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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

TIRRELL ALLEN,

Plaintiff,

v.

GLOBAL BLOOD THERAPEUTICS, INC. and PFIZER INC.,

Defendants.

Case No. 3:24-cv-07786-TLT

JOINT CASE MANAGEMENT STATEMENT

Date: February 13, 2025
Time: 2:00 p.m.
Place: Remote (Zoom)
Judge: Hon. Trina L. Thompson

JOINT CASE MANAGEMENT STATEMENT

Pursuant to Civil Local Rule 16-9, the Standing Order for All Judges of the Northern District of California regarding Contents of Joint Case Management Statement, and this Court's Standing Order for Civil Cases, Plaintiff Tirrell Allen ("Plaintiff") and Defendants Global Blood Therapeutics, Inc. and Pfizer Inc. ("Defendants") (collectively, "the Parties"), hereby submit the following joint statement.

1. Jurisdiction and Service

Plaintiff filed his Complaint on November 7, 2024 (ECF No. 1), and served Defendants on January 6, 2025 (ECF Nos. 18, 19). This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1367. No issues exist regarding personal jurisdiction or venue, and no Defendant remains unserved.

2. Facts

a. Plaintiffs' Statement

This is an action for damages related to Defendants' conduct in connection with the development, design, testing, manufacturing, labeling, packaging, promoting, advertising, marketing, distribution, and selling of Oxbryta (generic name: voxelotor), a prescription medication used to treat sickle cell disease. The FDA approved Oxbryta under the accelerated approval pathway in 2019 for the treatment of sickle cell disease in adults and pediatric patients 12 years of age and older. In 2021, FDA granted accelerated approval of Oxbryta for the treatment of sickle cell disease in patients 4 to 11 years of age. Accelerated approval is based on a surrogate or intermediate clinical endpoint that is reasonably likely to predict clinical benefit, allowing for earlier approval of drugs that treat serious conditions and fill an unmet medical need. In general, FDA requires post-marketing studies to verify and describe the clinical benefit of medications approved under this program. Defendants marketed Oxbryta through various forms of media and promised its purchasers would "experience less sickling."

On September 25, 2024, Defendants announced they were voluntarily withdrawing the medication from the market, ceasing distribution, and discontinuing all active clinical trials and expanded access programs for Oxbryta "because recent data indicate the benefit of Oxbryta does not

outweigh the risks for the sickle cell patient population." Defendants noted that their decision was "based on the totality of clinical data that now indicates the overall benefit of Oxbryta no longer outweighs the risk in the approved sickle cell patient population. The data suggest an imbalance in vaso-occlusive crises and fatal events which require further assessment."

Plaintiff Tirrell Allen is a 43-year old male who was diagnosed with sickle cell disease as a child. While on Oxbryta, he experienced an increased rate of vaso-occlusive crises (VOCs), suffered a stroke, and was hospitalized.

Defendants' Statement

This case is about Oxbryta (voxelotor), a prescription medicine developed by Global Blood Therapeutics, Inc. ("GBT") for the treatment of sickle cell disease ("SCD"). SCD is a lifelong, inherited disease that affects hemoglobin, the protein in red blood cells that is responsible for delivering oxygen throughout the body. It affects approximately 100,000 people in the United States. In patients with sickle cell disease, abnormal hemoglobin causes red blood cells to become rigid, sticky, and "sickle"-shaped. These sickled red blood cells clump together and restrict the flow of oxygen, causing pain events called vaso-occlusive crises ("VOCs"), acute chest syndrome, swelling, anemia, and strokes, among other complications.

In 2019, the FDA approved Oxbryta for use by adults and pediatric patients 12 years and older, based on clinical trial results as well as the significant unmet medical needs of patients with sickle cell disease; two years later, the agency expanded the medication's approved use to patients as young as 4 years old. Oxbryta was the first approved sickle cell treatment to target the root cause of sickle cell disease; by improving the ability of hemoglobin to bind to oxygen, the medicine helps red blood cells maintain their normal shape. In a clinical trial, patients treated with Oxbryta demonstrated a statistically significant improvement in hemoglobin response, and showed no increase in vaso-occlusive crises.[1]

Pfizer Inc. ("Pfizer") acquired GBT in October 2022, and continued to study the benefit of Oxbryta in both confirmatory studies and real-world registries. In September 2024, Pfizer

[1] Center for Drug Evaluation & Research, App No. 213137, Multi-Discipline Review & Evaluation (Division Director Summary Review for Regulatory Action at 12), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/nda/2019/213137Orig1s000Multidiscipline.pdf.

announced the voluntary withdrawal of Oxbryta following an initial review of available data from post-marketing and registry-based studies, which appeared to show an unexpectedly higher rate of VOCs in some Oxbryta patients, and a higher number of deaths among some patients taking Oxbryta for a longer period of time. Pfizer notified the FDA and other regulatory authorities that it was continuing to review all available data regarding Oxbryta; that analysis is ongoing.

