IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

TRICIA LYDAY and JEREMY LYDAY, Plaintiffs, v. APELLIS PHARMACEUTICALS, INC., Defendant,	Case No.: 3:24-cv-02044-K

MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF PLAINTIFFS' SECOND MOTION TO COMPEL DISCOVERY

Respectfully Submitted,

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Plaintiffs Tricia Lyday ("Tricia") and Jeremy Lyday (collectively with Tricia, "Plaintiffs") file this Second Motion to Compel Discovery from Defendant Apellis Pharmaceuticals, Inc. ("Apellis").

I. SUMMARY

This pharmaceutical products liability case arises from the severe adverse drug reaction suffered by Tricia when her physician injected Apellis' drug Syfovre into her left eye on September 22, 2023. The Syfovre injection caused Tricia to suffer a retinal vasculitis reaction that permanently blinded her in both eyes and required surgical removal of her left eye. Plaintiffs seek to compel production of six categories of relevant and discoverable documents improperly withheld by Apellis.

For the last decade, Apellis' "lead product candidate" and the most heavily marketed drug in the company's history has been what is now branded as Syfovre, a pegcetacoplan solution administered by intravitreal injection into the patient's eye to treat geographic atrophy ("GA"). In February 2023, Apellis received limited FDA approval for use of Syfovre in the U.S. to treat one specific type of GA – GA caused by age-related macular degeneration ("AMD").

The Complaint alleges, and the evidence now proves, that Apellis knew well *before* Tricia was injured that Syfovre causes vasculitis and blindness. Apellis received seven reports of vasculitis cases within three months of Syfovre's launch, almost six months before Tricia's injection. When Apellis belatedly reported those cases to the FDA in July, the FDA *immediately* instructed Apellis to change the Syfovre label to warn for this serious adverse drug event and to timely report future cases. The FDA reiterated that urgent instruction to Apellis at least *three times* during the two-month period before Tricia's injection. Apellis chose to oppose the FDA's label change instructions because Apellis knew that changing the Syfovre label to warn for vasculitis

would cause most retinal doctors to not prescribe the drug, with devastating effects on Syfovre sales and Apellis' stock price. So Apellis implemented a delay and obfuscation strategy to – according to its CEO, Dr. Cedric Francois – "buy time," thereby allowing Apellis' nascent drug to gain enough sales traction to withstand the severe impact the vasculitis cases would have on Syfovre sales and the company's stock price.

At the same time that it was stalling the FDA and opposing its urgent instructions to warn doctors that Syfovre causes vasculitis, Apellis aggressively spun a false public narrative – through, among other things, misleading medical updates and public presentations authored and made by Dr. Francois and Apellis' Chief Medical Officer, Dr. Caorline Baumal; a series of deceptive press releases; and misinformation relayed directly to physicians by Apellis sales representatives – that the vasculitis cases were caused by a 19-gauge needle and not Syfovre. Simultaneously, Apellis falsely assured the retinal community that Syfovre was safe by representing as the "main" and most important safety "fact" – *via* a blitz of public relations communications and public statements from its highest-ranking officers on an almost daily basis – the grossly misleading statistic that the vasculitis rate from Syfovre was an "extremely low" 1 in 10,000 injections (.01%). Apellis continued to propagate these falsehoods in medical conferences, paid publications, and through its paid speakers during the months leading up to Tricia's injury, and for months thereafter. Apellis did so even though both the FDA and the leading independent retinal society ASRS rejected Apellis "needle story" and its misleading .01% vasculitis incidence rate. Its motive was profits.

Tricia's prescribing physician, Courtney Crawford, MD, FACS ("Dr. Crawford"), a highly credentialed retinal specialist, retired U.S. Army officer, and former Apellis paid key opinion leader for Syfovre, has now testified consistently in a declaration and at his deposition:

- that Apellis did not warn him that Syfovre causes vasculitis and blindness prior to Tricia's injection;[1]

- that he would never have prescribed or injected Syfovre into Tricia's eye if he had been warned of the risk of vasculitis from Syfovre;[2] and

- that at the time of Tricia's injection, he had no reason to believe that Syfovre caused vasculitis or to warn Tricia of that risk because he believed Apellis' assurances that the cause of the vasculitis cases was the needle and not Syfovre.[3]

The Complaint also alleges, and the evidence now proves, that Apellis aggressively marketed Syfovre "off-label" to the retinal community, generally, and to Dr. Crawford, specifically. Dr. Crawford has likewise testified consistently on two occasions:

- that Apellis marketed Syfovre to him "off-label" both as a treatment for GA regardless of underlying cause, and as a treatment for Stargardt's disease, the specific condition suffered by Tricia – including naming specific Apellis sales representatives and several Apellis documents involved in that off-label promotion;[4] and

- that the off-label marketing by Apellis and its sales representatives caused him to prescribe and administer Syfovre to Tricia.[5]

A few weeks *after* Tricia received her Syfovre injection and lost her sight, Apellis abruptly changed its position and, faced with an impending FDA-ordered label change, finally acceded to the FDA's (at least fifth) instruction to change the drug label to warn for vasculitis. In a

[1] Dkt. No. 51 at Ex. A (Crawford declaration attached to Apellis' Motion to Compel); Ex. 1, Pl. Appx. 11-12, 22 (excerpts from the deposition of Dr. Crawford)
[2] *Id.* at 17-21.
[3] *Id.* at 11.
[4] *Id.* at 3-5, 22-24; As a result of this Court's April 7 order compelling Apellis to produce documents bearing on off-label promotion (Doc. 70), Apellis recently produced more than 500 pages of internal company documents that corroborate Dr. Crawford's off-label marketing testimony (including off-label promotion specific to Stargardt's disease) and further proving Plaintiffs' off-label marketing claims. Ex. 2, at Pl. Appx. 28 (a few of many unapproved indication/off-label documents reflecting that Apellis considered Stargardt's disease and other off-label indications to be substantial money-making business opportunities for the company and, in the months following FDA approval of Syfovre, tasked a team of employees to pursue those opportunities). Apellis' Court-ordered off-label production remains substantially incomplete. *See* Section H below. Pursuant to Judge Kinkeade's sealing Order (Doc. 4), Plaintiffs sent Apellis highlighted copies of all exhibits referenced in this Motion that Apellis produced with confidentiality designations. While Plaintiffs disagree that those records are entitled to sealing protection, Apellis has 14 days to prove the confidential nature of those documents for sealing purposes.
[5] Ex. 1, Pl. Appx. 4-5.

contemporaneous internal email, Apellis' CEO Dr. Francois *congratulated the team of employees responsible for implementing the delay strategy for buying months of (what Apellis characterized as) important time* before finally conceding to the FDA's demands for a retinal vasculitis label change. It was Tricia who paid the cost of the time Apellis bought, and the price was her sight.

During the 15-month period following Tricia's injury, European regulators rejected Apellis' application to sell Syfovre on three separate occasions based on safety concerns, including the drug's propensity to cause adverse events like vasculitis. During the same period, Apellis abandoned its debunked "needle story" and conceded what the FDA and ASRS had been telling Apellis all along - that vasculitis is a first injection phenomenon, the per patient rate of which is vastly higher than .01%.

