relevant target audience of medical professionals. Bayer failed to present any evidence that doctors would not understand the press release's headline claim in light of the release's repeated references to the real-world and observational nature of the Study. Further, J&J adequately rebutted any such contention, as witnesses repeatedly emphasized that doctors would look closely at the underlying study rather than relying just on one word in a headline. Tr. 165:9-18, 167:4-6 (Morris Direct). Accordingly, the Court finds that the use of the term "reduces" does not misrepresent the Study.

3. "Through 24 Months"

Bayer next attacks the Communications' use of the term "through 24 months" to describe the duration of the Study's tracking of outcomes. As several witnesses explained, the Study covered a 24-month period, but many patients were "in" the Study for only a portion of that time (e.g., because they began treatment after the Study commenced), and therefore were tracked for a shorter duration of time than a full 24-month period. Tr. 39:8-40:1 (Andres Direct); Tr. 340:9-24

(Vassilev Direct); Tr. 86:22-87:3 (Constantinovici Direct). Bayer contends that the phrasing here misrepresents the Study because it implies that all patients were followed for a full two-year period.

The Court cannot find that this phrasing is false (or even misleading). To begin, J&J's witnesses testified that "through 24 months" accurately (and literally) describes the period in which patients were included in the Study, a fact that no Bayer witness disputed. Tr. 452:13-20 (Gibbons Direct). Dr. Gibbons also testified that a reasonable doctor would recognize that it was impossible that every patient in the Study was followed for a full 24-month period, as, for example, patients died during the Study period. *Id.*; Tr. 466:9-13 (Gibbons Cross) ("Q: J&J did not post in its press release the proportion of patients alive at 24 months for the darolutamide cohort, did it? A: No. … But, it is a simple matter to compute it."); Tr. 73:16-25 (Andres Cross) (agreeing that it was "clear … from reading the [P]ress [R]elease as a whole" that not every patient received a full 24 months of follow-up). Readers familiar with health outcomes studies understand that the stated follow-up period is not universal. Tr. 452:13-453:1, 453:18-454:15 (Gibbons Direct); Tr. 526:15-21 (Drake Cross); ECF No. 51 ¶¶ 115-120. Accordingly, the Court finds that the phrase "through 24 months" does not misrepresent the Study's timeframe or methodology.

4. "Replicating the conditions of a randomized clinical trial"

As a final critique, Bayer takes issue with J&J's press release stating that IPTW had the effect of "removing bias from measured confounders and replicating the conditions of a randomized clinical trial." As discussed above, there are numerous limitations in retrospective observational studies that generally render them inferior to randomized trials. And as even one of J&J expert agreed, to claim that this Study "replicated" the conditions of a randomized clinical trial could be misleading in isolation. Tr. 471:15-472:6 (Malone Direct).

Nonetheless, the Court does not find that, in full context, the press release is misleading (let alone literally false) in how it portrays the Study. As one of J&J's experts, Dr. Malone,

testified, "emulate" may have been a better word than "replicate" to describe J&J's efforts to control for confounding variables. Tr. 475:16-21 (Malone Cross). Nevertheless, the Court finds that disclosure of the underlying methodological approach, including noting that the Study is a "real-world" study rather than an RCT at least 14 times throughout the press release, adequately discloses that this is an observational study rather than a randomized trial (and all the differences that this implies). Tr. 394:15-21 (Morrow Direct). The Court finds that a treating physician would not be misled into believing that the Study was an actual randomized trial based on the inclusion of the word "replicate." As one of Bayer's witnesses stated, no observational study can actually duplicate the effect of a randomized trial. Tr. 220:8-18 (Sullivan Direct). But the audience of medical professionals to whom the communications were targeted would know that. Accordingly, because the press release adequately discloses the Study's observational, retrospective nature, the Court finds that the claim that the trial "replicates" the conditions of a randomized control trial does not misrepresent the Study's methods or results.

