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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

TIRRELL ALLEN and LATOYA ALLEN,

Plaintiffs,

v.

GLOBAL BLOOD THERAPEUTICS, INC. and PFIZER INC.,

Defendants.

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

JOINT CASE MANAGEMENT STATEMENT

Date: June 26, 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, Plaintiffs Tirrell Allen and LaToya Allen ("Plaintiffs") and Defendants Global Blood Therapeutics, Inc. and Pfizer Inc. ("Defendants") (collectively, "the Parties"), hereby submit the following joint statement.

1. Jurisdiction and Service

Plaintiff Tirrell Allen filed his original Complaint on November 7, 2024 (Dkt. 1) and served Defendants on January 6, 2025 (Dkts. 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.

b. 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, Application 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.

3. Legal Issues

Plaintiffs' Amended Complaint alleges nine claims: (1) Strict Products Liability – Design Defect; (2) Strict Products Liability – Failure to Warn; (3) Negligence; (4) Negligent Misrepresentation; (5) Breach of Express Warranties; (6) Breach of Implied Warranties; (7) Quasi-Contract; (8) Violation of the Illinois Consumer Fraud and Deceptive Business Practices Act, 815 Ill. Comp. Stat. 505/1 - 505/12; and (9) loss of consortium.

a. Plaintiffs' Statement

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

b. Defendants' Statement

Defendants dispute Plaintiffs' allegations, deny that they are liable for any of the claims asserted by Plaintiffs in the Amended 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 Amended Complaint should be dismissed for Plaintiffs' 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

Defendants filed a motion to dismiss the amended complaint on April 23, 2025 (Dkt. 47). That motion is fully briefed, and set for hearing on July 8, 2025.

There are no other 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

Plaintiffs filed an amended complaint on March 12, 2025. Pursuant to the Court's Case Management and Scheduling Order (Dkt. 32), the last day to amend pleadings was May 22, 2025.

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 are 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' motion to dismiss the amended complaint.

8. Discovery

a. Discovery Taken to Date

Plaintiffs served initial discovery requests on Defendants on May 15, 2025.

b. Scope of Anticipated Discovery

i. Plaintiffs' 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 Medicines Agency Study GBT440-032 and Study GBT440-042 data; (e) summary basis of approval for application for Oxbryta; and (f) information related to Defendants' 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 currently 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.

9. Class Actions

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

10. Related Cases

a. Federal Court

On February 28, 2025, Plaintiff filed an administrative motion to consider whether *Jolly, et al. v. Global Blood Therapeutics, Inc. and Pfizer Inc.*, Case No. 3:24-cv-09345-TLT (N.D. Cal.) ("*Jolly*"), a putative class action involving claims of economic harm (not personal injury), should be related to this case (Dkt. 34). Defendants opposed the motion (Dkt. 38). On March 5, 2025, this Court ordered that *Jolly* be related to this case. Accordingly, *Jolly* was re-assigned to this Court (*Jolly* Dkt. 22). Plaintiffs in *Jolly* filed an amended complaint on April 2, 2025 (*Jolly* Dkt. 38). Defendants filed a motion to dismiss the amended complaint on April 23, 2025 (*Jolly* Dkt. 40). That motion is fully briefed and set for hearing on the same date as the pending motion to dismiss in *Allen*, July 8, 2025.

Two other product liability cases involving claims that plaintiffs suffered personal injuries from consuming Oxbryta were recently filed in this Court: (1) *Frazier v. Global Blood Therapeutics, Inc. and Pfizer Inc.*, Case No. 3:25-cv-04027-TLT (N.D. Cal.) ("*Frazier*"); and (2) *Ford v. Global Blood Therapeutics, Inc. and Pfizer Inc.*, Case No. 3:25-cv-04229-TLT (N.D. Cal.) ("*Ford*"). Plaintiffs in each case filed unopposed administrative motions to consider whether *Frazier* and *Ford* should be related to *Allen* (Dkts. 53, 58), which the Court granted (Dkts. 54, 59). Defendants have not been served in either case.

b. State Court

There are currently eight product liability cases pending in California state court that have been served on Pfizer and/or GBT involving claims that plaintiffs suffered personal injuries from consuming Oxbryta. Those cases are:

(1) *Leona Smith v. Global Blood Therapeutics, Inc. and Pfizer Inc.*, Case No. 24-CIV-08190 (Cal. Super. Ct. – San Mateo Cnty.) Status: Plaintiff filed an amended complaint on April 10, 2025. Defendants filed a demurrer to Plaintiff's

amended complaint on May 12, 2025, and further briefing on the demurrer is in progress. A hearing on Defendants' demurrer is set for January 15, 2026. The next case management conference is on September 3, 2025.