Against that backdrop, Plaintiffs served their first set of written discovery on Apellis in October 2024, more than six months ago.[6] In response, Apellis implemented a discovery-avoidance strategy routinely utilized by drug company defendants in pharmaceutical injury cases.[7] Apellis first artificially limits the scope of discovery based on its own overly restrictive interpretations of (i) what information is relevant to Plaintiffs' claims, and (ii) the time period during which Apellis will search for responsive documents. Apellis then buries its improperly

[6] This Motion implicates the following discovery requests: (i) Plaintiffs' First Set of Requests for Production of Documents, served on October 24, 2024; (ii) Defendants' Amended Responses to First Set of Requests for Production of Documents, served February 18, 2025, (iii) Plaintiffs' Second Set of Requests for Production of Documents, served on January 24, 2025, (iv) Defendants' Responses to Second Set of Requests for Production of Documents, served on February 24, 2025. Ex. 3 Pl. Appx. 75. For ease of review, the discovery requests and responses supporting Plaintiffs' request for relief are isolated in a table at Ex. 34, Pl. Appx 487.

[7] Apellis will argue that it has produced a large volume of documents, and that Plaintiffs agreed to postpone discovery until late January 2024. Four months have passed since the failed January 6, 2024, mediation and Apellis' document production remains vastly incomplete. The parties have conferred by Zoom and phone in excess of ten times and exchanged hundreds of pages of discovery correspondence. Ex. 4, Pl. Appx. 239 (containing a few examples of the parties' conference efforts). The issues presented in this Motion are ripe for court order, particularly given defense witnesses will be deposed in July and Plaintiffs' upcoming September 2025 expert designation deadline.

restricted responses beneath an impenetrable web of unexplained boilerplate objections that make it impossible to ascertain what information is being withheld on what basis.

After extensive conference efforts over a period of months, the parties reached impasse with regard to the six matters that are the subject of this Motion:

1. *Custodial files.* Apellis will produce custodial files for only five employees unilaterally selected by Apellis and only for an 11-month time period (February 2023-January 2024). Plaintiffs seek to compel Apellis to produce the custodial files of six additional Apellis employees responsible for Syfovre safety and labeling. Each of the six custodians at issue in this Motion was personally involved in the Syfovre events at the heart of this case. Plaintiffs ask the Court to compel production of six additional custodial files for the 18-month time period of February 17, 2023 (the date of Syfovre's FDA approval) to August 12, 2024 (the date of filing suit).

2. *Documents relating to European Medicines Agency's (EMA) rejections of Syfovre.* Plaintiffs seek documents, communications, and information ("Documents") relating to Apellis' thrice-rejected application to market Syfovre in Europe based on safety and efficacy concerns, including the drug's propensity to cause vasculitis.

3. *Post-injury documents bearing on claims and defenses.* Plaintiffs seek four narrow categories of Documents for the post-injury time period September 23, 2023 to present that bear on i) causation, including the "needle story," ii) the Syfovre vasculitis label change, iii) Apellis' promotion and subsequent abandonment of the misleading .01% incidence rate, and iv) Apellis' defense that Syfovre does not cause systemic and immune mediated adverse reactions like the one suffered by Tricia. Apellis' discovery responses object to the production of any documents or communications "prepared, finalized, sent, or received after September 22, 2023, the date Plaintiff received her injection of Syfovre" because (according to Apellis) none of these events is relevant.[8]

4. *FDA/ASRS Documents*. Plaintiffs seek Syfovre-related Documents relating to the FDA and the American Society of Retina Specialists (ASRS)[9] during the time period February 17, 2023 to August 12, 2024. These were the third-party organizations at the center of the movement to warn physicians (and force Apellis to warn physicians) that Syfovre causes vasculitis. There is no reasonable basis for Apellis to withhold Syfovre-related FDA/ASRS documents.

5. *Draft and final meeting minutes*. Plaintiffs seek draft and final meeting minutes for the various internal Apellis Syfovre committees for the time period February 17, 2023 to August 12, 2024. While Apellis has produced final meeting minutes from a select few committees, Apellis has not disclosed which committee meeting minutes have not been produced, and will not agree

[8] For custodial file purposes, Apellis recently advised it will produce documents from February 17, 2023 (date of Syfovre's FDA approval) to January 2024, two months after the November 2023 label change.

[9] ASRS is the largest organization of retina specialists in the world, representing over 3,000 physicians in all 50 US states, the District of Columbia, Puerto Rico, and 63 countries. The Society serves as a national advocate and is a primary source of clinical and scientific information and education for its members.

to search for and produce drafts of the meeting minutes, which bear directly on how Apellis internally considered, whitewashed, and ultimately framed the fundamental liability issues in this case.

6. *Off-label marketing/new and unapproved uses documents*. Plaintiffs seek Documents pertaining to Apellis' admitted investigation of new and unapproved uses of Syfovre and the off-label marketing of Syfovre as a treatment for (a) GA regardless of cause, and (b) Stargardt's disease. This Court has already ordered Apellis to produce information bearing on its analysis of off-label uses of Syfovre. Apellis complied in part by producing documents from a single custodial file, only seven emails sent by two employees, and limited its production to a one-month time period in early 2023. Plaintiffs ask the Court to compel Apellis to produce the Documents bearing on off-label promotion of Syfovre for the time period February 17, 2023 to present.

For these reasons, explained in detail below, Plaintiffs ask the Court to enter an order compelling disclosure of the six narrow categories of Documents that are the subject of this Motion.

II. LEGAL STANDARD

"The scope of discovery is broad." *Open Cheer & Dance Championship Series, LLC v. Varsity Spirit, LLC*, No. 2:23-CV-155-Z, 2024 WL 5048013, at *1 (N.D. Tex. Dec. 9, 2024). "Thus, Rule 26's only limitations are that discovery requests need to be '(1) relevant to a claim or defense in the case; and (2) proportional to the needs of the case.'" *Id*. Discovery should be allowed unless "the information sought can have no possible bearing on the claim or defense of a party." *Id*. at *2, quoting *Merrill v. Waffle House, Inc.*, 227 F.R.D. 467, 470 (N.D. Tex. 2005).