Approximately six weeks later, on November 7, 2024, Plaintiff filed his Complaint in this action, alleging that, during the one-month period he was taking Oxbryta, it caused him to experience a "higher rate of VOCs" than prior to taking the medication, and a stroke for which he was hospitalized. Compl. ¶¶ 24-26.

3. Legal Issues

Plaintiff alleges six claims under California law: (1) Strict Products Liability – Design Defect; (2) Strict Products Liability – Failure to Warn; (3) Negligence; (4) Breach of Express Warranties; (5) Breach of Implied Warranties; (6) Unjust Enrichment; (7) False and Misleading Advertising, in violation of California Business & Professions Code § 17200, *et seq.*; (8) False and Misleading Advertising, in violation of California Business & Professions Code § 17500, *et seq.*; and (9) Violation of California Civil Code § 1750, *et seq.*

a. Plaintiff's Statement

Plaintiff maintains that Defendants are liable based on the eight causes of action listed above and preliminarily identify the following legal issues: whether Defendants shall be held liable under Plaintiff's theories of recovery; Whether Defendant's conduct rises to the level of punitive damages; and whether Defendant's advertisements violate California law by being false and/or deceptive.

b. Defendants' Statement

Defendants dispute Plaintiff's allegations, deny that they are liable for any of the claims asserted by Plaintiff in the Complaint, and, at the appropriate time, will file an answer with affirmative defenses. The principal legal issues include, but are not limited to: whether the Complaint should be dismissed for Plaintiff's failure to state a claim; whether Plaintiff's strict liability claims are recognized under California law; whether any alleged defect in Oxbryta caused or contributed to Plaintiff's claimed injuries; whether the warnings for Oxbryta were adequate;

whether Plaintiff's claims are barred by the learned intermediary doctrine; whether Plaintiff's claims are barred by federal preemption; whether Plaintiff has standing to pursue injunctive relief for his claims; whether Defendants' alleged failure to warn caused Plaintiff's injuries; and whether Plaintiff relied on any statements or warranties about Oxbryta.

4. Motions

On January 24, 2025, the Parties stipulated to extend Defendants' time to answer or otherwise respond to the Complaint (ECF No. 20), which was granted on January 27, 2025 (ECF No. 22). Defendants anticipate filing a motion to dismiss the Complaint by February 26, 2025.

There are no other prior or pending motions. The Parties reserve the right to file other motions as appropriate, including motions for summary judgment (or partial summary judgment), and pretrial motions, including motions *in limine*.

5. Amendment of Pleadings

The Parties do not anticipate any amendments to the pleadings at this time.

6. Evidence Preservation

The Parties certify that they have reviewed the Guidelines Relating to the Discovery of Electronically Stored Information, and confirm that they have met and conferred pursuant to Fed. R. Civ. P. 26(f) regarding reasonable and proportionate steps taken to preserve evidence relevant to the issues reasonably evident in this action. The Parties are aware of and complying with their preservation obligations, and will advise the Court in the event they are unable to reach an agreement on ESI-related issues.

7. Disclosures

Neither party has exchanged initial disclosures as of the date of the filing of this Joint Case Management Statement. The Parties propose that they exchange their Initial Disclosures within 30 days after the Court rules on Defendants' forthcoming motion to dismiss.

8. Discovery

a. Discovery Taken to Date

There has been no discovery taken to date.

b. Scope of Anticipated Discovery

i. Plaintiff's Statement

Plaintiffs intend to seek discovery from Defendants and third party sources related to the following topics, among other things, a) all study data that led to the Oxbryta recall, b) Defendant Pfizer's acquisition and current relationship with Defendant Global Blood Therapeutics, c) adverse event reporting data, d) European Medicine Agency Study GBT440-032 and Study GBT440-042 data, e) summary basis of approval for application for Oxbryta and f) information related to Defendant's development, design, testing, manufacturing, labeling, packaging, promoting, advertising, marketing, distribution, and selling of Oxbryta.

ii. Defendants' Statement

If this case proceeds to discovery, Defendants intend to seek discovery from Plaintiff and third parties regarding, among other topics: (a) Plaintiff's past and ongoing medical evaluation and treatment; (b) the decision of Plaintiff's healthcare providers to prescribe Oxbryta to Plaintiff; (c) details concerning Plaintiff's ingestion of Oxbryta; (d) how and when Plaintiff learned of the alleged relationship between his ingestion of Oxbryta and his alleged injuries; (e) Plaintiff's alleged injuries and his support for his assertions that Oxbryta caused those injuries; (f) warnings, labels, and other promotional materials about Oxbryta, if any, that Plaintiff relied upon; and (g) Plaintiff's damages.

c. Modifications to the Discovery Rules

The Parties do not current request any modifications to the Discovery Rules but reserve the right to request modifications as the litigation proceeds.

d. Agreement to Enter a Stipulated E-Discovery Order

The Parties agree to cooperate and work in good faith toward reaching an agreement on a stipulation regarding the preservation and production of electronically stored information, as well as a protective order governing the discovery and use of confidential information. If agreement cannot be reached, the Parties will seek the Court's assistance.

e. Discovery Disputes

The Parties have not identified any discovery disputes at this time.