* * *

The Court finds that the challenged communications do not misrepresent the methodology and the results of the Study. As to whether the communications are targeted at the general public, the Court preliminarily finds that they are not, and that treating physicians are their relevant audience. Viewed in that context, the challenged communications adequately disclose the nature of the Study as an observational, retrospective study and therefore convey all the limitations that this fact would entail, such that a prescribing physician would not misunderstand the statements. The Court also finds that the disclaimers included in the press release and presentation adequately disclosed the potential limitations of the Study such that the topline conclusions were not themselves literally false (or even misleading) to a sophisticated population that would understand

the meanings and implications of the terms employed. Accordingly, the Court finds that the communications do not misrepresent the methodology or the results of the Study.

PRELIMINARY CONCLUSIONS OF LAW

I. Jurisdiction

As an initial matter, J&J argues that this Court lacks jurisdiction over Bayer's claims.[9] Because, for the reasons explained below, the Motion is ultimately denied on the merits, the Court may permissibly assume personal jurisdiction for the purposes of this opinion. *ONY, Inc. v. Cornerstone Therapeutics, Inc.*, 720 F.3d 490, 498 (2d Cir. 2013). Nevertheless, the Court has considered the issue of personal jurisdiction and concludes that Bayer has adequately established specific jurisdiction over J&J pursuant to New York's long arm statute.

"On a Rule 12(b)(2) motion to dismiss for lack of personal jurisdiction, the plaintiff bears the burden of showing that the court has jurisdiction over the defendant." *Metro. Life Ins. Co. v. Robertson-Ceco Corp.*, 84 F.3d 560, 566 (2d Cir. 1996). The Court may "consider matters outside the pleadings, 'including accompanying affidavits, declarations, and other written materials.'" *Dow Jones & Co., Inc. v. Perplexity AI, Inc.*, 797 F. Supp. 3d 305, 318 (S.D.N.Y. 2025) (citing *Vasquez v. Hong Kong & Shanghai Banking Corp., Ltd.*, 477 F. Supp. 3d 241, 245 n.1 (S.D.N.Y. 2020)); *see also Dorchester Fin. Sec., Inc. v. Banco BRJ, S.A.*, 722 F.3d 81, 86 (2d Cir. 2013).

Determining personal jurisdiction entails a two-part inquiry. First, the exercise of jurisdiction must comply with the personal jurisdiction rules of the forum state. *Licci ex rel. Licci v. Lebanese Canadian Bank, SAL*, 732 F.3d 161, 168 (2d Cir. 2013). Then, the Court must determine whether the exercise of personal jurisdiction comports with due process, "as set forth in

[9] Without prejudice to a renewed motion to dismiss for lack of jurisdiction, the Court construes Defendants' opposition briefing as such a motion and addresses it under the appropriate standard.

International Shoe Co. v. Washington and its progeny." *Dow Jones & Co., Inc.*, 797 F. Supp. 3d at 319. Minimum contacts are established where "the defendant purposefully avails itself of the privilege of doing business in the forum." *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 474-75 (1985). A defendant may be said to have purposely availed itself of this privilege based on its maintenance of an interactive website in combination with other relevant forum contacts. *See Chloe v. Queen Bee of Beverly Hills, LLC*, 616 F.3d 158, 171 (2d Cir. 2010) (finding minimum contacts inquiry met where defendant "offer[ed] bags for sale to New York consumers on the Queen Bee website and [sold] bags—including at least one counterfeit Chloé bag—to New York consumers"); *Hypnotic Hats, Ltd. v. Wintermantel Enters, LLC*, No. 15 Civ. 6478, 2016 WL 7451306, at *4 (S.D.N.Y. Dec. 27, 2016) (finding minimum contacts where defendants marketed and sold their products nationwide through websites and directly solicited New York customers via email).

