UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

BAYER HEALTHCARE LLC,	:	
Plaintiff,	:	No. 26 Civ. 1479
v.	:	**JURY DEMAND**
JOHNSON & JOHNSON and JANSSEN BIOTECH, INC.	:	
Defendants.	:	

COMPLAINT

Plaintiff Bayer HealthCare LLC ("Bayer"), by its attorneys Simpson Thacher & Bartlett LLP, for its Complaint against Defendants Johnson & Johnson and Janssen Biotech, Inc. (together "J&J"), respectfully alleges as follows:

NATURE OF THE ACTION

1. This is a case about false advertising in the prescription drug ("Rx") market for the treatment of prostate cancer. Prostate cancer is a malignancy that develops in the prostate gland and is one of the leading killers of men in the U.S., second only to heart disease. Every year, over 330,000 men in the U.S. are newly diagnosed with prostate cancer, with the death toll reaching over 35,000 annually.

2. There are three main therapies used to treat prostate cancer. The first is chemotherapy, usually with docetaxel, a drug that inhibits cell growth in both cancerous and healthy cells. The second treatment is called androgen deprivation therapy ("ADT"), which

reduces testosterone levels to slow cancer growth. These two therapies are often combined with a next generation treatment option for prostate cancer, a class of drugs called androgen receptor inhibitors ("ARIs"), used to treat prostate cancer by blocking androgen receptors, preventing testosterone from fueling cancer cell growth. When ADT is combined with androgen receptor inhibitors as a treatment plan, the therapy is often referred to as "doublet therapy."

Name	Shortform	Use
Androgen Receptor Inhibitors	ARI	Blocks androgen receptors, preventing testosterone from fueling cancer cell growth.
Androgen Deprivation Therapy	ADT	Reduces male hormone (androgen) levels, primarily testosterone, to slow prostate cancer progression.
Chemotherapy	Docetaxel	Destroys cancer cells by targeting and killing rapidly dividing cells throughout the body.

3. This case relates to androgen receptor inhibitors. Bayer is the maker of NUBEQA® (darolutamide), an ARI that achieved U.S. Food and Drug Administration ("FDA") approval as a doublet therapy with ADT for the treatment of metastatic castration-sensitive prostate cancer in June 2025. J&J is the maker of ERLEADA® (apalutamide), a competing ARI that obtained FDA approval as a doublet therapy with ADT for the treatment of metastatic castration-sensitive prostate cancer in September 2019. These two products are direct competitors in a relatively concentrated and highly competitive market.[1]

4. NUBEQA®, a recent entrant to the ARI doublet therapy market, has demonstrated significant growth in the last year. In the first nine months of 2025 alone, NUBEQA® sales totaled €1.63 billion globally (approximately $1.81 billion, using a 9/30/25

[1] Bayer's NUBEQA® received its first approval from the FDA in July 2019 for the treatment of *non*-metastatic castration-resistant prostate cancer. J&J's ERLEADA® received its first approval from the FDA in February 2018, also for the treatment of non-metastatic castration-resistant prostate cancer. NUBEQA® and ERLEADA® also compete with XTANDI®, an ARI manufactured by Pfizer.

conversion rate). NUBEQA®'s new FDA approval for doublet therapy in June 2025 has contributed to strong sales performance and increasing market share.

5. Faced with this new competition, J&J launched a false advertising campaign against NUBEQA® in February 2026. J&J issued a press release (the "Press Release") on its public-facing web portal making the following false claims:

(i) Prostate cancer patients treated with ERLEADA® had a "51% reduction in risk of death" compared to patients treated with NUBEQA® based on a "real world head-to-head analysis" "through 24 months" (the "Data Analysis").

(ii) The Data Analysis adhered to rigorous FDA standards and had a robust methodology that delivered robust, reproducible results, matched the two treatment arms, removed bias, and replicated the conditions of a randomized clinical trial.

6. J&J also sponsored these claims in two presentations made available on J&J's Medical Connect website for healthcare providers that provide a summary of the Data Analysis. One presentation consists of a one-page overview (the "Overview Slide"), and another consists of a six-slide summary of the Data Analysis (the "Presentation"). Together, the Press Release and the two presentations provide to both patients and healthcare professionals the false and hugely impactful claim that, based on sound data and science, taking ERLEADA® reduces the risk of death by 51% compared to taking NUBEQA®. A superiority claim of this magnitude is certain to affect prescribing decisions for doctors and patients, as well as erode trust in Bayer's NUBEQA® product.

7. J&J's substantiation for these claims is not the equivalent of a head-to-head randomized, appropriately-powered, placebo-controlled prospective clinical trial comparing similar patients under similar conditions, which is the gold-standard for establishing treatment superiority. Rather, the Data Analysis is a retrospective, non-interventional observational study

using real-world data derived from a urology-practice electronic medical records system linked to a database of administrative claims containing mortality information. This study captures patients who initiated treatment with either ERLEADA® or NUBEQA® under different circumstances. ERLEADA® has been FDA approved for doublet therapy since September 2019 and was thus prescribed on label during the time period of the study (ending in June 2025), but NUBEQA® was approved by the FDA for doublet therapy only in June 2025, making NUBEQA® doublet usage prior to June 2025 off-label. Differences in patient outcomes cannot be drawn from J&J's sponsored analayis because the patients were not comparable and the data used to evaluate differences is incomplete and contains significant confounders.

8. J&J's headline claim of a "51% Reduction in Risk of Death" for ERLEADA® versus darolutamide is therefore false. The claim conveys definitive and quantitative clinical superiority, but the Data Analysis does not meet FDA standards for "substantial evidence" required to support a superior efficacy claim between prescription drug treatments. Rather than a randomized and controlled comparison, J&J relies on a retrospective observational analysis of real-world data drawn from different patient populations and incomplete data sources, and then promotes the resulting association as a precise and causal reduction in risk of death. Furthermore, J&J repeatedly asserts that the Data Analysis's science is strong and meets rigorous FDA standards, stating in its press release that it used inverse probability of treatment weighting techniques, "removing bias from measured confounders and replicating the conditions of a randomized clinical trial." These claims are false.

9. A central problem with J&J's Data Analysis is that during 97% of the relevant study period, the NUBEQA® group of patients was being prescribed the drug off-label. The Data Analysis had a study period of August 5, 2022 to June 30, 2025, and the FDA did not

approve NUBEQA® as a doublet therapy until June 2, 2025. Doctors who prescribed NUBEQA® for doublet therapy off-label during this time period instead of an approved ARI like ERLEADA® made this choice for specific clinical reasons. Clinical reasons for selecting an off-label treatment are not captured in the data sources, and embed a selection bias, in the analysis, resulting in fundamental non-comparability in the Data Analysis. In fact, because NUBEQA® has a laudatory safety profile,[2] with low side effects and few drug-drug interactions, doctors may specifically choose NUBEQA® for compromised patients with underlying comorbidities or additional complicating conditions that can require the use of concomitant medications. The two study arms therefore had inherently different populations, and these differences cannot be measured, nor addressed by the study's "measured confounders." Additionally, the Data Analysis utilized a patient group for the ERLEADA® population that was five times greater than the patient group for the NUBEQA® population. The significant difference in cohort sizes can skew statistical analyses and lead to improper comparative results. Because the NUBEQA cohort was both much smaller and selectively prescribed off-label, the all cause mortality, or risk of death, comparison is inherently false.