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9. Class Actions

The Plaintiff does not assert claims on behalf of a class.

10. Related Cases

There are currently no other cases in this Court that satisfy the definition of a "related" case under Civil Local Rule 3-12(a).

There are currently four other cases pending in California state courts involving different plaintiffs who assert similar claims about Oxbryta as those raised by Plaintiff in this action: (1) *Hardiman v. Global Blood Therapeutics, Inc.*, CGC-24-619197 (Cal. Super. Ct. San Francisco Cnty.); (2) *L. Smith and A.S. v. Global Blood Therapeutics, Inc. & Pfizer, Inc.*, 24-CIV-08190 (Cal. Super. Ct. San Mateo Cnty.); (3) *M. Smith v. Global Blood Therapeutics, Inc.*, CGC-24-621022 (Cal. Super. Ct. San Francisco Cnty.); (4) *Afolabi v. Pfizer, Inc., et al.*, 24-CIV-08331 (Cal. Super. Ct. San Mateo Cnty.).

11. Relief

a. Plaintiff's Statement

Plaintiff seeks a jury trial and the following categories of damages: past, present and future general damages in an amount to be determined at trial; For past, present and future special damages, including but not limited to past, present and future lost earnings, economic damages and others, in an amount to be determined at trial; any appropriate punitive or exemplary damages; any appropriate statutory damages; for costs of suit; for interest as allowed by law; for attorney's fees and costs as applicable; for treble damages as applicable; for such other and further relief as the court may deem proper.

b. Defendants' Statement

Defendants dispute that they are liable to Plaintiff for any damages or other relief. If liability is established, damages expert(s) would likely be required to calculate damages, if any. Defendants have not yet filed their Answer but expect to do so, if appropriate, following the resolution of their forthcoming Motion to Dismiss. Defendants reserve all rights to seek all appropriate relief.

12. Settlement and ADR

The Parties have met and conferred in compliance with ADR L.R. 3-5 and agree that ADR

or early settlement at this time would be premature. Should the case be referred to ADR, the Parties agree that private, non-binding mediation is the best mechanism for alternative dispute resolution in this litigation.

13. Other References

The Parties agree that this case is not suitable for reference to a special master or the Judicial Panel on Multidistrict Litigation.

14. Narrowing Issues

The Parties have not agreed on any issues that can be narrowed at this time.

15. Expedited Trial Procedure

The Parties agree that this case is not suitable for the Expedited Trial Procedure set forth in General Order 64, Attachment A.

16. Scheduling

Event	Proposed Date
Rule 26(a)(1) Initial Disclosures	30 days after the Court's ruling on the Motion to Dismiss
Close of Fact Discovery	12 months after Court's ruling on the Motion to Dismiss
Affirmative Expert Disclosures	1 month after Close of Fact Discovery
Rebuttal Expert Disclosures	2 months after Affirmative Expert Disclosures
Close of Expert Discovery	4 months after Rebuttal Expert Disclosures
Dispositive motions and *Daubert* motions due	2 months after the Close of Expert Discovery
Hearing on dispositive motions and *Daubert* motions	2 months after dispositive motions and *Daubert* motions filed
Pretrial Conference	3 months after Court's ruling on dispositive motions
Trial	4 weeks after the Pretrial Conference

17. Trial

The Parties agree that the case will be tried to a jury. The Parties' position on the timing of the date for trial is set forth above, and they believe it is premature to estimate a length of trial at this time.

18. Disclosure of Non-Party Interested Entities or Persons

Plaintiff will file his Certificate of Interested Parties. Plaintiff does not have conflicts or interests to report outside of the parties.

Defendants filed their Certificate of Interested Entities or Persons on January 24, 2025. As disclosed therein, Pfizer Inc. is a publicly held corporation and there is no parent corporation or publicly held corporation that owns 10% or more of its common stock. Global Blood Therapeutics, Inc. is a wholly-owned subsidiary of Pfizer. Other than the parties, there is no other conflict or interest to report. *See* ECF No. 21.

19. Professional Conduct

All attorneys of record for the Parties have reviewed the Guidelines for Professional Conduct for the Northern District of California.

20. Other

At this time, the Parties are not aware of other matters that may facilitate the resolution of this matter.

DATED: February 7, 2025

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SIGNATURE ATTESTATION

I, Kiley Grombacher, am the ECF User whose ID and password are being used to file this document. In compliance with Civil Local Rule 5-1, I hereby attest that all counsel whose e-signatures (/s/) appear on this document concurred in this filing.

DATED: February 7, 2025 By: /s/ *Kiley Grombacher*