CPLR § 302(a)(1) provides, in relevant part, that a court may exercise personal jurisdiction "over any non-domiciliary . . . who in person or through an agent . . . transacts any business within the state," so long as the cause of action "aris[es] from" that transaction. *Dow Jones & Co., Inc.*, 797 F. Supp. 3d at 320 (quoting CPLR § 302(a)(1)). Courts in this District assess activity based on "the totality of circumstances concerning the party's interactions with, and activities within, the state." *Id.* (citing *Seiden v. Baker Tilly Hong Kong Ltd.*, No. 23 Civ. 1254, 2024 WL 4441582, at *2 (2d Cir. Oct. 8, 2024) (summary order)).

The Court concludes that J&J's conduct in this case is sufficient for the exercise of personal jurisdiction. As Plaintiff alleges, J&J targeted doctors, including New York doctors, through the presentation of the Study's findings at the IPCU conference. J&J also referenced the Study in sales calls with urologists nationwide. *See* Dinello Reply Decl. ¶ 9, ECF No. 57. J&J did so with every expectation that those doctors would respond to those findings in choosing treatment plans

for their patients directly impacting Bayer's sales, including in this District. Tr. 303:16-304:24 (Dinello Redirect); PX-71 ¶¶ 4, 14-16; PX-80 ¶ 10. Bayer also notes the high concentration of prostate cancer treatment facilities and research institutions in New York. *See* Dinello Reply Decl. ¶¶ 12-14. It is difficult to imagine J&J was not targeting New York doctors who were flown out to a conference in Vail, as well as a forthcoming conference in Florida in which New York doctors are expected to attend. While, by itself, the mere availability of the press release and presentation online is insufficient "to support jurisdiction under Section 302(a)(1)," *see Capitol Recs., LLC* v. *VideoEgg, Inc.*, 611 F. Supp. 2d 349, 358 (S.D.N.Y. 2009), providing allegedly false advertising to New York prescribers while causing alleged financial harm to Bayer satisfies the requirements of CPLR § 302(a)(1), *see* Pl. Proposed Findings of Fact ¶ 4, ECF No. 67.

The Court also concludes that jurisdiction would be proper under CPLR § 302(a)(3)(ii), which has five elements:

> (1) the defendant committed a tortious act outside New York; (2) the cause of action arose from that act; (3) the tortious act caused an injury to a person or property in New York; (4) the defendant expected or should reasonably have expected the act to have consequences in New York; and (5) the defendant derived substantial revenue from interstate or international commerce.

Penguin Grp. (USA) Inc. v. Am. Buddha, 16 N.Y.3d 295, 302 (2011). For reasons discussed above, the first, second, and fifth elements are clearly met. The Court further concludes that Bayer suffered or will suffer financial harm from lost sales in New York state, and that J&J, through presenting the results of the Study at a conference and on sales calls that included New York doctors knew or should have known that there would be financial ramifications in New York from advertising the Study results. *See Sony Music Ent. v. Univ. of S. Cal.,* No. 25 Civ. 2042, 2026 WL 96694, at *8 (S.D.N.Y. Jan. 13, 2026) (concluding that outreach to New York consumers for donations as well as ticket and merchandise sales to New York consumers was sufficient to put Defendant on notice of New York tortious impact); *Starmedia Network, Inc. v. Star Media, Inc.*,

No. 00 Civ. 4647, 2001 WL 417118, at *3 (S.D.N.Y. Apr. 23, 2001) (holding that in-state consequences were foreseeable where "[t]he defendant used its website to attract and service business across the nation, including in New York").

Turning to due process, the Court concludes that both Janssen and Johnson & Johnson have "purposefully availed" themselves of the privilege of doing business in New York state such that the exercise of jurisdiction would not offend due process principles. There is no real dispute that Defendants both own and operate websites accessible in New York, transact business in the state, and target New York doctors and patients for sales of a number of drugs, including but not limited to apalutamide. *See Gucci Am., Inc. v. Frontline Processing Corp.*, 721 F. Supp. 2d at 245 (finding minimum contacts where company "consider[ed] itself to be a nationwide service provider, operate[d] a website that can be viewed in New York, [did] business with internet merchants [...] who [sold] goods into New York, and even [had] some New York-based clients who they earn revenue from (however insubstantial)"). Defendants have also "failed to present any evidence to demonstrate that, in this modern age and for a litigant with obvious familiarity with internet communication, litigation in New York would present so great an inconvenience as to constitute a deprivation of due process." *Savage Universal Corp. v. Grazier Const., Inc.*, No. 04 Civ. 1089, 2004 WL 1824102, at *11 (S.D.N.Y. Aug. 13, 2004). Accordingly, the Court will assert jurisdiction over this matter.[10]