10. The Data Analysis also relied on a low quality dataset. Unlike data collected in a controlled clinical trial—where trained personnel follow strict protocols, use

[2] *See* Bolek H, Yazgan SC, Yekedüz E, Kaymakcalan MD, McKay RR, Gillessen S, Ürün Y. *Androgen receptor pathway inhibitors and drug-drug interactions in prostate cancer*. ESMO Open. 2024 Nov;9(11):103736. ("Darolutamide stands out as having the least potential for interactions, which could make it a preferable option in certain cases."); Zurth C, Koskinen M, Fricke R, Prien O, Korjamo T, Graudenz K, Denner K, Bairlein M, von Bühler CJ, Wilkinson G, Gieschen H. *Drug-Drug Interaction Potential of Darolutamide: In Vitro and Clinical Studies.* Eur J Drug Metab Pharmacokinet. 2019 Dec;44(6):747-759 ("darolutamide is unique among AR-targeted therapies in having demonstrated a low potential for clinically relevant DDIs [drug-drug interactions]"); Crawford ED, Stanton W, Mandair D. *Darolutamide: An Evidenced-Based Review of Its Efficacy and Safety in the Treatment of Prostate Cancer.* Cancer Manag Res. 2020 Jul 13;12:5667-5676. doi: 10.2147/CMAR.S227583. PMID: 32765070; PMCID: PMC7367726. ("Darolutamide moreover has shown low penetration of the blood–brain barrier (BBB) in animal and healthy human studies").

standardized definitions, and record the relevant data points—real world data originates from insurance billing systems, electronic health records, and pharmacy claims that exist solely for administrative and reimbursement purposes. Physicians entering a diagnosis code are focused on getting a patient's treatment covered, not on ensuring scientific accuracy for a future research study they know nothing about. Critical information is routinely missing: the exact date symptoms began, whether a patient actually took the medication that was prescribed, the reason a particular test was or was not ordered, and countless other details that a clinical trial would capture as a matter of course. Patients appear and disappear from datasets without explanation as they change insurance plans, switch providers, or simply stop seeking care. There is no independent verification, no quality auditing, and no one ensuring that the millions of fragmented data entries scattered across the healthcare system accurately reflect what actually happened to real patients. In short, these datasets were built to process payments, not to serve as the foundation for scientific conclusions, and treating them as reliable evidence ignores their fundamental limitations.

11. There are multiple other problems with the Data Analysis and J&J's characterization. As an example, J&J's Press Release states that the Data Analysis compared patients "through 24 months of follow-up." However, J&J did not have 24 months of follow-up data on the 1,460 patients initiating apalutamide and the 287 patients initiating darolutamide. J&J's presentations indicate that at least 60% of patients initated their treatment after June 2023. Those patients therefore could not have been evaluated for 24 months of follow-up before the study ended in June 2025. This truncated patient data skews the Data Analysis's results and records more deaths from patients who died early after initiating treatment. Importantly, the Presentation provides some information that is absent in the Press Release, preventing the

general public from understanding a key limitation of the Data Analysis, the small number of patients evaluated for a full 24 months of follow-up.

12. All of these factors make J&J's ultimate comparison between ERLEADA® and NUBEQA® based on the Data Analysis unsubstantiated and invalid. J&J selectively uses off-label data for only the NUBEQA® arm from a low-quality source to make the bold impactful claim that ERLEADA® reduces risk of death by 51% compared to NUBEQA®. It compounds the impact of the claim by asserting that the analysis meets FDA standards and claims a level of rigor that is unsubstantiated. These are false claims based on inherently flawed science that should not have been promoted to the public or to the scientific community as conclusive evidence.

13. J&J's advertising campaign contains improper and misleading claims that are negatively impacting Bayer's legitimate business. These statements also are causing ongoing harm by misinforming healthcare providers and their patients, which in turn influences important treatment decisions. For these reasons, the campaign should be halted immediately.

14. Bayer therefore brings this action to enjoin J&J's advertising of ERLEADA® based on its false and misleading claims about the relative reduction in risk of death between the NUBEQA® and ERLEADA® products and the reliability and validity of the Data Analysis. The Court should immediately enjoin J&J from further dissemination and promotion of J&J's claims to prevent irreparable harm to Bayer and stop misinformation from being disseminated to doctors and consumers.

JURISDICTION AND VENUE

15. This Court has federal question subject matter jurisdiction over Bayer's claim for violation of Section 43(a) of the Lanham Act pursuant to Section 39 of the Lanham

Act, 15 U.S.C. § 1121, and 28 U.S.C. § 1331. This Court has supplemental jurisdiction over Bayer's claims for violation of New York's General Business statutes and common law pursuant to 28 U.S.C. § 1367(a).

16. Venue is proper in this district pursuant to 28 U.S.C. § 1391(b) and (c) because J&J transacts business, markets and sells its ERLEADA® product in this district.

PARTIES

17. Plaintiff Bayer is a limited liability corporation organized under the laws of the state of Delaware with its principal place of business in New Jersey. Bayer is engaged in the business of, among other things, manufacturing and selling prescription, or Rx, medicines and other health and personal care products. Bayer's products in the U.S. market include its NUBEQA® Rx drug, used in the treatment of prostate cancer.

18. Upon information and belief, Johnson & Johnson is a corporation organized under the laws of New Jersey and with its principal place of business in New Jersey. Johnson & Johnson is authorized to do business and transact business in New York. Johnson & Johnson manufactures and sells a variety of Rx medicines, including ERLEADA®, in the U.S. market. J&J's name is prominently displayed on all ERLEADA® promotional materials at issue in these proceedings.

19. Upon information and belief, Janssen Biotech, Inc. is an indirect subsidiary of Johnson & Johnson and is a corporation organized under the laws of Pennsylvania and with a principal place of business in Pennsylvania. Janssen Biotech, Inc. is authorized to do business and transact business in New York. Janssen Biotech, Inc. manufactures and sells a variety of Rx medicines, including ERLEADA®, in the U.S. market. Janssen Biotech, Inc. has

sent Bayer two letters defending J&J's claims and taking responsibility for the promotion of the ERLEADA® drug. As a result, it has been added as a defendant to this action.

FACTUAL BACKGROUND

The Products

20. Since 2019, Bayer's NUBEQA® drug has competed in the Rx prostate cancer market with J&J's ERLEADA® drug. Both drugs are ARIs and can work in conjunction with ADT to prevent the spread of cancer to other parts of the body and slow down the progression of the disease. NUBEQA® is also approved for use in combination with chemotherapy.

21. Prostate cancer cells need male hormones, called androgens, to grow and survive. The main androgen in the body is testosterone. Testosterone acts as fuel for prostate cancer—without it, the cancer cells have a much harder time growing and spreading. For this reason, one of the main treatment approaches for prostate cancer involves reducing testosterone levels in the body, often through medications or surgery. When prostate cancer responds to these hormone-lowering treatments, doctors call it "castration-sensitive," meaning the cancer remains sensitive to changes in hormone levels. If the cancer does not respond to hormone-lowering treatment, it is called "castration-resistant."

22. When prostate cancer spreads beyond the prostate gland to other parts of the body, such as the bones or lymph nodes, it is called "metastatic" cancer. Metastatic castration-sensitive prostate cancer ("mCSPC") is cancer that has spread but still responds to treatments that lower testosterone. Although standard hormone therapy helps, cancer cells can still find ways to use the small amounts of testosterone that remain in the body. This is where ARIs like Bayer's NUBEQA® are useful.

23. ARIs like NUBEQA® work by blocking the doorway that testosterone uses to enter and activate cancer cells. Every prostate cancer cell has special proteins on it called androgen receptors. These receptors act like locks, and testosterone acts like a key. When testosterone attaches to the receptor, it unlocks a signal that tells the cancer cell to grow and multiply. NUBEQA® works by fitting into these locks and blocking testosterone from attaching. Without that signal, the cancer cells cannot grow as effectively and may even die.

24. What makes drugs like NUBEQA® especially helpful is that they are used alongside standard hormone therapy, which blocks testosterone from being made. While traditional hormone therapy lowers the overall amount of testosterone in the body, the androgen receptor inhibitor provides an extra layer of protection by blocking whatever testosterone remains from interacting with the cancer cells. This two-pronged approach attacks the cancer from multiple angles, making it harder for the disease to progress.