III. DISCUSSION

A. Proportionality. Retinal vasculitis is a sight-threatening condition that can lead to permanent blindness. It is a public health concern due to its potential for serious complications and the need for prompt diagnosis and management. The injuries suffered by Tricia as a result of her Syfovre-induced vasculitis reaction – the total loss of vision in both eyes and surgical removal of her left eye – are undeniably catastrophic. Tricia, a 45-year-old wife, mother and former schoolteacher, is housebound and can no longer work or perform routine functions without daily

assistance from immediate family members. Her injuries are permanent, and they have robbed her of the ability to live a normal life forever. Almost two years later, Tricia continues to treat for her injuries. She has been permanently removed from the workforce and will require substantial medical and other care for the rest of her life. While the core of Tricia's damages are the unfathomable non-economic harms from the physical and emotional toll of her permanent blindness and loss of an eye, the projected economic cost of her future medical and attendant care alone exceeds $5,000,000.[10]

As a result of its aggressive marketing efforts and the delay and obfuscation strategy that cost Tricia her sight, Apellis generated $887 million in Syfovre sales between February 2023, when the FDA granted limited approval of the drug and the end of 2024.[11] Apellis is a sophisticated, well-financed, and rapidly growing biopharmaceutical company which, according to recent public filings, carries at least $50 million in product liability insurance that has been used to hire and pay defense counsel's fees and Apellis' expert expenses.[12] Apellis and its insurance carrier have assigned at least seven senior litigators to aggressively defend this case, including demanding Tricia's medical and other confidential personal records (spanning decades) from over 20 medical care providers, serving subpoenas on and deposing third parties including Tricia's family members; aggressively pursuing extensive discovery from Dr. Crawford and his employees

[10] Ex. 5 at Pl. Appx. 274, 309 (lifecare plan outlining Tricia's current and future needs, including medical, therapeutic, and financial aspects, to ensure that she receives necessary care and resources); Ex. 6 at Pl. Appx. 312-316 (Tricia's deposition testimony providing examples of her daily pain, suffering and changes to routine); Ex. 7 at Pl. Appx. 320 (medical records relating to the enucleation procedure).

[11] https://investors.apellis.com/news-releases/news-release-details/apellis-pharmaceuticals-reports-fourth-quarter-and-full-year-6; https://investors.apellis.com/news-releases/news-release-details/apellis-pharmaceuticals-reports-fourth-quarter-and-full-year-6#:~:text=For%20the%20full%20year%202023,associated%20with%20the%20Sobi%20collaboration.

[12] Ex. 8 at Pl. Appx. 325-326 (SEC Form 10-K noting Apellis carries over $50 million in product liability insurance).

in furtherance of Apellis' efforts to blame-shift responsibility for Tricia's injuries; and staffing multiple senior lawyers on every deposition, phone call, and basic discovery task in this case.[13]

Apellis has ready electronic access to the information at issue. And while Apellis complains of the purported burden associated with the production of additional custodial files, it was Apellis who selected the document review protocol through its steadfast insistence on using the TAR discovery collection process (instead of Plaintiffs' proposed search terms) to search the files.[14] Like all pharmaceutical companies, Apellis is required by U.S. law to store the information Plaintiffs seek in a readily retrievable format for government reporting purposes. It maintains its records in centralized global databases and electronic employee files that are easily searchable.[15]

The issues raised in this case are undoubtedly important to Tricia and Dr. Crawford; to every other doctor deciding whether to inject Syfovre into a patient's eye; to all of those prospective patients who are risking blindness by consenting to that injection; to the FDA; to the public; and even to Apellis. Considering all of these issues and the vast disparity in the comparative resources of the parties, the handful of narrow issues raised in this Motion are anything but disproportional to this case.[16]

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[13] As a limited example, three lawyers (two partners and an associate) recently traveled to Boston to defend the deposition of a single fact witness. *See Wal-Mart Stores, Inc. v. Tex. Alcoholic Beverage Commis'n*, No. 15-CV-134, 2016 WL 5922315 (W.D. Tex. Oct. 11, 2016) (commenting the "sheer number of attorneys who have made appearances in the case" was considered "a persuasive demonstration" of the significance of the case such that proportionality was "not at issue in this discovery dispute").

[14] Ex. 4, Pl. Appx. 273 (defense counsel email insisting on TAR search process).

[15] *Hodges v. Pfizer, Inc.*, 14-cv-4855, 2015 WL 13804602 (D. Minn. Dec. 17, 2015) (Magistrate opinion in single plaintiff pharmaceutical case handled by Plaintiffs' counsel; overruling Pfizer's proportionality and burden objections and ordering production of over 10 million pages of documents in dual blindness case); *Hodges v Pfizer*, 14-cv-4855, 2016 WL 1222229 (D. Minn. March 28, 2016) (District Court opinion overruling Pfizer's proportionality-based objection and affirming, in full, Magistrate's discovery order) (collectively, "Hodges"); *Goes Int'l AB v. Dodur Ltd*., No. 14-CV-05666-LB, 2016 WL 427369 (N.D. Cal. Feb. 4, 2016) (granting motion to compel and holding the discovery requests were proportional because the information at issue was readily accessible through data-analysis software); *Webb v. Ethicon Endo-Surgery, Inc*., No. 13-CV-1947 (JRT/JKK), 2015 WL 317215, at *7 (D. Minn. Jan. 26, 2015) (affirming magistrate's discovery order over undue burden objection, stating "[t]he fact that a corporation has an unwieldy record keeping system which requires it to incur heavy expenditures of time and effort to produce requested documents is an insufficient reason to prevent disclosure of otherwise discoverable information).

[16] Apellis contends that Plaintiffs should reimburse Apellis' insurance company for the cost of attorney review and

The importance of the issues in this case is underscored by the stunning liability facts established by the substantially incomplete evidence developed to date. Plaintiffs provide a detailed discussion of those facts in the next section of this Motion because they bear directly on the proportionality and relevance of the discovery in issue. While the amount of compensation that Tricia should receive for her injuries is ultimately for the jury to decide, it is not unreasonable to anticipate a substantial verdict on these facts in a plaintiff-favorable Dallas venue.[17]

B. Liability Facts and Timeline. In February 2023, the FDA approved Syfovre for the treatment of the limited indication of GA secondary to AMD. During April, May, and June, Apellis received seven reports of retinal vasculitis in patients injected with Syfovre. Apellis waited until July 9, when it finally called the FDA to report the vasculitis cases. According to FDA records documenting that July 9 call, "Apellis was advised of the *urgency* to gather information on the cases *and submit updates to the [Syfovre] labeling*."[18] This was 75 days before Syfovre was injected into Tricia's eye.

Less than one week later, on Saturday July 15, the ASRS Research and Safety in Therapeutics (ReST) Committee sent a letter to its member doctors warning them of multiple vasculitis cases following Syfovre injections – cases that had been reported to ASRS directly by physicians, not by Apellis.[19] In the words of Dr. Francois, the public disclosure of the Syfovre

production of additional custodial file productions. There is no legitimate basis for an insurance company to cost-shift to a blind former schoolteacher.

[17] *Thomas v. Charter Spectrum* ($7 billion verdict in wrongful death case in 2023); *Smith v Graystar* ($860 million verdict in crane collapse wrongful death case in 2023); *In re Depuy Hip Implant Litigation* ($30 million in actual damages and over $1 billion in punitive damages awarded to six plaintiffs in hip implant product liability case in N.D. Tex. in 2018; another jury awarded over $500 million to five hip implant plaintiffs in the same case in 2015).

[18] Ex. 9, Pl. Appx. 327 (FDA – Division of Ophthalmology Clinical/Labeling Review) (emphasis supplied).

[19] The ASRS ReST Committee is dedicated to keeping members apprised of adverse events (AEs) associated with all retina drugs and devices. The ASRS peer-to-peer reporting system serves as a post-market data and safety monitor to help protect patients.

cases created a "panic moment" for Apellis.[20] Over the next two weeks, Apellis stock price fell from $84.50 to $25.75, a decline of more than 70%.