[10] Defendants also argue that the Southern District of New York is an improper venue for this matter. However, "the venue inquiry collapses into the personal jurisdiction inquiry for entities that are not natural persons." *Glob. Merch. Servs., Ltd. v. Sunfrog, LLC*, No. 17 Civ. 10154, 2018 WL 11223365, at *4 (S.D.N.Y. Aug. 9, 2018); *see also Dow Jones & Co., Inc. v. Perplexity AI, Inc.*, 797 F. Supp. 3d 305, 333-34 (S.D.N.Y. 2025). Assuming jurisdiction, the Court concludes venue is also proper. *Sony Music Ent. v. Univ. of S. California*, No. 25 Civ. 2042, 2026 WL 96694, at *10 (S.D.N.Y. Jan. 13, 2026) (finding venue proper where Defendant-corporation subject to personal jurisdiction).

II. Merits

In considering an application for a preliminary injunction, the Court must evaluate the plaintiff's showing (1) for "a likelihood of success on the merits," (2) "that [the plaintiff] is likely to suffer irreparable injury in the absence of an injunction," (3) that "the balance of hardships tips in the plaintiff's favor," and (4) "that the public interest would not be disserved by the issuance of [the] injunction." *Salinger v. Colting*, 607 F.3d 68, 79-80 (2d Cir. 2010). As discussed herein, the Court finds that Plaintiffs have failed to establish a likelihood of success on the merits of their false advertising claims. Therefore, the Motion is **DENIED**.

A. General Framework for Lanham Act Claims

"The Lanham Act generally prohibits false advertising." *ONY, Inc. v. Cornerstone Therapeutics, Inc.*, 720 F.3d 490, 496 (2d Cir. 2013) (citing (15 U.S.C. § 1125(a)(1)). To make out a claim for false advertising under Section 43(a) of the Lanham Act,[11] a plaintiff must first show the falsity of the challenged statement. *Int'l Code Council, Inc. v. UpCodes Inc.*, 43 F.4th 46, 56 (2d Cir. 2022). The challenged statement must also be material in that "the false or misleading representation involved an inherent or material quality of the product," i.e., something that would influence a consumer's choice in selecting between products. *Apotex Inc. v. Acorda Therapeutics, Inc.*, 823 F.3d 51, 63 (2d Cir. 2016). Finally, the plaintiff must prove "that the defendant placed the false or misleading statement in interstate commerce, and that the plaintiff has been injured as a result of the misrepresentation, either by direct diversion of sales or by a

[11] Bayer also asserts two claims under New York law. The elements of a false advertising claim under N.Y. Gen. Bus. Law §§ 349 and 350 and an unfair competition claim under common law are identical to those of a Lanham Act claim, except to the extent a common law claim also requires proof of bad faith. *See Int'l Code Council*, 43 F.4th at 56 n.3; *Mattel, Inc. v. Arming*, No. 18 Civ. 8824, 2021 WL 3683871, at *6 (S.D.N.Y. Aug. 18, 2021). Because, as explained below, the Court concludes that Bayer fails to state a claim under the Lanham Act, it does not separately analyze Bayer's state law claims.

lessening of goodwill associated with its products." *Merck Eprova AG*, 760 F.3d 247, 255 (2d Cir. 2014).