25. Both NUBEQA® and ERLEADA® belong to the same class of drugs and work in similar ways, but they have some differences in their chemical makeup. These differences can affect issues like side effects and how the drugs interact with other medications a patient might be taking. For example, NUBEQA® is often noted for having few drug-drug interactions and low side effects.[3]

26. The ultimate goal of using ARIs in mCSPC is to slow down the progression of the disease, help patients live longer, and maintain quality of life. Clinical studies have shown that adding these medications to standard hormone therapy can significantly delay the time it takes for the cancer to worsen and can in some cases improve survival rates. By

[3] *See* supra at 4, fn 2.

cutting off the cancer's fuel supply more completely, ARIs give patients a powerful tool in the fight against advanced prostate cancer.

27. NUBEQA® was first approved by the FDA in July 2019 for non-metastatic castration-resistant prostate cancer, meaning non-metastatic prostate cancer that no longer responded to ADT. In August 2022, the FDA approved NUBEQA® for men with mCSPC for use in combination with chemotherapy and ADT ("triplet therapy"). In June 2025, the FDA approved NUBEQA® to treat men with mCSPC in combination with ADT as a doublet therapy, the treatment type that was observed in the Data Analysis.

28. J&J's ERLEADA® product was approved by the FDA for the treatment of non-metastatic castration-resistant prostate cancer in February 2018. It was approved in September 2019 for the treatment of mCSPC in combination with ADT as a doublet therapy.

29. The ARI market in the U.S. is very competitive, with three main drugs offered to patients and healthcare providers: NUBEQA®, ERLEADA® and Pfizer's XTANDI®, which was approved for doublet therapy in December 2019. Pfizer currently holds the largest U.S. market share of the three drugs in the prostate cancer therapeutic space. Bayer, with its recent approval for doublet therapy, holds the second largest share. J&J holds the third largest.

Communications With J&J

30. J&J published its Press Release on February 2, 2026 and presented its Presentation at the 36th Annual International Prostate Cancer Update conference to a colloquium of medical professionals the same day. The Presentation contains QR codes for medical professionals to access copies of both the Overview Slide and the Presentation.

31. On February 6, 2026, Bayer sent a cease-and-desist letter to J&J stating that J&J's ERLEADA® Press Release and slide presentations were false and misleading and

demanding that J&J cease disseminating its claims, including by removing its claims from J&J's website, and issue a public retraction and correction of its false and misleading public statements.

32. On February 11, 2026, Bayer reiterated its concerns and requested that J&J provide the full analysis forming the foundation for J&J's slides, press release and web postings. J&J refused to provide the underlying data.

33. On February 13, 2026, J&J sent Bayer a letter defending its false and misleading claims and asserting that its "51 percent reduction in the risk of death" claim is "entirely plausible".

34. Bayer and J&J representatives subsequently had further discussions. J&J has refused to remove the claims, and Bayer determined it had no choice but to bring suit.

J&J's Press Release Making False Claims

35. J&J's false claims misinform patients and healthcare providers as to the relative reduction in the risk of death for patients taking ERLEADA® as compared to NUBEQA®. Specifically, J&J's central claim in its Press Release – that its drug demonstrated a 51% reduction in risk of death as compared to NUBEQA® based on the Data Analysis – is false and unsubstantiated.

36. Overall survival rates – the inverse is referred to as the risk of death – are a key metric for prostate cancer patients looking to make decisions about their treatment plans as well as for healthcare providers seeking to provide the best care possible for their patients.

37. J&J published a Data Analysis in a Press Release on J&J's website. See Exhibit A. The Press Release is titled "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." The

Press Release is found at: https://www.jnj.com/media-center/press-releases/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. The Press Release characterizes the Data Analysis as follows: "first ever head-to-head analysis compares overall survival outcomes of ERLEADA® versus darolutamide." The Press Release also states that the Data Analysis "adhere[s] to the rigorous standards set by the U.S. FDA."

38. The Press Release is publicly posted on J&J's website, with "Johnson & Johnson" in clear red letters at the top of the page. The Press Release's title in large, bolded letters references J&J's ERLEADA® by name and compares it to darolutamide, the active ingredient in Bayer's NUBEQA®:

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

First ever head-to-head analysis compares overall survival outcomes of ERLEADA® versus darolutamide

39. J&J thus proclaims a clinical causative message – that treatment with ERLEADA® reduces the risk of death compared to treatment with NUBEQA® – when a retrospective Data Analysis like the one J&J sponsored cannot establish that. J&J's Data Analysis was an observational look at the association between patients who start an ERLEADA® prescription or a NUBEQA® prescription and all-cause mortality through 24 months. Yet, J&J reported out the results as though the Data Analysis had reached a clinical finding of superiority for its drug over Bayer's drug to the precision of 51%, and that is exactly how the media has picked up its message.[4]

40. J&J amplifies the error of its message by repeatedly positioning its Data Analysis as strong science that is robust, reliable and reproducible. J&J states in the Press Release that the Data Analysis "adhere[s] to the rigorous standards set by the U.S. FDA." J&J overstates the rigor of its Data Analysis with multiple additional claims, including that the following:

(i) the "methodological safeguards [of the Data Analysis] deliver robust, reproducible insights that inform real-world treatment decisions"

(ii) the Data Analysis was the "first ever head-to-head analysis [that] compares overall survival outcomes of ERLEADA® versus darolutamide"

(iii) "[t]hese real-world data show the survival benefit of apalutamide versus darolutamide in patients with mCSPC without the concurrent use of docetaxel," and the Data Analysis "us[ed] rigorous methodology to support clinical decision-making"[5]

[4] *See, e.g.*, DiEugenio, *Real-World Analysis Establishes OS Advantage With Apalutamide Plus ADT vs Darolutamide in mCSPC*, OncLive, February 10, 2025, *available at* https://www.onclive.com/view/real-world-analysis-establishes-os-advantage-with-apalutamide-plus-adt-vs-darolutamide-in-mcspc; Clarke, *Head-to-head analysis shows OS benefit with apalutamide vs darolutamide in mCSPC*, Urology Times, February 3, 2026, *available at* https://www.urologytimes.com/view/head-to-head-analysis-shows-os-benefit-with-apalutamide-vs-darolutamide-in-mcspc.

[5] These quotations were attributed to Mehmet Bilen, a physician affiliated with the Winship Cancer Institute of Emory University who has provided various paid services to J&J.

(iv) the Data Analysis "provid[ed] comparative effectiveness evidence"

(v) "a propensity score matching statistical method… was employed to balance baseline characteristics between treatment groups, removing bias from measured confounders and replicating the conditions of a randomized clinical trial"

(vi) "this head-to-head analysis supports apalutamide being a key standard of care treatment for patients with mCSPC"[6]

41. In reality, J&J's method was to retrospectively match data from two separate databases: the Precision Point Specialty Analytics Database, an electronic medical records database that contains patient demographic data and prostate cancer-related clinical information (*e.g.*, time from diagnosis to ARI treatment initiation, laboratory measurements, etc.), and the Komodo Research Claims Database, an insurance claims database that contains information on comorbid conditions and mortality data. J&J's sponsored team compared this data, allegedly "using 24-month follow-up data," for patients who initiated treatment with NUBEQA® and ERLEADA®. J&J then published sensationalist claims that its drug had a quantified 51% superior efficacy over NUBEQA® with respect to the reduction in the risk of death. This approach does not meet rigorous FDA standards and is full of inherent confounders and biases that cannot be remedied with a propensity score statistical method.

42. The FDA requires "substantial evidence" to support claims about prescription drugs, defined as evidence from adequate and well-controlled investigations conducted by qualified experts to fairly and responsibly conclude that a drug will have its claimed effect.[7] The agency treats promotional materials as false, misleading, or misbranded when they rely on studies that are inadequate in design, scope, or conduct—including those with

[6] This statement was provided in the Press Release by Mahadi Baig, vice president of U.S. Medical Affairs at J&J.