On July 19, in a further attempt to distance its drug from this serious adverse reaction – and despite the FDA's July 9 (and subsequent) mandates to update the label to warn for vasculitis – Apellis sent a "safety" letter directly to the retinal community and Dr. Crawford blatantly misrepresenting that the vasculitis "[c]ases were reviewed by the FDA, and there is no indication that an update to the US Prescribing Information [the drug label] is necessary."[21] To this day, Apellis has not disclosed to prescribing physicians that the FDA instructed it to change the Syfovre label both before and (repeatedly) after Apellis' July 19 misrepresentation.

On Saturday July 29 – still 55 days before Syfovre was injected into Tricia's eye – Drs. Francois and Baumal co-authored a second letter "To the Retina Community," which Apellis delivered to Dr. Crawford two days later.[22] Apellis kept going, falsely assuring Dr. Crawford and retinal specialists across the U.S. that based on Apellis' "thorough evaluation following these reported (vasculitis) events…*there are no indications of drug product or manufacturing issues that may have contributed to these events*… ." and misrepresented that there was "no indication of drug-related immunogenicity."[23]

In its July 29 letter, Apellis also debuted what would become its key talking point regarding the safety of Syfovre for the next eight months – the grossly misleading statistic that "*[t]he estimated rate of Apellis-confirmed retinal vasculitis events [as] approximately 0.01% per*

[20] Apellis and Dr. Francois were aware that, in 2020, Novartis' drug, Beovu, exhibited vasculitis side effects soon after its FDA approval and launch. The FDA forced Novartis to update its label to warn for vasculitis. These events destroyed the market for Beovu and severely damaged Novartis stock price. *See* Ex. 10, Pl. Appx. 332 (July 8, 2023, email); Ex. 11, Pl. Appx. 334 (deposition of Cedric Francois, M.D.).
[21] Ex. 12, Pl. Appx. 344.
[22] Ex. 13, Pl. Appx. 350.
[23] *Id.* at 351 (emphasis supplied).

injection"[24] (1 in 10,000 injections) – a figure widely known to retinal specialists to be the base rate of infection from any intravitreal injection of any drug. Apellis repeatedly promoted this misleading safety statistic even though it knew that vasculitis from Syfovre was a first injection event and that a per patient incidence rate would be multi-fold higher, and far more accurate because each Syfovre patient receives injections on a monthly or every other month basis.[25] Apellis also took the opportunity to continue its off-label promotion of Syfovre as a treatment for GA regardless of cause, assuring the retina community of the safety of this "*important product for the 1 million patients in the US that are impacted by geographic atrophy*".[26]

On August 3 – still 50 days before Tricia's injection – the FDA sent a Labeling Supplement Request letter instructing Apellis for a second time to change the Syfovre label to warn of the risk of vasculitis, and included the FDA's specific requested warning language.[27] Apellis waited two more weeks until August 17 – 36 days before Tricia's injection – to decline the FDA's request and submit a rebuttal objecting to the proposed label change.[28] On August 21 – still 32 days before Tricia's injection – the FDA called Apellis and requested the Syfovre label change for the third time.[29]

On August 23 – still 30 days before Tricia's injection – Apellis sent Dr. Crawford and the retinal community another safety update, entitled "Updates on Injection Kits and Rare Safety Events with SYFOVRE…from Apellis."[30] Apellis touted its "commitment to keep you

[24] *Id.* at 351.
[25] The intended effect of including an enormous number of post-first-injection injections that Apellis knew were highly unlikely to trigger vasculitis reactions was to dramatically water down the vasculitis incidence rate to a figure that Apellis could sell to the retinal community as (in the words of Dr. Francois), a rare event "that physicians and patients feel very comfortable with… ." Dkt. 44-1 at Ex. 3, Pl. Appx. 171 (September 6, 2023 call transcript).
[26] *Id.* at 352 (emphasis supplied).
[27] Dkt. No. 44-1, Ex. 5, Pl. Appx. 443-44.
[28] Ex. 35, Pl. Appx. 516 (Apellis letter to the FDA opposing the FDA's instructed label change).
[29] Ex. 14, Pl. Appx. 355.
[30] Ex. 15, Pl. Appx. 360.

informed" and, as a result of its "comprehensive investigation into the real-world safety events" presented "**Recommended actions related to the filter needle included in certain injection kits**" (emphasis in original). In its August 23 safety update, Apellis overtly blamed the 19-gauge needle as the cause of the vasculitis cases and advised physicians to stop using that needle and instead use the 18-gauge needle recommended by Apellis. And Apellis re-emphasized the "rare" .01% per injection reaction rate. In stark contrast, *nothing in the August 23 safety update* even suggests the possibility that the cause of the vasculitis cases could be Syfovre and not the needle. Nor is there even a hint of the FDA's urgent efforts – *happening and being opposed by Apellis at the exact same time* – to force Apellis to change the Syfovre label to warn that the drug causes retinal vasculitis.

On August 28 – still 25 days before Tricia's injection – Apellis and the FDA held a meeting at the FDA's request to further discuss the cause of the vasculitis cases and the requested label change.[31] During the meeting, the FDA (i) instructed Apellis to provide a justification for not listing retinal vasculitis in the Warnings & Precautions section of the label; and (ii) advised Apellis that the 0.01% per injection vasculitis rate that Apellis continued to promote to the retinal community was misleading and did not accurately reflect the risk to patients. The FDA also rejected the 19-gauge "needle story," finding that Apellis and its experts had not provided *any evidence* supporting Apellis' claim that the needle could cause retinal vasculitis:[32]

> Apellis initially suggested the events could be related to anomalies or structural variations with the B. Braun 19-gauge 5-micron filter needle included in some Altaviz Needle Kits. Apellis stated the B. Braun 19-gauge 5-micron filter needle was associated with the majority of reported retinal vasculitis cases, based on their analysis of supply chain records. However, some FAERS cases stated the BD 18-gauge 5-micron filter needle was used which conflicted with information from what Apellis stated from their analysis of supply chain records. *Only*

[31] Dkt. No. 44-1, at Ex. 5, Pl. Appx. 444, 455-56.
[32] Dkt. No. 44-1, at Ex. 5, Pl. Appx. 455-56.

> *two FAERS cases reported the B. Braun 19-gauge 5-micron filter needle was used to prepare the Syfovre injection. Five cases reported the BD 18-gauge 5-micron filter needle was used. The remaining six cases did not report which filter needle was used.* From our perspective, we are unable to provide a reason to preferentially implicate the B. Braun 19-gauge filter needle, that is used to withdraw the drug product from supplied vial, over the pharmacologically active component of a dose. *During our August 28, 2023, meeting with Apellis, we also asked the company's subject matter experts to provide their thoughts for how the filter needle lies within the causal pathway for these cases, but a plausible explanation was not provided.*

Two business days after the August 28 FDA meeting and armed with the knowledge that an FDA-mandated retinal vasculitis label change was coming, Dr. Francois sold 150,000 shares (five times as much stock as he had sold on any prior occasion) of his personal Apellis stock for $6.2 million.[33]