A plaintiff can demonstrate falsity either by showing: (1) literal falsity, i.e., "that the challenged advertisement is . . . false on its face," or (2) implied falsity, i.e., "that the advertisement, while not literally false, is nevertheless likely to mislead or confuse consumers." *Tiffany (NJ) Inc. v. eBay Inc.*, 600 F.3d 93, 112 (2d Cir. 2010). Here, Bayer pursues a literal falsity claim, not a claim for misleading representations. "[A] district court evaluating whether an advertisement is literally false must analyze the message conveyed in full context, i.e., it must consider the advertisement in its entirety and not engage in disputatious dissection." *Time Warner Cable, Inc. v. DIRECTV, Inc.*, 497 F.3d 144, 158 (2d Cir. 2007). "A court may find a statement literally false by necessary implication, without considering extrinsic evidence, when the advertisement's 'words or images, considered in context, necessarily and unambiguously imply a false message.'" *Church & Dwight Co. v. SPD Swiss Precision Diagnostics, GmBH*, 843 F.3d 48, 67 n.8 (2d Cir. 2016). Courts analyze the full context of a defendant's statements to determine whether consumers would be left with a false impression of a provable fact. *See Int'l Code Council, Inc. v. UpCodes Inc.*, 43 F.4th 46, 60 (2d Cir. 2022) (determining that a generic disclaimer did not cure representations of completeness for a database of building regulations).

"One kind of literally false claim is a claim of test-proven superiority. The premise is that the 'defendant's ad[vertisement] explicitly or implicitly represents that tests or studies prove its product superior' and 'plaintiff satisfies its burden by showing that the tests did not establish the proposition for which they were cited.'" *Apotex Inc.*, 823 F.3d at 63 (quoting *Castrol, Inc. v. Quaker State Corp.*, 977 F.2d 57, 63 (2d Cir. 1992)).

B. Scientific Context

Because matters of scientific debate raise particular concerns under the First Amendment, the Second Circuit has held that courts must be cautious in applying the Lanham Act to "empirical research" that is "tentative and subject to revision, because they represent inferences about the nature of reality based on the results of experimentation and observation." *ONY*, 720 F.3d at 496. Indeed, in "a sufficiently novel area of research, propositions of empirical 'fact' advanced in the literature may be highly controversial and subject to rigorous debate by qualified experts." *Id.* at 497. This makes determinations of falsity of scientific claims difficult, as what is or is not a provable fact evolves rapidly in scientific literature. *See Cassava Scis., Inc. v. Bredt*, No. 22 Civ. 9409, 2024 WL 1347362, at *9 (S.D.N.Y. Mar. 28, 2024) (explaining the hesitancy to take sides in "ongoing discourse in scientific communities").

1. The Second Circuit's Decision in *ONY*

The Second Circuit held in *ONY* that, "to the extent a speaker or author draws conclusions from non-fraudulent data, based on accurate descriptions of the data and methodology underlying those conclusions, on subjects about which there is legitimate ongoing scientific disagreement, those statements are not grounds for a claim of false advertising under the Lanham Act." *ONY*, 720 F.3d at 498. The facts of that case are similar in many ways to the facts here. There, the plaintiff challenged statements in a scientific article, and in a press release touting its conclusions, regarding a retrospective pharmaceutical study alleging a roughly 50% reduction in the risk of death compared to a competitor drug. While the *ONY* plaintiff identified possible methodological flaws in the underlying study, the Circuit noted that the study's conclusions were qualified; that it acknowledged the limitations of observational research, including potential confounding factors; and that it disclosed the fact that it was funded at the behest of the company that manufactured the drug purportedly shown to have a lower death rate. *See id.* at 494. The plaintiff did not allege that

the study data were "fabricated or fraudulently created," or that the study and press release misrepresented the underlying data in some way—only "that the inferences drawn from those data were the wrong ones, and that competent scientists would have included variables that were available to the defendant authors but that were not taken into account in their analysis." *Id.* at 497.