[7] 21 C.F.R. § 202.1(e)(6)(ii).

inconsistent patient selection criteria, failure to control for confounding variables such as patient frailty and performance status, and notably imbalanced sample sizes between treatment arms. Through enforcement actions by the Office of Prescription Drug Promotion, the FDA has consistently explained that these methodological deficiencies are not merely technical limitations but constitute primary sources of misbranding that can mislead patients and healthcare providers about a drug's true clinical profile.[8] The Data Analysis is invalid for precisely these reasons. It does not adhere to the rigor required to be deemed "substantial evidence" necessary to make bold superior efficacy claims.

43. FDA draft guidance concerning real-world evidence emphasizes that observational analyses must be carefully designed to minimize bias, ensure comparability between treatment populations, and avoid drawing causal conclusions where confounding variables cannot be adequately controlled.[9] The FDA has stated that "sponsors [of real world evidence trials] should… briefly summarize alternative study approaches and candidate data sources they considered before deciding on the proposed approach and discuss why alternative approaches (*e.g.*, randomized trials, single-arm trials) were not feasible in answering the specific study questions."[10]

44. The FDA does not hold real-world evidence analyses to be equal to or sufficiently robust to replace traditional clinical trials, as these analyses require an explanation as

[8] *See, e.g.*, FDA, Warning Letter from The Office of Prescription Drug Promotion to Amgen (July 7, 2021); FDA, Warning Letter from The Office of Prescription Drug Promotion to Edenbridge Pharmaceuticals, LLC (Feb. 3, 2025); FDA, Warning Letter from The Office of Prescription Drug Promotion to Cornerstone Therapeutics Inc. (Oct. 31, 2012).

[9] FDA Draft Guidance Document, *Real-World Evidence: Considerations Regarding Non-Interventional Studies for Drug and Biological Products*. March 2024.

[10] *Id.*

to why the superior testing methodology was not used. In addition, FDA guidance makes it clear that:

> [w]hen relying on a non-interventional study… the inference(s) drawn may be incorrect if based on estimates that are affected by (1) confounding (e.g., due to noncomparable treatment groups) or (2) other forms of bias (e.g., how patients are selected for the study, if follow-up periods for assessing outcomes are incorrectly specified, when the accuracy for measuring the outcome is different in exposed and unexposed patients, data on key variables are missing not at random).

Identifying and addressing the presence of such confounding and other sources of bias is critical when planning and conducting non-interventional studies."[11]

45. Contrary to these principles, J&J relied upon a retrospective observational analysis that had fundamentally non-comparable patient populations, misrepresented the follow-up period, had severe imbalances in group sizes, and had missing data on key prognostic variables. J&J's claim that its Data Analysis was designed to meet rigorous FDA guidance is plainly false, as the Data Analysis's numerous deficiencies render it unsuitable for public claims of drug superiority. By invoking FDA authority to lend unwarranted credibility to scientifically flawed analyses, J&J has misled patients and healthcare providers regarding the evidentiary reliability and regulatory legitimacy of its promotional claims.

46. The Data Analysis is fundamentally flawed due to structural disparities between the cohorts that render the two patient groups inherently non-comparable. NUBEQA® was not FDA-approved for use as a doublet therapy in the United States during 33 out of the 34 months in the Data Analysis period, meaning that patients who received NUBEQA® for 97% of the study period were taking the medication off-label.[12] These patients had doctors who chose to

[11] *Id.*

[12] Although the National Comprehensive Cancer Network ("NCCN") incorporated the use of darolutamide with ADT in its Clinical Practice Guidelines in Oncology for Prostate Cancer on December 4, 2024, this guideline was

prescribe NUBEQA® after considering approved therapies and determining that NUBEQA® was most appropriate.

47. This reflects a clinical judgment by doctors that other FDA-approved androgen receptor inhibitors, including ERLEADA®, were unsuitable for those particular patients. When physicians deviate from labeled use, they do so for patient-specific reasons, such as intolerance risks, comorbidity burdens, drug–drug interaction concerns, or prior treatment history, that are not fully observable in administrative datasets. Those unrecorded clinical drivers necessarily shape who enters the NUBEQA® cohort and create a systematic difference between the populations being compared. Because the data sources employed in the Data Analysis cannot capture the nuanced medical reasoning underlying those prescribing decisions, no amount of adjustment for so-called "measured confounders" can restore true comparability between the two groups. Indeed, NUBEQA®'s strong tolerability profile and limited interaction potential make it particularly attractive for medically complex or fragile patients, precisely the types of characteristics that are incompletely reflected in claims data. The resulting comparison is therefore not between clinically interchangeable populations, but between cohorts assembled through materially different treatment-selection processes.

48. These structural disparities are compounded by the dramatic imbalance in sample size: the ERLEADA® cohort was approximately five times larger than the NUBEQA® cohort. Disproportionate group sizes in time-to-event modeling can distort variance estimates and magnify the influence of individual outcomes within the smaller arm. As follow-up progresses and patients are censored or lost, the number of individuals remaining "at risk" in the

still for off-label use of darolutamide as a doublet therapy. Even if this guideline is considered, 79% of the observation period in the Data Analysis was during a time when daralutamide was neither FDA-approved nor subject to NCCN guidelines for doublet therapy.

smaller NUBEQA® cohort contracts even further, rendering the calculated hazard ratio, a measure used in survival analysis to compare the relative risk of an event occurring at any given time between two groups, increasingly dependent on a limited number of events. Under such conditions, modest changes in event timing can materially shift the reported risk estimate.

49. Patients who begin treatment with higher unrelated underlying comorbidities are independently more likely to have a greater risk of death regardless of treatment. This necessarily skews patient outcomes in a way that cannot be accounted for in a retrospective data analysis. J&J states in its Press Release that it "remov[ed] bias" between groups through the use of a "propensity score matching statistical method." This is false. There is no statistical method that can account for fundamentally non-comparable patient cohorts.[13]

50. J&J claims to have accounted for the non-cancer comorbidity differences through the use of propensity score weighting based on the "Quan-CCI score," a scoring system that assigns weighted numerical values to certain diagnosed medical conditions in an attempt to estimate overall patient illness burden and mortality risk. In simple terms, the Quan-CCI aggregates select coded diagnoses from administrative claims data—such as cardiovascular conditions, diabetes, liver, or renal disease—into a single score intended to approximate general health status. However, reliance on the Quan-CCI score cannot remedy the fundamental non-comparability between the cohorts analyzed here. The index captures only a limited subset of pre-defined conditions reflected in billing codes and does not measure critical clinical factors

[13] Certain authors of the Data Analysis have previously commented on the differences between on-label and off-label patient cohorts. In a November 2025 letter, they asserted that a "clinically valid population" would include patients "who appropriately initiated ARPI therapy only after regulatory approval." *See* Mehmet A. Bilen et al., *Response to Letter to the Editor Regarding: 'Overall Survival with Apalutamide Versus Enzalutamide in Metastatic Castration-Sensitive Prostate Cancer'* 43 Adv. Therapy 445, 445–448 (2026), *available at* https://link.springer.com/article/10.1007/s12325-025-03436-9.

that substantially influence mortality risk in real-world oncology populations, including frailty, functional status, treatment tolerance, severity or progression of comorbid conditions, or physician prescribing rationale.

51. In addition, the Quan-CCI score largely assigns binary weights based on the presence or absence of specific diagnoses rather than the severity, progression, or clinical complexity of those conditions. Thus, patients with materially different health profiles and mortality risks can receive identical scores, masking meaningful differences between cohorts. Because the Quan-CCI score relies on incomplete and indirect proxies for patient health derived from administrative data, it cannot eliminate bias arising from structurally different patient populations. Where, as here, one cohort was predominantly treated off-label, the use of a generalized comorbidity score creates only the illusion of adjustment while ignoring substantial unmeasured confounding factors. Accordingly, any claim that statistical matching based on Quan-CCI scores "removes bias" or renders the treatment groups comparable is scientifically unfounded and materially false.