(2) *Tolulope Afolabi v. Pfizer Inc., Global Blood Therapeutics, Inc., and Does 1 through 100*, Case No. 24-CIV-08331 (Cal. Super. Ct. – San Mateo Cnty.) Status: Defendants filed a demurrer to Plaintiff's complaint on March 17, 2025, and further briefing on the demurrer is in progress. A hearing on Defendants' demurrer is set for January 15, 2026. The next case management conference is on September 3, 2025. Plaintiff has served initial discovery requests.

(3) *Raven Favor v. Global Blood Therapeutics, Inc.*, Case No. 25-CIV-01314 (Cal. Super. Ct. – San Mateo Cnty.) Status: Defendant filed a demurrer to Plaintiff's complaint on April 21, 2025, and further briefing on the demurrer is in progress. A hearing on Defendant's demurrer is set for December 4, 2025. The next case management conference is on September 3, 2025.

(4) *Asja Joseph v. Global Blood Therapeutics, Inc.*, Case No. 25-CIV-01315 (Cal. Super. Ct. – San Mateo Cnty.) Status: Defendant filed a demurrer to Plaintiff's complaint on April 21, 2025, and further briefing on the demurrer is in progress. A hearing on Defendant's demurrer is set for December 4, 2025. The next case management conference is on September 3, 2025.

(5) *Deborah Majeeda Snead v. Pfizer Inc. and Global Blood Therapeutics, Inc.*, Case No. 25-CIV-02200 (Cal. Super. Ct. – San Mateo Cnty.) Status: Plaintiff served the complaint on Defendant Global Blood Therapeutics, Inc. on April 18, 2025, and on Defendant Pfizer Inc. on May 6, 2025. Defendants filed a demurrer to Plaintiff's complaint on May 19, 2025, and further briefing on the demurrer is in

progress. The initial case management conference is set for July 15, 2025. A hearing on Defendants' demurrer is set for August 26, 2025.

(6) *Trebor Hardiman v. Global Blood Therapeutics, Inc.*, Case No. 25-CIV-03836 (Cal. Super. Ct. – San Mateo Cnty.) Status: Plaintiff served the complaint—originally filed in the Superior Court of San Francisco County—on Defendant Global Blood Therapeutics, Inc. on November 4, 2024. A joint stipulation for change of venue to the Superior Court of San Mateo County was filed on February 24, 2025. The case was transferred to the Superior Court of San Mateo County as of May 20, 2025. Defendant intends to file a demurrer to Plaintiff's Complaint. The next case management conference is on September 3, 2025.

(7) *Marcia Smith, as Administrator for the Estate of Marissa Harris v. Global Blood Therapeutics, Inc.*, Case No. CGC-24-621022 (Cal. Super. Ct. – San Francisco Cnty.) Status: Plaintiff served the complaint on Defendant Global Blood Therapeutics, Inc. on February 14, 2025. A joint stipulation for change of venue to the Superior Court of San Mateo County was filed on March 17, 2025. The court ordered that the action should be transferred to the Superior Court of San Mateo County on May 21, 2025. The venue transfer is pending.

(8) *Laura Christine Matteliano-Madu v. Children's Hospital & Research Center at Oakland, et al.*, Case No. 25CV117566 (Cal. Super. Ct. – Alameda Cnty.) Status: Plaintiff filed the complaint on March 27, 2025, and served Pfizer Inc. on June 10, 2025. An initial case management conference is set for September 4, 2025.

11. Relief

a. Plaintiffs' Statement

Plaintiffs seek a jury trial and the following categories of damages: past, present and future general damages in an amount to be determined at trial; 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; costs of suit; interest as allowed by law; attorney's fees and costs as applicable; treble damages as applicable; such other and further relief as the court may deem proper.

b. Defendants' Statement

Defendants dispute that they are liable to Plaintiffs 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 Motion to Dismiss. Defendants reserve all rights to seek all appropriate relief.

12. Settlement and ADR

The Parties have agreed to mediation before a private mediator.

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

The Court entered a Case Management and Scheduling Order on February 14, 2025 (Dkt. 32), attached hereto as ***Exhibit A.***

17. Trial

The Court has set this case for a jury trial to commence on June 7, 2027 and last 12–15 days.

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* Dkt. 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: June 18, 2025

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SIGNATURE ATTESTATION

I, Jessica Bodger Rydstrom, 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: June 18, 2025 By: /s/ *Jessica Bodger Rydstrom*