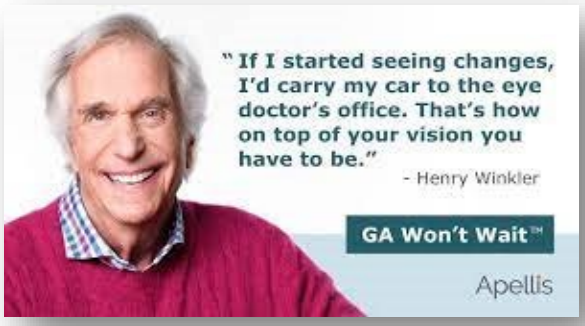
Citron Research Reports on Apellis Pharmaceuticals (APLS)

Happy Days Are OVER for Apellis, as the Experts Give a Thumbs Down to Syfovre. Citron Expects FDA Warning Letter.

Citron Research was committed to ensuring that its return to short selling was marked by a report that would not only hinge on valuation concerns but also spotlight a company whose activities could be detrimental to the public interest. We held ourselves to the highest standard, making sure the information we disclosed would be irrefutable, lucid, and would empower the appropriate regulators to take necessary actions. With that we present Apellis Pharmaceuticals

Background (Readers Digest Version)

"In 2023, Apellis Pharmaceuticals released Syfovre, marking it as the first FDA-approved treatment for Geographic Atrophy. Remarkably, the drug attained approval without the convening of an FDA advisory committee, a decision that has sparked considerable debate since its launch. To connect with an aging demographic, Apellis brought on the The Fonz as the face of its marketing campaign. This move proved effective, leading to widespread early adoption, and a buzz of excitement on Wall Street regarding the drug's potential.



Four months after releasing Syfovre, the drama began. Apellis Pharmaceuticals was hit with reports from the ASRS of retinal vasculitis as a side effect, causing their stock to drop. The company attributed the problem to the filter needle, not the drug itself, a claim met with skepticism from healthcare professionals. Despite the doubts, Apellis has continued to stand by the safety of Syfovre

https://www.fiercepharma.com/pharma/apellis-flags-needle-problems-hunt-syfovre-side-effect-source
https://www.fiercepharma.com/pharma/experts-flag-eye-inflammation-reports-tied-apellis-geographic-atrophy-med-syfovre

The following month Favus Research initiated a report claiming the Apellis trials didn't sufficiently report 14 cases of retinal vasculitis, an inflammatory condition that kills blood vessels in patients receiving the therapy. The media covered this as a “short seller attack”, Instead of describing Favus accurately as an equity research firm. The firm focuses its research on the healthcare sector with a specific focus on commercial and clinical data.

https://www.barchart.com/story/news/20641506/why-shares-of-apellis-pharmaceuticals-were-down-wednesday

Everything Has Now Changed!!

Last week was the first meeting of the American Academy of Ophthalmology in San Francisco since the approval of Syfovre. The Academy has the world's largest association of eye physicians and surgeons with more than 32,000 doctors. This is the association that the FDA will turn to when they review the warnings around Syfovre.

https://www.aao.org/annual-meeting

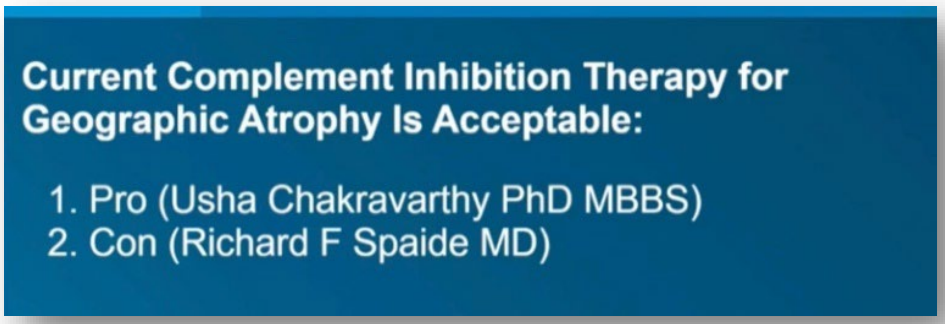
AMERICAN ACADEMY OF OPHTHALMOLOGY® | AAO 2023

Friday, November 3, 2023 is the day Syfovre "Jumped the Shark"

This past Friday was the first meeting of the AAO since the approval of Syfovre, there was a panel debate on Syfovre, questioning whether the treatment is "acceptable". You would hope that before approved, we would at least be at consensus that it is acceptable.

Following the presentations, the audience gave a real time vote on this controversial drug.

For full video please contact the AAO. In this report Citron will provide screenshots of the presentations.



The PRO - Dr. Chakravarthy, a respected academic, described the new treatment as a progressive development in the quest for effective therapies. She emphasized the ongoing necessity for innovation and investment in addressing the disease. By no means was Syfovre presented as a definitive cure.

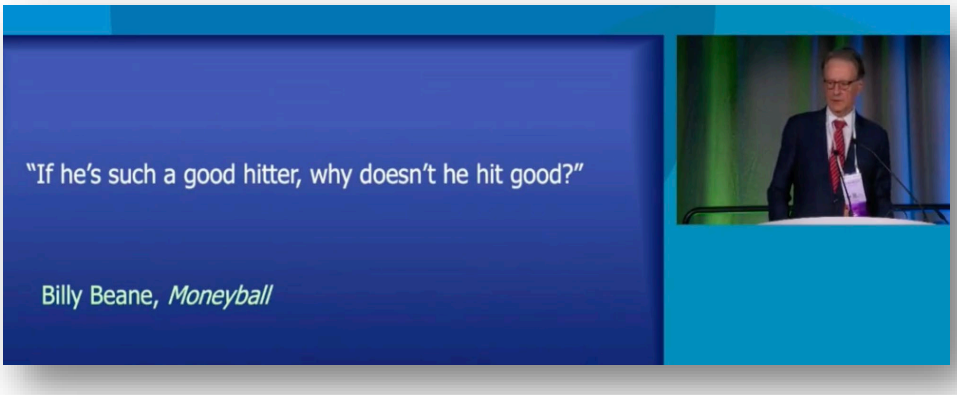
It is important to note that her analysis relied primarily on data from the Derby/Oaks and Gather clinical trials, which focus on controlled environments rather than practical real-world applications.