52. J&J's analysis is further undermined by its reliance on two proprietary real-world databases, the Komodo Research Database ("KRD") for mortality data and Precision Point Specialty Analytics ("PPS") for patient data, whose structural limitations render the resulting comparison unreliable. A recent article in the Journal of the American Medical Association showed that 40% of patients considered eligible for real-world studies according to structured data were not actually eligible.[14] The KRD appears to utilize open claims data, which are inherently incomplete because individual patients may have only partial medical or pharmacy

[14] *Supplementary Online Content: George DJ, et al. Androgen receptor inhibitors in patients with nonmetastatic castration-resistant prostate cancer. JAMA Netw Open. 2024;7(8):e2429783. doi:10.1001/jamanetworkopen.2024.29783* (*eFigure 2)*.

histories captured within the dataset. As a result, key clinical events, comorbidities, and treatment exposures may be missing or inconsistently recorded, introducing systematic bias that cannot be corrected through statistical weighting. In addition, the KRD asserts without published evidence that it updates mortality data monthly and utilize multiple third-party sources, and that in external validation, the KRD database has identified >90% of all deaths reported in oncology settings to the US Centers for Disease Control. There are no published or publicly available validation studies to support this assertion, however. The PPS database presents a similar concern: there is no publicly available validation establishing the accuracy, completeness, or clinical representativeness of its variables. The choice of a urology practice database for this study is also problematic. Medical management of patients with metastatic prostate cancer primarily occurs in medical oncologist practices. If the PPS database did not include information from oncologists' offices, large and critical portions of care may be excluded.

53. J&J compounded these independent weaknesses by linking the two databases to generate its study population and outcomes, thereby layering incomplete claims data onto a specialty dataset of uncertain validity. Where neither source independently provides comprehensive clinical information, combining them amplifies the risk of misclassification, missing data, and unmeasured confounding. The resulting dataset cannot reliably support head-to-head survival comparisons, particularly in a study already affected by off-label prescribing patterns and non-comparable patient populations.

54. In its Press Release, J&J represents that patients initiating treatment between August 2022 and June 2025 were followed "through 24 months of follow-up." The underlying index-year data in the Presentation, however, demonstrates that at least 60% of both

cohorts began treatment after June 2023—less than 24 months before the study endpoint in June 2025. Any patient initiating treatment after June 2023 could not have satisfied a 24-month follow-up requirement. In fact, fewer than 40% of the patients could have been followed for 24 months.[15] Patients reading the Press Release are told that "there were 1,460 ERLEADA® patients and 287 darolutamide initiators who met study criteria," but the Press Release does not convey that more than 60% of those patients could not have been followed "through 24 months of follow-up".

55. Although J&J presents its Data Analysis as reflecting outcomes "through 24 months of follow-up," the underlying methodology calls for many patients to contribute only partial follow-up, excludes deaths occurring after censoring, *i.e.*, the date the patient is removed from the data set, and emphasizes early events regardless of whether they relate to treatment efficacy. Here, as reflected in the Presentation, the emphasis on early deaths is clear, as early deaths at 6 months show the initial and only noticeable separation between the two cohorts in the hazard ratio curves. For the remainder of the follow-up period, the two curves tracking deaths between both cohorts remain fairly parallel. As seen in the Presentation, the reported number of patients at risk after 24 months is 87 for the NUBEQA® cohort and 456 for the ERLEADA® cohort. Despite the final cohort shrinking dramatically in size, J&J still flaunts that 287 patients "met study criteria" in its Press Release. This is clear misrepresentation of the Data Analysis's actual design and results. A methodology that purports to evaluate outcomes over a defined observation window must accurately report on the outcomes, particularly in a Press Release

[15] The Patient Population table on Slide 4 of the Presentation indicates that 11.8% of the patients initiated treatment with darolutamide in 2022, and 39% of the patients initiated treatment in 2023. Using half of the 2023 patients (which is generous because June 2 is five twelfths into the year), the math shows that no more than 30.6% of the patients were followed for a full 24 months.

being issued to the general public that is not savvy about how to critically assess scientific studies. J&J made deliberate choices in how it worded its Press Release to obfuscate these facts and weaknesses in its Data Analysis.

56. In addition, the Press Release headline states that the Data Analysis observed patients who were "treated" with ERLEADA® versus darolutamide. This too is false. The Presentation clearly states the Data Analysis observed patients who "initiat[ed]" apalutamide versus darolutamide. To meet study criteria, patients had to initiate one or the other treatment, but it is unknown whether patients remained on the same treatment or switched to a separate treatment at some point after initiation or "rescued" from ERLEADA® to NUBEQA® due to side effects and tolerability issues.

57. In addition to the methodological flaws described above, J&J's own prior public statements concerning comparative survival analyses involving ERLEADA® further demonstrate the unreliability and misleading nature of the challenged claims. On October 2, 2024, J&J published a press release describing a retrospective real-world comparison between ERLEADA® and enzalutamide, the ARI sold by Pfizer as XTANDI®.[16] In that communication, J&J characterized the study as a large real-world analysis involving nearly 4,000 patients with balanced cohort sizes and treatment populations prescribed within approved indications. Despite those comparatively stronger methodological attributes, J&J employed measured language regarding the magnitude and implications of the findings. For example, the 2024 press release quoted a medical director at the Carolina Urologic Research Center, stating "[h]ead-to-head, randomized and controlled Phase 3 studies have been the gold standard for comparing the

[16] *Available at* https://www.jnj.com/media-center/press-releases/erleada-apalutamide-demonstrates-statistically-significant-and-clinically-meaningful-improvement-in-overall-survival-compared-to-enzalutamide-in-patients-with-metastatic-castration-sensitive-prostate-cancer.

effectiveness of oncology medicines" and noting that "prospective [ARI] comparator trials have not been conducted."

58. Moreover, J&J's retrospective analysis of survival data concerning ERLEADA® demonstrates that the reported overall survival rates vary substantially depending on study design, time period, and data set, further illustrating the instability and sensitivity of retrospective analyses. For example, J&J's Phase 3 TITAN clinical trial on ERLEADA® reported an approximately 82.4% overall survival rate for apalutamide at 24 months.[17] J&J's real-world comparison against enzalutamide reported a 24-month survival rate of approximately 87.6% for apalutamide. By contrast, the challenged Data Analysis reports an even higher survival rate of approximately 92.1% for apalutamide. These substantial shifts in survival outcomes across different analyses involving the same drug demonstrate that survival metrics are dependent on study parameters and patient selection and that real-world evidence analyses can vary significantly from clinical trials against placebo.

59. There are also significant logic flaws in J&J's comparative claim of superiority over NUBEQA®. In the Phase 3 TITAN clinical trial, ERLEADA® was shown to have a 35% reduced risk of death compared to ADT alone, which has never shown an Overall Survival benefit compared to placebo. Unlike ADT, NUBEQA® has shown an Overall Survival benefit as compared to placebo.[18] Yet, J&J claims that the Data Analysis demonstrates that ERLEADA® had 51% reduced risk of death compared to NUBEQA®. This facial inconsistency

[17] Chi KN, Agarwal N, Bjartell A, Chung BH, Pereira de Santana Gomes AJ, Given R, Juárez Soto Á, Merseburger AS, Özgüroğlu M, Uemura H, Ye D, Deprince K, Naini V, Li J, Cheng S, Yu MK, Zhang K, Larsen JS, McCarthy S, Chowdhury S; *TITAN Investigators. Apalutamide for Metastatic, Castration-Sensitive Prostate Cancer*. N Engl J Med. 2019 Jul 4;381(1):13-24. doi: 10.1056/NEJMoa1903307.