Apellis waited another nine days – until September 6, still 16 days before Tricia's injection – to deliver a letter to the FDA presenting its purported basis for not including a vasculitis warning in the Syfovre label.[34] Over the next two weeks, Dr. Francois made almost daily public statements doubling and tripling down on the "main fact" that there is an "extremely low 1 in 10,000 injection rate" "that physicians and patients feel very comfortable with…" and a "quite striking…association that was quite profound with [the] 19-gauge needle."[35]

On September 22, Dr. Crawford injected Syfovre into Tricia's left eye using the Apellis-recommended 18-gauge needle. In a matter of days, she was permanently blind in both eyes and suffering such excruciating pain in her dying left eye that she elected, in consultation with Dr. Crawford, to have her eye surgically cut from her head.[36]

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[33] Ex. 16, Pl. Appx. 369. *See also Hodges v. Pfizer, Inc.,* 14-cv-4855, 2015 WL 13804602, at *10 (D. Minn. Dec. 17, 2015) ("There is an inherent tension between the desire for profit and scientific decisions that suggest warnings may well shrink the customer base because of the cautionary tone struck by the warnings.").
[34] Ex. 17, Pl. Appx. 372.
[35] Dkt. No. 44-1 at Ex. 3, Pl. Appx. 168-169, 171 (Apellis earnings call transcript).
[36] Ex. 18, Pl. Appx. 396 (Nahar et al. article on Tricia's case noting Syfovre blinded her in both eyes and that Izervay does not cause retinal vasculitis); Ex. 1, Pl. Appx. 17-18 (Crawford testimony opining Syfovre blinded

By early October, the number of reported Syfovre vasculitis cases had nearly doubled to 13.[37] Later that month, Drs. Francois and Baumal co-authored an Apellis-sponsored article in Retina Today – essentially a paid-for advertisement in the guise of a medical journal article directed to the retinal community – to continue promoting the 19-gauge "needle story" as the cause of the vasculitis cases.[38] At the very same time, Apellis was warning its investors:[39]

> A causal relationship has not been established between the structural variations in this 19-gauge filter needle and the events of retinal vasculitis, and there can be no assurance that this change will affect the rate of adverse events following SYFOVRE treatment. We cannot provide any assurances that the FDA and the retinal community will continue to believe that the expected benefits of SYFOVRE treatment outweigh its potential risks to patients following these reported events or that our applications for marketing approval of SYFOVRE in other jurisdictions will not be adversely impacted. *A change in the perception of the benefit/risk profile of SYFOVRE may reduce market acceptance of the product and our product revenues may be adversely affected.*"

On November 27, 2023, Dr. Francois sent an email to the team of senior employees involved in Apellis' response to the vasculitis crisis *congratulating them* on buying months of time before changing the label to warn for vasculitis. Days later, Apellis updated the Warnings and Precautions and the Adverse Reactions sections of the Syfovre label to include a warning for vasculitis. Tricia was permanently blinded in both eyes as a result of the months of time Apellis bought through its profit-driven delay strategy.

In January 2024, the ASRS/ReST published a new medical journal article reporting an expert panel's retrospective review of the vasculitis cases. In that article, the authors emphasized the lack of an established causal relationship with the 19-gauge needle, and that "the incidence of retinal

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Tricia in both eyes).

[37] Dkt. No. 44-1 at Ex. 5, Pl. Appx. 438, 444-46, 455-57, 459, 462 (excerpts from FDA's Newly Identified Safety Signal (NISS) Integrated Safety Assessment of retinal vasculitis following intravitreal administration of Syfovre).

[38] Dkt. No. 44-1 at Ex. 6, Pl. Appx. 487-95 (SYFOVRE: Insights on Case Reports of Retinal Vasculitis and Removal of 19-Gauge Filter Needle, published in October 2023 Retina Today).

[39] Dkt. No. 44-1 at Ex. 7 Pl. Appx. 496, 538-9, 544 (Apellis' Form 10-Q for quarter ending September 30, 2023) (emphasis supplied).

vasculitis after pegcetacoplan (i.e., the 0.01% injection rate that Apellis had been representing as a "fact" since July 2023) remains unclear for several reasons… ."[40]

In February 2024, Dr. Francois abruptly pivoted from the "needle story" and offered a new excuse, now claiming the vasculitis cases were not caused by Syfovre, but rather a glycol allergy in certain patients: [41]

> And then maybe briefly on the safety, right, that risk that exists on the first injection of developing vasculitis, which is very rare, *is something that we now firmly believe is caused by a pre-existing allergy towards polyethylene glycol,* something that is shared between the products.

Through at least March 2024, Apellis continued to parrot the 1/10,000 (.01%) vasculitis rate that had been its key safety "fact" since July 2023: [42]

> So when we saw this happen in July of last year, we felt that the rate was approximately 1 per 10,000 injections. That was never an issue to start with. The question was, will it stay there? *And the answer is we now know definitively, yes, it does.* So this is a very rare event that occurs in approximately 0.01% of injections. And because of that, the physicians are very comfortable using this product in patients.

Suddenly, Apellis' story changed. On May 7, 2024, Dr. Francois offered the following new approach in Apellis' earnings call to investors (but not to prescribing doctors): [43]

> So the rate has been stable since the very beginning at about 1 in 10,000, *and this is predominantly a first injection phenomenon where the odds are about 1 in 4,000,* which is in the same range of what you would find, for example, infectious endophthalmitis but it is really that first injection.

By June 2024, Apellis had abandoned the supposedly "definitive," "stable," and "very, very rare" 1/10,000 rate that it had represented as the "main fact" about Syfovre safety to Dr. Crawford, the retinal community, and the public since July 2023:

> June 12: "The risk of [indiscernible] events that last year kind of dominated the noise *is now firm at 1 in 4,000 more or less only on the first injection* and when treated aggressively,

[40] Ex. 32, Appx. 478-481 (ASRS article).
[41] Dkt. No. 44-1, at Ex. 3, Pl. Appx. 304 (corresponding source transcript) (emphasis supplied).
[42] Dkt. No. 44-1, at Ex. 3, Pl. Appx. 314 (corresponding source transcript) (emphasis supplied).
[43] Dkt. No. 44-1, at Ex. 3 Pl. Appx. 322 (corresponding source transcript) (emphasis supplied).

> that promotes also favorable outcomes where these patients don't have to have severe vision loss.[44]
>
> August 1: And three, regarding safety, vasculitis is rare and appears to be a first injection phenomenon. *The estimated rate has remained stable at one in 4,000 per first injection*.[45]
>
> September 11: And you have to remember, I mean, doing an injection in the eye is not something that you can do hundreds of thousands of times without ever running into issues. *That risk of an intravitreal injection and getting an infection is approximately 1 in 4,000 every single time.*[46]

Around the same time, the combined results of two real-world scientific studies were published putting the risk of developing vasculitis from Syfovre at 1 in 1,330.[47]

Meanwhile, on three separate occasions during 2024 – in January, June, and September, *i.e.*, the 12-month period immediately after Tricia was blinded by Syfovre – the EMA rejected Apellis' application to market Syfovre in Europe. The EMA rejected multiple attempts by Apellis to have the evidence supporting Syfovre's purported benefits reevaluated, concluding as a result of its reviews that Syfovre "did not lead to clinically meaningful benefits for patients" in clinical testing and that regular injections carried "a significant risk" of serious adverse events including vasculitis.[48]

In December 2024, Apellis updated the Syfovre label again,[49] this time to warn that Syfovre causes systemic hypersensitivity reactions throughout the body, meaning that a vasculitis reaction from injection of Syfovre into one eye can affect both eyes simultaneously. That is precisely what happened to Tricia.