The Circuit ultimately concluded that there could be no liability under the Lanham Act on these facts. It explained that the scientific community, rather than the courts, should adjudicate disputes in this context: "when the conclusions reached by experiments are presented alongside an accurate description of the data taken into account and the methods used, the validity of the authors' conclusions may be assessed on their face by other members of the relevant discipline or specialty." *Id.* at 497-98. These sorts of scientific debates are of a kind that "courts are ill-equipped to undertake to referee." *Id.* at 497; *see also Underwager v. Salter*, 22 F.3d 730, 736 (7th Cir. 1994) ("Scientific controversies must be settled by the methods of science rather than by the methods of litigation . . . . More papers, more discussion, better data, and more satisfactory models—not larger awards of damages—mark the path toward superior understanding of the world around us.").

That is not to say that, under *ONY*, there can never be Lanham Act liability for false statements in scientific research. But, where *ONY* applies, such claims are essentially limited to two circumstances. First, where data in a scientific study is fabricated in some way, courts still have a role to play because, as the Second Circuit explained, "if the data were falsified, the fraud would not be easily detectable by even the most informed members of the relevant scientific community." *Id.* at 497. Second, where statements about a study misrepresent the study's methodology (e.g., stating that a study was a randomized trial when, in fact, it was not) or its conclusions (e.g., stating that a study found "X" when, in fact, it found "not X"), a court can assess

the veracity of such statements without purporting to referee a matter of scientific debate. *Cf. id.* at 498 (holding that statements "based on accurate descriptions of the data and methodology underlying those conclusions" are immune from challenge). But outside of these two exceptions, "a statement . . . made as part of an ongoing scientific discourse about which there is considerable disagreement" is entitled to First Amendment protection exempting it from Lanham Act liability.

Here, J&J argues that, under *ONY*, Bayer must prove that the Study in this case is based on fraudulent or false data, or that J&J has falsely described the underlying methodology. *See* Opp. at 16. According to J&J, it is not enough to show that the Study suffered from methodological defects—even severe ones—because *ONY* all but immunizes statements that are matters of scientific debate, and permits claims under the Lanham Act only where defendants have essentially committed (in colloquial terms) some sort of fraud—i.e., by falsifying the underlying data or misrepresenting the underlying study.

2. The Applicability of *ONY* Outside of the Academic Context

It is unclear, however, if *ONY* sweeps broadly to encompass *all* statements regarding matters of ongoing scientific debate, or if it applies only to those made in certain specific contexts. *ONY* itself dealt with statements made "in a scientific article reporting research results," and also in "a press release touting [the article's] conclusions." *See id.* at 490, 495. *ONY* did not expressly hold that statements about scientific research made in a broader commercial context—such as representations on sales calls, advertising, or other marketing materials—are subject to the same degree of First Amendment protection. And since *ONY*, other courts have held that *ONY*'s protection of legitimate scientific discourse does not broadly immunize statements made outside of an academic context. For example, the Fifth Circuit has affirmed a permanent injunction against distributing a marketing brochure that contained excerpts of a peer-reviewed study. *Eastman Chem. Co. v. Plastipure, Inc.*, 775 F.3d 230, 236 (5th Cir. 2014). In *Eastman*, the Fifth Circuit

distinguished *ONY* as concerning statements "made within the academic literature and directed at the scientific community," and explained that the same degree of First Amendment protection does not apply to "statements made in commercial advertisements and directed at customers." *Id.* The Fifth Circuit explained that "[g]iven the applicable binding precedent, it is of no moment that the commercial speech in this case concerned a topic of scientific debate. Advertisements do not become immune from Lanham Act scrutiny simply because their claims are open to scientific or public debate. Otherwise, the Lanham Act would hardly ever be enforceable . . . ." *Id.*