[18] *See* Fizazi K, Shore N, Tammela TL, Ulys A, Vjaters E, Polyakov S, Jievaltas M, Luz M, Alekseev B, Kuss I, Kappeler C, Snapir A, Sarapohja T, Smith MR; *ARAMIS Investigators. Darolutamide in Nonmetastatic, Castration-Resistant Prostate Cancer.* N Engl J Med. 2019 Mar 28;380(13):1235-1246.

is further supported by a host of multicenter retrospective studies that observe the relative outcomes of different ARIs. For example, a multicenter retrospective study of apalutamide versus enzalutamide in a population of non-metastatic castration-resistant prostate cancer concluded that "enzalutamide and apalutamide were shown to exhibit comparable oncological outcomes but quite different adverse event profiles."[19] A multicenter comparison of abiraterone, enzalutamide, and apalutamide for metastatic castration-sensitive prostate cancer patients also concluded that "[a]biraterone, enzalutamide, and apalutamide have *comparable oncologic outcomes* in terms of overall survival (OS), CSS, and time to CRPC in patients with high-risk m[C]SPC."[20] In addition, a recent paper by Dr. Naqvi presented at the prestigious American Society of Clinical Oncology concluded that based on a network meta-analysis observing multiple prospective, phase 3, randomized, double-blind clinical trials, the three ARI agents produced similar survival outcomes.[21] These analyses show no survival benefit of one agent versus another and underscore how unreliable J&J's conclusions are.

J&J's Data Analysis Slide Presentations Making False Claims

60. In addition to the false claims contained in the Press Release, J&J posted a one-page "Overview Slide" on its Medical Connect website for healthcare providers, payers and healthcare decision-makers that repeats and amplifies the same misleading superiority messaging. The Overview Slide can be found at:

[19] Hara S, et al. Int J Clin Oncol. 2024 Aug;29(8):1191-1197. doi: 10.1007/s10147-024-02548-6. Epub 2024 May 20. PMID: 38769191.

[20] Yanagisawa T, et al. *Comparison of abiraterone, enzalutamide, and apalutamide for metastatic hormone-sensitive prostate cancer: A multicenter study*. 2025 Feb;85(2):165-174. doi: 10.1002/pros.24813. Epub 2024 Oct 17 (emphasis added).

[21] *See* Naqvi, *Comparative survival in metastatic castration-sensitive prostate cancer (mCSPC) by prognostic subgroups: A living network meta-analysis*, available at: https://www.asco.org/abstracts-presentations/230216.

https://www.jnjmedicalconnect.com/media/attestation/congresses/oncology/2026/ipcu/real-world-comparison-of-overall-survival-in-patients-with-metastatic-castration-pls.pdf. See Exhibit B. J&J makes the Overvew Slide available to anyone willing to check a box identifying as a "U.S. healthcare professional" or a "U.S. payer or population health decision maker", which could encompass millions of people.

61. The Overview Slide is false by both omission and commission. Under a section titled "[w]hat were the limitations," J&J fails to disclose one of the most fundamental constraints on the analysis: that during nearly the entire study period, NUBEQA® lacked approval for doublet therapy and was therefore prescribed only off-label, resulting in a materially different patient population. This omission deprives readers of critical information necessary to interpret the results and creates the false impression that the comparison involved similarly situated treatment cohorts. Where an advertiser highlights purported superiority while withholding core limitations that undermine comparability, the resulting communication is false.

62. The Overview Slide prominently states that "[p]atients 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)." This statement is literally false and misleading because the Data Analysis does not measure inherent patient risk or demonstrate that one therapy changes the underlying probability of death relative to another. Rather, it reports crude outcome differences observed among materially different patient populations that did not uniformly have 24 months of follow-up. By framing the results as showing that patients "were less likely to die" with reference to the treatment they had, J&J conveys a causal benefit to risk of death and treatment-driven advantage that cannot be derived from the study design.

63. The Overview Slide further answers the question "How well did apalutamide work" with a large graphic emphasizing a "51% lower risk of death through 24 months with apalutamide compared with darolutamide." Presented with a prominent downward arrow, this statement communicates an absolute therapeutic benefit suggesting that treatment with apalutamide itself cuts mortality risk roughly in half. The underlying analysis does not establish such a causal effect. Instead, it relies on retrospective analysis of non-comparable cohorts and does not control for important clinically significant baseline differences. Transforming a hazard ratio generated from an observational data set into a direct claim about treatment efficacy constitutes a false statement of cause and effect and materially misrepresents the evidentiary strength of the analysis.

64. The Overview Slide also falsely states, five times, that the Data Analysis provides conclusions regarding survival through 24 months. The Overview Slide states: "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." The Overview Slide concludes that "[t]hrough 24 months, patients who started treatment with apalutamide (without docetaxel) were less likely to die than those who stated darolutamide (without docetaxel)." This central message here is fundamentally unsubstantiated. As demonstrated above, the key premise is just wrong: although the Overview Slide states that "287 [s]tarted darolutamide without docetaxel," the Data Analysis does not show conclusions for 287 patients at 24 months of follow-up because more than 60% of the 287 patients could not have received 24 months of observation. J&J's presentation is beyond slick – it is blatantly false.

65. The Overview Slide presents purported findings in simplified question-and-answer form as though the Data Analysis findings are true clinical conclusions. The

Overview Slide explicitly invites healthcare providers to ask "how well did apalutamide work," and answers with a false superiority claim. In doing so, J&J transforms statistical observations drawn from a flawed retrospective analysis into categorical claims about treatment outcomes that the underlying data cannot support.

66. J&J also disseminated the six-slide Presentation, which contains additional independent misrepresentations beyond those made in the Press Release and the Overview Slides. J&J presented these slides at the annual International Prostate Cancer Update conference and makes the slides available on its Medical Connect website. The Presentation presents the Data Analysis in a format resembling scientific reporting but employs language and visual framing that falsely convey the strength, duration, and substance of the findings. The Presentation can be found here: https://www.jnjmedicalconnect.com/media/attestation/congresses/oncology/2026/ipcu/real-world-comparison-of-overall-survival-in-patients-with-metastatic-castration-presentation.pdf. See Exhibit C.

67. Slide 3 of the Presentation identifies the "study period" as January 1, 2016 through June 30, 2025, indicating a lengthy and comprehensive evaluation spanning nearly a decade. In reality, the relevant comparative analysis covers a substantially shorter effective observation window from August 5, 2022 through June 30, 2025. J&J states that the actual start date is the "index date," which is the earliest date of a "first paid claim or dispensation" of the medicine "on or after August 5, 2022." By presenting an extended date range without clarifying the limited duration of usable comparative data, J&J falsely indicates that the findings are supported by long-term evidence and mature follow-up, thereby overstating the reliability and clinical significance of the results.

68. Slide 4 of the Presentation asserts that "Through 24 months: Apalutamide demonstrated ↓ 51% reduction in risk of death." Unlike comparative statements elsewhere, this language presents the alleged effect as an absolute outcome attributable solely to apalutamide, rather than as a relative statistical comparison between groups. J&J falsely states that patients taking apalutamide experience a direct and quantified reduction in mortality risk. The Data Analysis cannot support such an absolute efficacy claim.

69. The "24-month" claim is also invalidated by the information on slide 4, which clearly states that 48.9% of apalutamide patients and 49.2% of darolutamide patients initiated treatment in 2024 or 2025, and that 39.0% of darolutamide patients and 39.1% of apalutamide patients initiated treatment in 2023. Assuming constant treatment initiation rates, at least half of the 2023 patients and all of the 2024 and 2025 patients could not have been evaluated for 24 months of follow-up, since the study period concluded on June 30, 2025.