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[44] Dkt. No. 44-1, at Ex. 3, Pl. Appx. 341 (corresponding source transcript) (emphasis supplied).
[45] Dkt. No. 44-1, at Ex. 3, Pl. Appx. 354 (corresponding source transcript) (emphasis supplied).
[46] Dkt. No. 44-1, at Ex. 3, Pl. Appx. 377 (corresponding source transcript) (emphasis supplied)
[47] Ex. 19, Pl. Appx. 412.
[48] Ex. 20, Pl. Appx. 417.
[49] Ex. 21, Pl. Appx. 420 (December 2024 Syfovre label).

C. Custodial Files. In pharmaceutical litigation, there is no better source of liability evidence than the drug company's custodial files. Plaintiffs seek the custodial files maintained and controlled by six additional Apellis employees. Apellis refuses to produce the six requested custodial files below and, instead, will agree to produce custodial files for only five employees unilaterally selected by Apellis. The custodial files of Apellis' employees are the primary repository for evidence of Apellis' internal acts and omissions regarding Syfovre, vasculitis, and the labeling and safety issues at the heart of this case. The documents in those files prove what Apellis knew about the safety risks of Syfovre and its propensity to cause vasculitis; when and how Apellis first became aware of those risks; how that knowledge evolved over time; and whether Apellis failed to make appropriate safety and labeling decisions based on the information available to it. Employee custodial files are readily accessible to Apellis and easily sortable and searchable. A thorough search of the files of each employee with significant involvement in these matters is critical. Apellis and its attorneys enjoy unlimited access to that data and will use it (selectively) to defend Plaintiffs' claims. A level playing field is possible only if Plaintiffs can access and analyze the same universe of Syfovre safety and labeling information.

The relevance of each of the six custodians' files sought by Plaintiffs is described below:

1. Tuan Dong Si: Senior Vice President of Global Drug Safety and Pharmacovigilance, 2021 to 2024; member of Syfovre Executive Committee;[50] co-authored the August 23, 2023 "safety letter" to the retinal community;[51] attended August 2023 FDA Sponsor Meeting regarding the addition of vasculitis to Syfovre label;[52] led internal discussion on which cases of vasculitis should be included in the August 2023 FDA presentation;[53] participated in internal discussions to oppose FDA instruction to change the Syfovre label.[54]

[50] Ex. 22, Pl. Appx. 437
[51] Ex. 15, Pl. Appx. 363.
[52] Ex. 23, Pl. Appx. 442.
[53] Ex. 24, Pl. Appx. 443.
[54] Ex. 25, Pl. Appx. 449.

2. Valerie Goguen: Director of Regulatory Affairs, 2019 to September 2023; regulatory (FDA) point of contact for Apellis for 2023 label change discussions;[55] authored letters the FDA opposing the vasculitis label change;[56] attended August 2023 FDA Sponsor Meeting regarding addition of vasculitis to Syfovre label;[57] participated in internal discussion on which cases of vasculitis should be included in the August 2023 presentation to the FDA.[58]

3. Michelle LaRosa: Executive Director of Investor Relations, February 2022 to January 2023, Head of Corporate & Portfolio Strategy, January 2023 to February 2024, current Vice President of Corporate Strategy for Apellis; coordinated editing and publication of October 2023 Retina Today article regarding 19-gauge filter needle;[59] coordinated internal discussions and strategy re: off-label marketing of Syfovre for new indications including Stargardt's disease;[60] participated in internal discussion on which cases of vasculitis should be included in August 2023 FDA presentation;[61] sole named document custodian for the 500 pages of internal company documents that relate to new and unapproved indications and off-label uses, including for Stargardt's disease.

4. Stacie Lallier: Director of PV Sciences, May 2021 to September 2023, Senior Director and Head of Medical Safety and PV Science for Apellis since September 2023; led Pegcetacoplan IVT Monthly Signal Detection Meetings throughout 2023;[62] Dr. Lallier is the only custodian in the group of 11 who is a member of the Apellis safety signal detection team.

5. Tim Sullivan: CFO since October 2017; unique knowledge of Syfovre sales, research and development costs, marketing budgets and spend; participated in earnings and analyst calls and public presentations regarding Syfovre and financial impacts of vasculitis crisis;[63] participated in internal discussions to oppose FDA's instruction to change the Syfovre label;[64] and participated in drafting proposed self-serving safety statements for the ASRS to send to the retinal community.[65]

6. Cedric Francois. The Court has already compelled Dr. Francois' deposition as the first defense fact witness in the case, finding that he has unique, personal, and non-repetitive knowledge of relevant facts, as further established by the liability timeline, *supra*, and attached exhibits. His custodial file is discoverable for the same reasons.[66] Aware of Dr. Francois' direct involvement in every aspect in this case, Apellis has refused to produce his custodial file since well before it self-selected the five document custodians it agreed to produce.[67] Dr. Francois' deposition revealed what Apellis already knew – that his custodial file was likely the most important one

[55] Ex. 26, Pl. Appx. 453.
[56] Ex. 35, Pl. Appx. 505.
[57] Ex. 23, Pl. Appx. 442.
[58] Ex. 24, Pl. Appx. 443.
[59] Ex. 36, Pl. Appx. 518.
[60] Ex. 2, Pl. Appx. 28, 74; Ex. 27 Pl. Appx. 456.
[61] Ex. 24, Pl. Appx. 443.
[62] Ex. 28, Pl. Appx. 458.
[63] Dkt. No. 44-1 at Ex.3, Pl. Appx. 150 (Apellis earning's calls statements regarding Syfovre's safety and profitability).
[64] Ex. 25, Pl. Appx. 449.
[65] Ex. 10, Pl. Appx. 332; Ex. 29, Pl. Appx. 462.
[66] *See* Ex. 10, Pl. Appx. 332; Ex.14, Pl. Appx. 355; Ex. 22, Pl. Appx. 437.
[67] Ex. 4, Pl. Appx. 266 (emails opposing production of Francois custodial file).

in the entire case. For example, even though he has no regulatory affairs, labeling or other FDA training,[68] Dr. Francois took a highly unusual approach for a CEO and assumed the lead role on verbal communications with the FDA when Apellis repeatedly opposed the FDA's request for the vasculitis labeling change.[69] Dr. Francois also testified in deposition that – despite the overwhelming weight of science to the contrary – based on his (unpublished, non-peer reviewed, Apellis-funded) recent research Syfovre is not immunogenetic and does not cause immune mediated adverse reactions (*i.e.*, vasculitis).[70] Accordingly, Dr. Francois' custodial file will be the best (and perhaps only) resource for the contents and internal analysis regarding those critical FDA communications and the company's unsupportable defense that Syfovre does not cause the adverse reaction that dually blinded Tricia.