Since *ONY* and *Eastman*, some district courts have held that statements relating to scientific research made outside of an academic context are not automatically subject to the same degree of First Amendment protections for scientific discourse that the Second Circuit found applicable in *ONY*. *See, e.g.*, *Mimedx Grp., Inc. v. Osiris Therapeutics, Inc.*, No. 16 Civ. 3645, 2017 WL 3129799, at *7 (S.D.N.Y. July 21, 2017) ("*ONY* does not necessarily immunize commercial materials such as" a press release or a brochure). Perhaps most on-point for this case are a series of decisions from Judge Chen in the Northern District of California concerning a counterclaim arising from statements in a PowerPoint presentation and press release regarding an unreleased study that claimed to demonstrate one product's superiority over another in detecting cancer. *See Guardant Health, Inc. v. Natera, Inc.*, 580 F. Supp. 3d 691, 702 (N.D. Cal. 2022) (*Guardant I*); *Guardant Health, Inc. v. Natera, Inc.*, No. 21 Civ. 4062, 2025 WL 2106522, at *2 (N.D. Cal. July 28, 2025) (*Guardant II*). While Judge Chen denied preliminary injunctive relief based on insufficient evidence to demonstrate the underlying falsity of the study results, he also denied motions to dismiss and for summary judgment. Judge Chen held that the counterclaim plaintiff had plausibly alleged not only that its competitor's statements were based on a study that was itself "based on fraudulent data and inaccurate descriptions of the data and methodology" (which is actionable under *ONY*), but also that the challenged statements were "based on a study in which

[the counterclaim defendant] manipulated the methodology and analysis to reach predetermined conclusions." *Guardant I*, 580 F. Supp. 3d at 702. *Guardant* held that *ONY* was "inapplicable" to this latter set of claims challenging the methodology of the underlying study. *Id.* At trial, the counterclaim plaintiff then presented evidence showing that the data comparison on which the challenged statements were based suffered from severe methodological flaws, such that they amounted to an "apples-to-oranges" comparison. *See Guardant II*, 2025 WL 2106522, at *2-3. The jury found for the counterclaim plaintiff, and Judge Chen denied a post-trial motion to overturn the jury verdict. *See id.*

These cases stand for the proposition that the broad immunity the Second Circuit applied in *ONY* does not extend to statements about a scientific study made in the context of advertising or marketing materials aimed at ordinary consumers. And Judge Chen's decisions in the *Guardant* litigation hold that, in this latter context, statements about a study's results may still be challenged as false under the Lanham Act if the underlying study can be shown to suffer from severe methodological defects such that the study cannot be said to support the statements in question.

We are then left with two possible standards for liability, depending on whether *ONY*, properly understood, applies here: (1) if *ONY* does apply here, Bayer can succeed only if it can show that the Study was based on falsified data, or if that J&J misrepresented the Study's methodology or results; or (2) if *ONY* does not apply here, Bayer can also succeed by showing that the Study's underlying methodology was so flawed that it cannot be said to support the challenged statements.

Ultimately, however, the Court need not resolve whether *ONY* applies here,[12] because even assuming that it does *not*—i.e., that Bayer could establish Lanham Act liability based solely on severe methodological defects in the Study—the Court concludes that Bayer's request for preliminary relief fails. That is, the Court assumes for purposes of this Opinion that Bayer can establish literal falsity for purposes of its Lanham Act claim if its methodological critiques are so substantial as to render J&J's statements about the relative efficacy of darolutamide and apalutamide an "apples to oranges" comparison, even in the absence of falsified data or inaccurate representations of the Study's methodology. As explained below, even assuming the applicability of this relatively more lenient standard, Bayer has not shown that it is entitled to preliminary injunctive relief.