70. Slide 5 acknowledges that "unknown confounders may be present," but this disclaimer does not cure the false and misleading nature of the Presentation. The most significant confounding factors affecting the analysis—the unevaluated factors underlying the doctors' decisions to use an off-label drug when alternative regimens (including darolutamide as a triplet therapy with ADT and docetaxel) were available and the unmeasured potential confounding factors (frailty, performance status, life threatening conditions, and other non-cancer attributes)—are not hypothetical or unknown. By characterizing confounding factors as speculative while failing to disclose known sources of bias, J&J minimizes critical methodological defects and reinforces the false message that any limitations are minor or theoretical rather than fundamental.

71. Taken together, the statements in the Overview Slide and the Presentation go beyond merely reporting weak data and instead convey definitive clinical conclusions that are unsupported by the underlying methodology. Through selective phrasing, visual emphasis, and omission of material limitations, J&J communicates to healthcare providers, just as it does in the Press Release, that ERLEADA® has been shown to provide a meaningful survival advantage over NUBEQA®, when in fact the Data Analysis cannot reliably establish any such causal or comparative superiority.

J&J's Press Release and Presentation Slides Are Commercial Speech

72. J&J's Press Release and presentation slides constitute commercial speech and commercial advertising and promotion within the meaning of the Lanham Act. The communications are not found in a neutral scientific publication or independent academic commentary but instead are promotional statements disseminated by a pharmaceutical manufacturer to advance the commercial interests of its branded ERLEADA® product over its competitors in the marketplace.

73. The challenged Press Release takes the form and appearance of an advertisement. J&J issued the communication through its corporate media center, a channel used to distribute marketing and promotional messaging. The Press Release is structured to highlight the purported efficacy advantages of J&J's drug in a manner designed to attract attention and persuade readers. The headline prominently promotes an alleged "51% reduction in risk of death," a marketing-oriented claim framed to convey superiority and influence prescribing and purchasing behavior. The Press Release incorporates promotional elements typical of pharmaceutical advertising, including prominently featuring the ERLEADA® branded product name, comparative efficacy assertions, corporate executive quotations emphasizing product

value, and standardized safety disclosures. These features collectively demonstrate that the communication is formatted and intended to be promotional advertising, not a publication meant to foster scientific discourse. As for the J&J presentation slides, they are readily available on J&J's Medical Connect website for anyone willing to check a box self-identifying as a healthcare professional or payer or population health decision maker.

74. The Press Release repeatedly references and promotes a specific commercial product, ERLEADA®, and compares it directly against a competing therapy. The communication identifies ERLEADA® by brand name throughout and highlights alleged advantages over darolutamide, Bayer's product, thereby positioning J&J's product as superior within the relevant market. Indeed, J&J includes a quote from one of its medical employees stating that "this head-to-head analysis supports apalutamide being a key standard of care treatment for patients with mCSPC." This quote is clearly directed at doctors and their prescribing decisions. Speech referring to specific products and touting comparative performance constitutes paradigmatic commercial promotion. J&J emphasizes purported survival benefits, describes ERLEADA®'s clinical role and regulatory status, and directs readers to product-specific information and ERLEADA®'s product website, all of which are designed to increase demand for the branded therapy and influence patients' purchasing and healthcare providers' prescribing decisions.

75. The overall context and dissemination of the Press Release demonstrates that it constitutes commercial speech. J&J distributed the Press Release through its publicly accessible corporate channels, ensuring that the messaging would reach healthcare professionals, investors, patients, and the broader marketplace. The Press Release selectively emphasizes favorable findings and frames them as evidence of product superiority, while employing

persuasive language characteristic of marketing communications. The inclusion of "Important Safety Information" mirrors regulatory requirements associated with pharmaceutical advertising and further reflects J&J's intent to promote a branded therapy within a commercial context.

76. The Press Release does not resemble independent scientific or academic publications. The Press Release contains no links to the Data Analysis's underlying data, protocol, or methodology, making any scientific discourse or review of the analysis impossible. In addition, the Press Release does not mention that two of the seven "authors" are J&J employees and does not include information about conflicts of interest for the other authors. The Press Release highlights J&J's preferred interpretation of data in a manner designed to promote ERLEADA®'s alleged competitive advantages. The messaging is crafted to shape market perception and encourage the purchase and prescription of J&J's product. The longer these false claims remain present online, the more likely they are to be picked up by third party publications and generative AI search functions and further disseminated to the general public.

77. Already, a Google search regarding ERLEADA® and NUBEQA® and risk of death provides an AI response at the top of the search page that repeats J&J's false superiority claims, causing immediate and irreparable harm to Bayer. The AI Overview states:

> A February 2026 real-world, head-to-head analysis found that **Erleada (apalutamide)** reduces the risk of death by **51%** more than Nubeqa (darolutamide) in patients with metastatic castration-sensitive prostate cancer (mCSPC) not receiving chemotherapy. Erleada demonstrated a statistically significant superior overall survival advantage over Nubeqa.

This message is blatantly false, harmful to Bayer, and most importantly, dangerously misleading to people who have prostate cancer or whose loved one has prostate cancer and are being fed unsubstantiated messages about the risk of dying with NUBEQA®. Furthermore, J&J has succeeded in causing even Gen AI into playing back that its lower-grade retrospective analysis of

two historical data sets constitutes "real-world head-to-head data" as though ERLEADA® and NUBEQA® were set up in a one-on-one clinical trial in the real world and these are the results.[22] J&J has played beyond "fast and loose" with its terminology and promotion to the general public of inherently invalid observations from a flawed look-back at non-comparable data.

Irreparable Injury to Bayer

78. Because Bayer and J&J are direct competitors in the Rx market for androgen receptor inhibitors, J&J's false advertising injures Bayer by misinforming consumers that based on a head-to-head analysis, ERLEADA® offers a 51% reduction in risk of death as compared to NUBEQA®. J&J's advertisements will continue to cause irreparable harm to Bayer in the form of lost market share in the Rx market for prostate cancer patients and damaged goodwill and reputation to Bayer, Bayer products, and NUBEQA® because they misinform patients and healthcare providers that ERLEADA® is a superior drug to NUBEQA® with respect to the reduction in the risk of death.

79. NUBEQA® is a flagship oncology product within Bayer's pharmaceutical portfolio and represents a significant commercial and strategic asset for Bayer's Rx business, generating €1.63 billion globally in the first nine months of 2025 alone. NUBEQA® is a key growth driver within Bayer's oncology franchise and a central component of its long-term pharmaceutical strategy. NUBEQA® has achieved blockbuster status, reflecting its rapidly expanding adoption and material contribution to Bayer's financial performance. NUBEQA®

[22] Bayer notes that companies can pay Google to prioritize certain results in the AI summary field at the top of a search. In addition, the AI algorithm is designed to find and feature the latest and most trendy information on a particular topic. Given their sensationalist nature, J&J's claims are primed for AI play-back despite their false messages and premises.

plays a substantial role in Bayer's revenue growth, investor expectations, and competitive positioning within the prostate cancer therapeutic market.

80. Bayer has invested substantial resources into building the reputation of its NUBEQA® and educating doctors and patients about the efficacy and safety of its medicine, including its low potential for interacting with other drugs.

81. Bayer has also invested substantial resources in educating healthcare providers about the benefits of Bayer's products, which is crucial to obtaining market share and the trust and support of patients.

82. J&J is now attempting, in making false superiority claims about its ERLEADA® product, to unfairly obtain a larger market share than it would otherwise command by misinforming patients and healthcare providers as to the relative reduction in the risk of death as a result of taking J&J's product as compared to Bayer's product.

83. J&J's claims attack the market position of Bayer's product by making false and misleading claims about the reduction in risk of death for its ERLEADA® product and by providing an invalid comparison between ERLEADA® and NUBEQA®. Patients and healthcare providers misled by J&J's claims will disfavor Bayer's medicine when comparing it to ERLEADA® directly, and J&J will usurp market share that would otherwise go to NUBEQA®. In addition, doctors wrongly influenced by this misinformation may make prescribing decisions for their patients that are not best suited to the unique circumstances of the individual patient.