The production of custodial files is the norm in any complex litigation. *See In re: Xarelto (Rivaroxaban) Prod. Liab. Litig.*, 313 F.R.D. 32, 33 (E.D. La. 2016) ("The parties do not dispute that Plaintiffs are entitled to the 'custodial file' of any employee or former employee of Defendants who Plaintiffs seek to depose"). The number of custodians identified by Plaintiffs in this case is consistent with or less than those ordered by other federal courts in similar single-plaintiff pharmaceutical cases and proportional to the issues raised in this case. *See Hodges v. Pfizer, Inc.*, 14-cv-4855, 2015 WL 13804602 (D. Minn. Dec. 17, 2015) (ordering production of over 20 custodial files in a dual blindness single plaintiff pharmaceutical case for a ten year time period). Searching 11 total custodial files for an 11-month period of time, using Apellis' selected TAR search method, and the proceeds of a $50 million insurance policy to directly pay for that routine participation in discovery is not an undue burden on an international drug company making hundreds of millions of dollars a year selling the drug that blinded Tricia.

D. EMA Rejections of Apellis' Application to Market Syfovre in Europe.[71] Apellis first filed a Marketing Authorization Application for Syfovre for treatment of GA secondary to

[68] Dr. Francois received his medical degree in Belgium. His time treating patients in a medical setting is limited to the less than one year in 1999 (*i.e.*, over 25 years ago) that he spent treating patients as a doctor on a Carnival Cruise Line ship.
[69] Ex. 14, Pl. Appx. 355; Ex. 25, Pl. Appx. 449.
[70] Ex. 11, Pl. Appx. 339-340.
[71] The applicable Requests for Production are Nos. 84, 85. Ex.3-b., Pl. Appx. 173-175 (Responses to Requests for Production); Ex. 33, Pl. Appx. 484 (separate table containing discovery requests at issue).

AMD with the EMA in late 2022. The EMA's review of that application was ongoing in September 2023 at the time of Tricia's injury. The EMA first rejected that application four months post-injury, in January 2024, and then again in June and September.[72] The effect of the EMA's decision(s) was to eliminate the possibility of Syfovre reaching the market in Europe, thereby preventing European doctors from prescribing the only drug ever approved by the FDA for treatment of GA secondary to AMD to European patients, and preventing Apellis from making billions more dollars in Syfovre sales. Without question, the two-year process culminating in the EMA's refusal to allow Apellis to sell Syfovre in Europe involved detailed communications regarding and careful consideration of Syfovre safety and efficacy data.

Plaintiffs' request for EMA Documents are limited to the i) filings exchanged between Apellis and EMA, ii) the EMA's rulings, and iii) Apellis' internal analysis and commentary regarding the EMA's rulings. Courts around the country routinely affirm not only the relevance and discoverability, but the *admissibility* of foreign adverse event, product labeling, and regulatory data in drug cases.[73] In this case, Plaintiffs seek far narrower relief – production of three limited categories of readily-available Documents pertaining to a single foreign regulatory body over a

[72] Dr. Crawford's declaration also references the relevancy of the EMA rejections. *See* Dkt. No. 51 at Ex. A (Crawford declaration attached to Apellis' Motion to Compel).

[73] *Hodges v. Pfizer, Inc.*, 14-cv-4855, 2015 WL 13804602 (D. Minn. Dec. 17, 2015) (Magistrate Opinion, affirmed by District Court) (ordering production of documents over 10-year period from seven different countries [including documents in the direct files of the drug company's seven overseas affiliates] pertaining to (i) labeling and package inserts, (ii) adverse events and pharmacovigilance, (iii) regulatory actions and correspondence with regulatory authorities, and (iv) restrictions or withdrawals from the market; "…communications with foreign regulators is relevant to defendant's knowledge of the drug's risks"); *Hardy v. Pharmacia Corp.*, No. 4:09-CV-119, 2011 WL 2118983 (M.D. Ga. May 27, 2011) (ordering defendant pharmaceutical company to produce foreign labeling and foreign regulatory information and refusing to cost-shift to plaintiff); *In re Levaquin Prods. Liab. Litig.*, Nos. 08-1943, 08-5743, 2010 WL 4676973, at *5 (D. Minn. Nov. 9, 2010) (holding evidence of foreign regulatory actions admissible at trial); *In re Incretin-Based Therapies Prods. Liab. Litig.*, 721 Fed. Pl. Appx. 580, 583 (9th Cir. 2017) (reversing district court's preemption order on the basis that the court improperly denied discovery of foreign data and adverse event information relevant to the preemption defense); *Mahaney v. Novartis Pharmaceuticals Corp.*, 835 F.Supp.2d 299, 318 (W.D. Ky 2011) (denying Novartis' motion in limine and holding evidence of foreign regulatory actions and foreign product labels were not only discoverable but admissible at trial to show Novartis' knowledge of its drug's side effects).

two-year period. Documents pertaining to the EMA's rejections of Syfovre three times during the one-year period after Tricia's injury bears directly on the drug's propensity to cause vasculitis; when/what Apellis knew about the risk; and whether Apellis timely and adequately disclosed Syfovre safety data to the FDA and U.S. prescribers. Such information is not rendered irrelevant by arbitrary lines drawn on a map.

E. Post-Injury Documents.[74] Plaintiffs seek four narrow categories of Documents for the post-injury time period September 2023 to present that bear on i) causation, including the needle story, ii) the vasculitis label change, iii) the .01% incidence rate, and iv) Apellis' defense – contradicted by peer-reviewed medical literature and a recent (second) Syfovre label change – that Syfovre does not cause systemic and immune mediated adverse reactions like the one suffered by Tricia. The evidence developed to date proves that, in the 15-month period following Tricia's injury in September 2023, Apellis (i) abandoned its opposition to the FDA's repeated label change instructions and updated the drug label twice, first to include FDA-mandated warnings that Syfovre causes vasculitis, and then to warn that a single Syfovre injection can cause systemic (*i.e.*, full body system) adverse drug reactions like what happened to Tricia's right eye;[75] (ii) abandoned the 19-gauge "needle story" that it long promoted as the cause of the vasculitis cases; and (iii) reframed and dramatically increased the 0.01% incidence rate it had unequivocally assured doctors was the "main fact" regarding Syfovre safety in the months leading up to and following Tricia's injury.

[74] The applicable Requests for Production are Nos. 1, 23-24, 26-27, 46, 55, 59-60, 79, 86-88, 100. Exs. 3-b., 3-d., Pl. Appx. 112-113, 129-134, 148, 154-155, 157-158, 170-171, 175-177, 229-230 (Responses to Requests for Production); Ex. 33, Pl. Appx. 485-492 (separate table containing discovery requests at issue).

[75] Ex. 21, Pl. Appx. 427 (FDA-mandated December 2024 label change warning for systemic adverse reactions). *See also* Ex. 18, Pl. Appx. 403, 406-407 (Nahar et al peer reviewed article noting Syfovre caused Tricia's right eye blindness); Ex. 1, Pl. Appx. 17-21 (Crawford deposition testimony stating same). While this issue will be reserved for expert testimony, there is no evidence that Izervay (injected into Tricia's right eye) causes retinal vasculitis.