C. Application

First, assuming that *ONY* is in fact applicable here: Bayer's claim for preliminary relief fails because its principal argument here is the same one that the Second Circuit rejected in that case—i.e., that "the differences in the results were a result of differences in the groups of patients treated." *ONY*, 720 F.3d at 495. Moreover: (1) there is no assertion of fraudulent data or analysis in the Study; and (2) the Court further concludes, based on its factual findings described above, that Bayer has failed to prove that the challenged communications misrepresented the Study's

[12] For example, it is unclear to the Court that *Eastman* is correct that *ONY* is limited only to the academic context. After all, *ONY* involved not only an academic paper in a scientific journal, but also a press release about that paper. *See ONY*, 720 F.3d at 495. That is, it may not be possible to harmonize the Fifth Circuit's decision in *Eastman* with the Second Circuit's decision in *ONY*; the two cases may simply embody different and irreconcilable legal standards. And it is also unclear to this Court if the extent of First Amendment protections for statements of scientific research deemed applicable by the Second Circuit in *ONY* could properly be limited to academic fora. That is, even if the distinction between academic and commercial speech might be compatible with the holding in *ONY* itself, it may be the case that the reasoning underlying its holding cannot cabined to the academic context. Fortunately, the Court need not attempt to resolve these questions here in order to decide this Motion.

methodology or its conclusions. *Cf. Eastman*, 775 F.3d at 236. The statement that the Study demonstrates a 51% lower risk of death for apalutamide as compared to darolutamide in the context of doublet therapy for mCSPC patients does not misrepresent the Study's results. J&J accurately described both its calculation of the relative survival rates of the two treatment cohorts and the time period of the Study. While the use of the words "reduces" and "replicates" (in comparison to a randomized clinical trial) might not have been the most accurate way of describing the Study, the challenged communications qualified those statements through explicit disclaimers that adequately described the Study's overall methodological approach and accurately disclosed the limitations of that approach. Accordingly, Bayer has failed to establish a false advertising claim under the Lanham Act based on purported misrepresentations of the Study's methodology in the challenged communications.

Second, assuming that *ONY* does *not* apply here: Bayer's claim for preliminary relief still fails because, as described in the Findings of Fact, the Court finds that Bayer has failed to prove that the Study's methodology was so flawed that it fails to support the challenged statements. As explained above, the Court has found, at least based on the current record, that the methodological choices made by the authors of the Study were not errant or out-of-step within the relevant scientific community. Indeed, Bayer has used the same methodologies and data sources for its own research. While Bayer presented, *inter alia*, testimony from various experts hypothesizing that the Study's underlying data were flawed and that the treatment cohorts were not comparable, J&J presented persuasive counter-testimony on these issues from its own experts; and ultimately there was no empirical evidence in the record indicating that the Study's methodological choices *actually* biased the results in J&J's favor (e.g., that the treatment cohorts were in fact substantially different in terms of underlying characteristics and that the controls used were inadequate to account for such differences). *Compare with Guardant II*, 2025 WL 2106522, at *2 (upholding

jury finding that comparative data analysis was an apples-to-oranges comparison). The Court cannot find, on the current record, that the treatment cohorts were materially different; and it further preliminarily finds, again on the current record, that the Study's methods for controlling for any differences between the cohorts were reliable and efficacious. That is, the Court cannot conclude that the potential limitations in the Study identified by Bayer invalidate J&J's comparison of the efficacy of the two drugs in the relevant context (i.e., for mCSPC in doublet therapy). *Cf. Cassava Scis., Inc.*, 2024 WL 1347362, at *10 (dismissing similar allegations of a flawed methodology in a pharmaceutical study). Accordingly, Bayer has failed to establish a false advertising claim under the Lanham Act based on purported methodological flaws in the Study itself.

In sum, regardless of which legal standard applies here (*ONY* or *Eastman*), the Court concludes that Bayer has failed to establish a likelihood of success on the merits on its Lanham Act claim. As a result, it has similarly failed to establish a likelihood of success on its state law claims. The Court, therefore, need not analyze the remaining injunction factors.

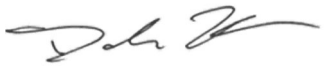
CONCLUSION

Because, for the reasons stated above, Plaintiff has failed to establish a likelihood of success on the merits, the Motion for a Preliminary Injunction is **DENIED**.

SO ORDERED.

Dated: April 17, 2026

New York, New York



DALE E. HO
United States District Judge