84. Because NUBEQA® is a core growth product and a substantial contributor to Bayer's pharmaceutical revenues, misleading statements about mortality outcomes threaten to erode physician confidence, distort competition, and permanently shift prescribing

patterns in ways that cannot be fully quantified or remedied through monetary damages. Loss of control over brand reputation, diminished physician and patient trust, and erosion of competitive positioning within a critical therapeutic market constitute injuries that are ongoing and difficult to measure with precision.

85. Moreover, Bayer has invested significant resources in the research, development, regulatory approval, and commercialization of NUBEQA®, including clinical trials designed to demonstrate its safety and efficacy across multiple indications. J&J's false superiority claims undermine these investments by conveying false information regarding comparative clinical performance, thereby impairing Bayer's ability to compete fairly and to realize the value of its substantial investments in NUBEQA®. Unless enjoined, J&J's conduct will continue to cause Bayer irreparable harm.

86. Because there are very few FDA-approved androgen receptor inhibitors on the market, strong unfounded superiority claims cause significant disruptions to sales and market share. NUBEQA® has low side effects such as fatigue, cognitive impairment, and falls, and a low potential for drug-drug interactions, making it a useful drug for those suffering from other conditions that require prescription medicine. J&J's claims seek to undermine these benefits by promulgating the unsupported message that J&J's drug reduces the risk of death more than Bayer's drug.

87. J&J's campaign is obviously intentional. The Data Analysis specifically targets NUBEQA® patients and the NUBEQA® product. This campaign is thus specifically targeted at Bayer and Bayer's market share in the prostate cancer therapeutic space. J&J wants patients and healthcare specialists to choose its product out of fear that the risk of death is higher with Bayer's drug. This leads to additional concerns involving patient safety. NUBEQA®'s

inherently low number of side effects and drug-drug interactions make it a suitable choice for various patients with sensitivities or other underlying conditions. If those patients switch to a less tolerated therapy based on J&J's false claims, they could be harmed in the process.

88. J&J knows that its claims are false but has nonetheless refused to stop disseminating its false and misleading advertising campaign, including taking down its Press Release, exacerbating the ongoing damage to the reputation and competitiveness of Bayer's product and specifically undercutting the growing success of Bayer's NUBEQA®.

89. Bayer has no adequate remedy at law for these injuries. No monetary remedy would be adequate to compensate Bayer for the injury that J&J's wrongful acts have caused to Bayer's reputation, goodwill, market share, and sales, and for the injury that Bayer will suffer should those acts not be enjoined.

FIRST CLAIM FOR RELIEF
(False Advertising Under the Lanham Act)

90. Bayer repeats and realleges paragraphs 1 through 89 above as though fully set forth herein.

91. Defendants' advertising campaign includes materially false and misleading representations of fact about the characteristics of Defendants' and Bayer's products.

92. J&J's claims have the tendency to deceive, and will actually deceive, a substantial segment of the patients and healthcare providers at which they are directed and will influence their purchasing decisions.

93. Defendants are waging their advertising campaign with knowledge of their false, misleading and disparaging nature and of its tendency to deceive.

94. Defendants' foregoing acts constitute false advertising in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a).

95. Bayer has no adequate remedy at law to compensate it for all the damage that already has been caused by Defendants' wrongful acts and that will continue to be caused should those acts not immediately cease.

SECOND CLAIM FOR RELIEF
(False Advertising Under New York Business Law)

96. Bayer repeats and realleges paragraphs 1 through 95 above as though fully set forth herein.

97. Defendants' foregoing acts constitute false advertising in violation of Sections 349 and 350 of New York General Business Law.

98. Bayer has no adequate remedy at law to compensate it for all the damage that already has been caused by Defendants' wrongful acts and that will continue to be caused should those acts not immediately cease.

99. Bayer believes it has suffered monetary damages as a result of Defendants' acts of false advertising in an amount not yet determined but that already exceeds $75,000.

THIRD CLAIM FOR RELIEF
(Common Law Unfair Competition)

100. Bayer repeats and realleges paragraphs 1 through 99 above as though fully set forth herein.

101. Defendants' foregoing acts constitute unfair competition under the common law of the State of New York.

102. Because J&J and Bayer are head-to-head competitors in the Rx market for prostate cancer treatment, Defendants' false and misleading campaign harms Bayer and will continue to harm Bayer as long as it is being disseminated.

103. Defendants are aware of the misleading nature of the current advertising campaign.

104. Defendants are acting in bad faith by continuing to disseminate the false and misleading advertising campaign despite having knowledge of its false and misleading nature.

105. Bayer has no adequate remedy at law to compensate it for all the damage that already has been caused by Defendants' wrongful acts and that will continue should those acts not immediately cease.

106. Bayer believes it has suffered monetary damages as a result of Defendants' acts of unfair competition in an amount not yet determined but that already exceeds $75,000.

WHEREFORE, Bayer is entitled to judgment against J&J as follows:

A. For a declaratory judgment that J&J has engaged in:

(i) false advertising in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a);

(ii) false advertising in violation of Sections 349 and 350 of the New York General Business Law; and

(iii) unfair competition in violation of the common law of the State of New York.

B. For a preliminary injunction restraining Defendants and their agents, servants, officers, employees, and all those acting under their control and/or on their behalf and/or in concert with them, during the pendency of this action, from disseminating or causing to be disseminated the information set forth in J&J's Press Release and J&J Medical Connect website presentations, and from falsely claiming, in words or substance, that (a) prostate cancer patients treated with ERLEADA® had a 51% reduction in risk of death compared to patients

treated with NUBEQA®, (b) the Data Analysis sponsored by Defendants provides comparative evidence of the survival benefit of apalutamide versus darolutamide, and (c) the Data Analysis sponsored by Defendants adhered to rigorous FDA standards and had a robust methodology that delivered robust, reproducible results, matched the two treatment arms, removed bias, and replicated the conditions of a randomized clinical trial.

C. For a permanent injunction restraining Defendants and their agents, servants, officers, employees, and all those acting under their control and/or on their behalf and/or in concert with them from disseminating or causing to be disseminated the information set forth in J&J's Press Release and J&J Medical Connect website presentations, and from falsely claiming, in words or substance, that (a) prostate cancer patients treated with ERLEADA® had a 51% reduction in risk of death compared to patients treated with NUBEQA®, (b) the Data Analysis sponsored by Defendants provides comparative evidence of the survival benefit of apalutamide versus darolutamide, and (c) the Data Analysis sponsored by Defendants adhered to rigorous FDA standards and had a robust methodology that delivered robust, reproducible results, matched the two treatment arms, removed bias, and replicated the conditions of a randomized clinical trial.

D. For an order directing Defendants and their agents, servants, employees, and all those acting under their control and/or on their behalf and/or in concert with them:

(i) to issue a corrective Press Release, in a form to be approved by this Court, to dispel the impact and effect of the false, misleading, disparaging and/or otherwise unlawful advertisements and promotional materials they previously disseminated;

(ii) to take all steps necessary to secure the return and destruction of all false, misleading, disparaging and/or otherwise unlawful advertising and promotional materials previously disseminated by or on behalf of J&J; and

(iii) to file with this Court and serve upon Bayer, within 30 days after entry of an injunction order, a report in writing and under oath, setting forth in detail the manner and form in which J&J complied with the relief ordered herein.

E. For a judgment requiring Defendants to pay to Bayer:

(i) Compensatory damages in an amount to be determined at trial;

(ii) Defendants' unjust profits after an accounting;

(iii) three-fold and/or punitive damages on account of the egregious conduct complained of herein; and

(iv) Bayer's costs, disbursements, expenses, and attorneys' fees.

F. For such other, further and different relief as this Court shall deem just and proper.

Dated: New York, New York
February 23, 2026

Respectfully submitted,

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