According to Apellis, however, any "documents and/or communications *prepared, finalized, sent, or received after September 22, 2023*, the date Plaintiff received her injection of Syfovre…is irrelevant to Plaintiff's claims and allegations."[76] Setting aside the absurdity of the position that any document "prepared, finalized, sent, or received" after September 22, 2023 is irrelevant – an incredibly wide net that Apellis could use to conceal any number of highly relevant pre-injury documents and at the same time defend the case using documents from that same post-injury time period, it is axiomatic that evidence of post-injury liability facts is not only *discoverable* in product liability cases but is routinely *admitted* at trial. That is particularly the case here, where: (i) the scope and timeframe of the post-injury documents at issue is narrow (September 2023 to the present, a total of less than two years, and involving four limited categories of documents); (ii) the information bears directly on Plaintiffs' claims and Dr. Crawford's testimony; (iii) Plaintiffs' retained expert witnesses will rely on that information in formulating their opinions; and (iv) the information is needed to rebut Apellis' chosen defenses, including its unsupportable positions that Syfovre does not cause vasculitis or systemic and immune mediated adverse drug reactions. The relevance of Syfovre safety information does not arbitrarily end on the day the drug was injected into Tricia's eye.

Apellis promotes the safety profile of Syfovre to the U.S. public and physicians such as Dr. Crawford, spending hundreds of millions of dollars in advertising in order to sell as much of its drug to U.S. consumers as possible and maximize profits. Apellis will tell the jury that U.S. physicians still prescribe Syfovre to patients who safely use it. Dr. Crawford has repeatedly testified that if Apellis had warned him of the risk of vasculitis from the drug (and not the needle), he would not have prescribed Syfovre to Tricia or injected it in her eye.[77] Post-injury documents

[76] Ex. 33, Pl. Appx. 485 (quoted objection asserted by Apellis in response to virtually every discovery request).
[77] Ex.1, Pl. Appx. 11-13 (Crawford deposition excerpt).

regarding the context and labeling for Syfovre from the date of Tricia's injection and resulting blindness through the present bear directly on his testimony and the reasonableness of his reliance on Apellis' pre-warning label bear directly on the claims and defenses in the case.

F. FDA/ASRS Documents.[78] Plaintiffs seek to compel all Syfovre-related FDA and ASRS Documents regarding Syfovre and vasculitis during the time period February 17, 2023 to August 12, 2024. As detailed above, the FDA and ASRS were the two third-party organizations at the forefront of the movement to warn physicians (and force Apellis to warn physicians) that Syfovre causes vasculitis in the months leading up to and following Tricia's injury. Both the FDA and ASRS repeatedly warned Apellis that its "needle story" lacked support and that its .01% per injection rate of retinal vasculitis was misleading and inaccurate.[79] Despite these warnings, Apellis repeatedly represented to the retina community and Dr. Crawford the exact opposite. The internal communications reflect that Apellis was concerned about how the independent conduct of these organizations' public reporting of the risk of vasculitis could affect sales.[80] There is no reasonable basis for Apellis to withhold FDA/ASRS Documents regarding Syfovre and vasculitis.

G. Meeting Minutes.[81] While Apellis does not deny that meeting minutes are discoverable, it has failed to produce all of the Syfovre meeting minutes, has not disclosed which committee minutes have not been produced, and refuses to produce drafts of the minutes that will reflect the committee's initial impressions before the minutes are whitewashed for finalization.[82] Meeting minutes are not difficult to produce, and Plaintiffs require them to educate their experts and take

[78] The applicable Requests for Production are Nos. 24, 26, 46, 56, 87, 90-95. Ex.3-b., Pl. Appx. 130-133 148, 155-156, 175-176, 178-181 (Responses to Requests for Production); Ex. 33, Pl. Appx. 492-497 (separate table containing discovery requests at issue).
[79] Dkt. No. 44-1, at Ex. 5, Pl. Appx. 455-456; Ex. 32, Pl. Appx. 480.
[80] Ex. 10, Pl. Appx. 332; Ex. 30, Pl. Appx. 465; Ex. 31, Pl. Appx. 468; Ex. 25, Pl. Appx. 449.
[81] The applicable Requests for Production are Nos. 30, 42. Ex.3-b., Pl. Appx. 135-136, 144-146 (Responses to Requests for Production); Ex. 33, Pl. Appx. 497-498 (separate table containing discovery requests at issue).
[82] Ex. 4, Pl. Appx. 270 (discovery correspondence).

fair and complete defense witness depositions in July. Despite Plaintiffs' repeat requests over a period of months for a priority production of draft and final meeting minutes, Apellis' meeting minute production remains substantially incomplete.

H. Off-label Promotion and Apellis' Exploration of New and Unapproved Uses of Syfovre.[83]

The Court has already ordered Apellis to produce documents relating to Apellis' corporate strategy to market Syfovre off label as a treatment for GA regardless of cause, and for Stargardt's disease, the specific condition suffered by Tricia. Apellis produced some responsive off-label documents, but artificially restricted its production to one employee's custodial file (Michelle LaRosa, who unsurprisingly is not one of the five Apellis-selected document custodians), containing only seven emails spanning a one month period of time (April 13, 2023 - May 17, 2023) from only two individuals, even though the 73 documents in the production were created through months-long collaboration between over 20 Apellis employees. The Court-ordered document production reveals that Apellis' exploration of off-label/unapproved uses was a substantial money-driven expedition (broken down to the projected millions of dollars in Syfovre sales, including for use in the Stargardt's population) that did not start and end in one month or materialize through seven emails from two people. Plaintiffs ask the Court to order Apellis to complete its production of all documents that refer to, discuss, reflect, or bear on Apellis' off-label and new/unapproved use analysis for Syfovre as a treatment for GA regardless of cause or Stargardt's disease from February 17, 2023 – present.

[83] The applicable Requests for Production are Nos. 46, 64, 82-83, 104-108. Exs. 3-b., 3-d., Pl. Appx. 148, 160-161, 172-173, 233-236 (Responses to Requests for Production); Ex. 33, Pl. Appx. 498-502 (separate table containing discovery requests at issue).

IV. REQUEST FOR RELIEF

Plaintiffs ask the Court to enter an order granting this Motion, overruling Apellis' improper objections and compelling full and complete production within 30 days of the following categories of Documents:

1. Custodial files for Tuan Dong Si, Valerie Goguen, Michelle LaRosa, Stacie Lallier, Tim Sullivan, and Cedric Francois for the time period February 17, 2023 to August 12, 2024 (*i.e.*, an 18-month timeframe);

2. EMA filings, rulings, and Apellis' internal consideration of the EMA rulings;

3. Post-injury documents regarding causation (including the "needle story"); the retinal vasculitis label change; Apellis' .01% per injection rate of retinal vasculitis; and Apellis' defense that Syfovre does not cause systemic and immune mediated adverse reactions from September 23, 2023 to present;

4. FDA/ASRS Documents relating to retinal vasculitis from February 17, 2023 – August 12, 2024;

5. Draft and final Syfovre-related committee meeting minutes from February 17, 2023 – August 12, 2024; and

6. Off-label promotion and new and unapproved uses Documents from February 17, 2023 to present.

Plaintiffs request all other relief to which they are entitled to at law and equity.