The Con- Dr. Richard Spaide - Apellis Shareholders - Do you know more than this guy?????

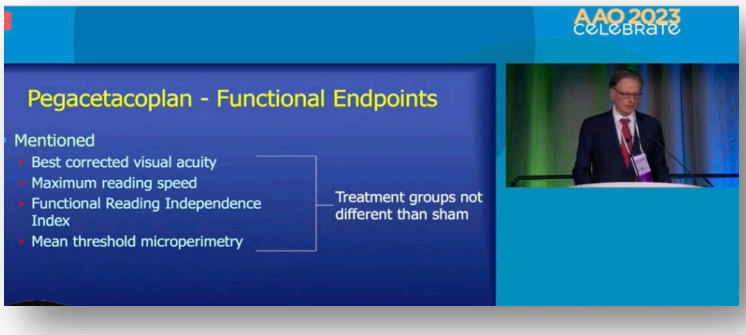
Beyond being the premier practicing ophthalmologist at the Vitreous Retina Macula Consultants in New York Dr Spaide also has this on his resume.

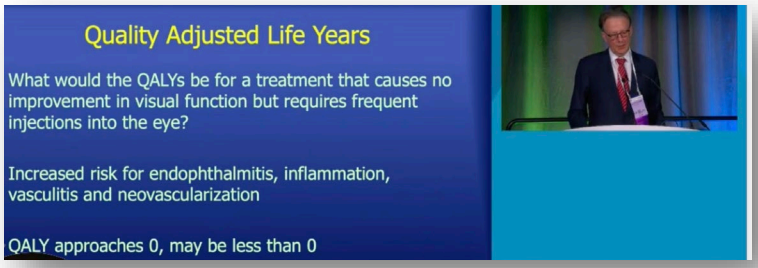
- **2022 winner of the Herman Wacker Award given every second year to one of the top vitreoretinal surgeons in the world.**
- **Publisher of more than 400 articles and 50 book chapters and 9 books about the diagnosis and treatment of Retinal Diseases**
- **Richard Spaide was ranked in the top 0.01%. In a recent publication by John Ioannidis, MD, D Sc recently published a study of the impact of publications by nearly 7 million scientists around the globe.**
- **Past executive editor of the American Journal of Ophthalmology.**

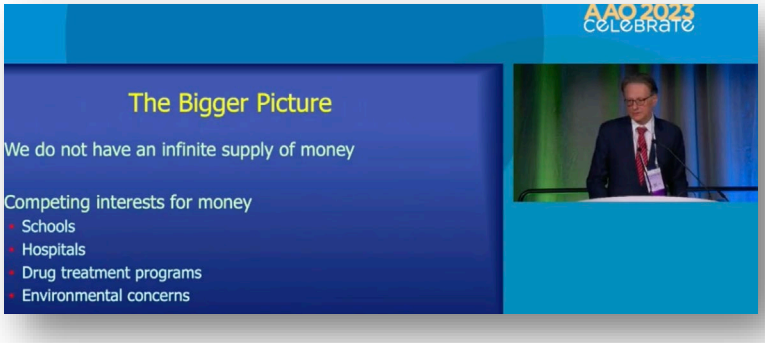
Dr Spaide completely discredits the questionable studies of Syfovre in relation to real life practice, but more importantly he ALSO discredits the efficacy of the treatment quoting the classic movie line.



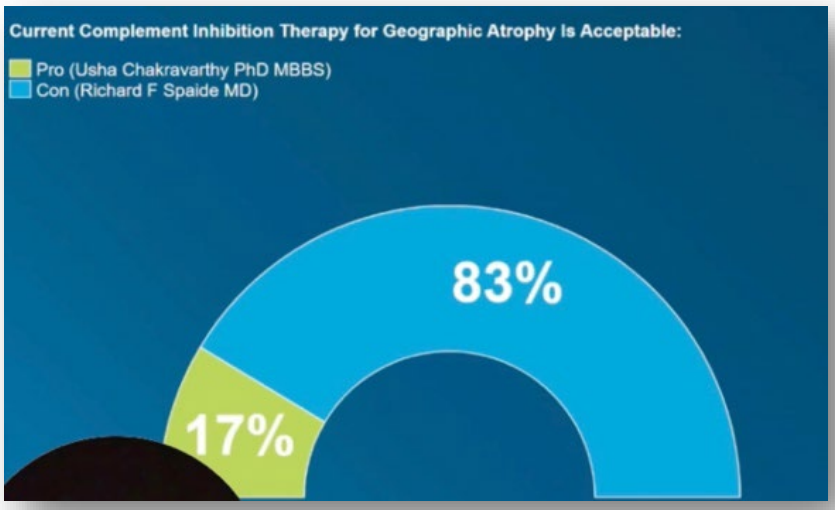
Note these harsh criticisms come from a doctor whose practice stands to profit significantly from Medicare reimbursements for administering the costly Syfovre, which ranges from $20,000 to $30,000 annually, He sharply criticizes the use of government funds for a drug that just slows the progression of retina lesions in an elderly patient. Syfovre does not make you see better.







After the conclusion of both presentations, the audience cast their votes, and the outcome was a resoundingly unanimous decision. This is from an audience who would financially benefit from voting Pro.



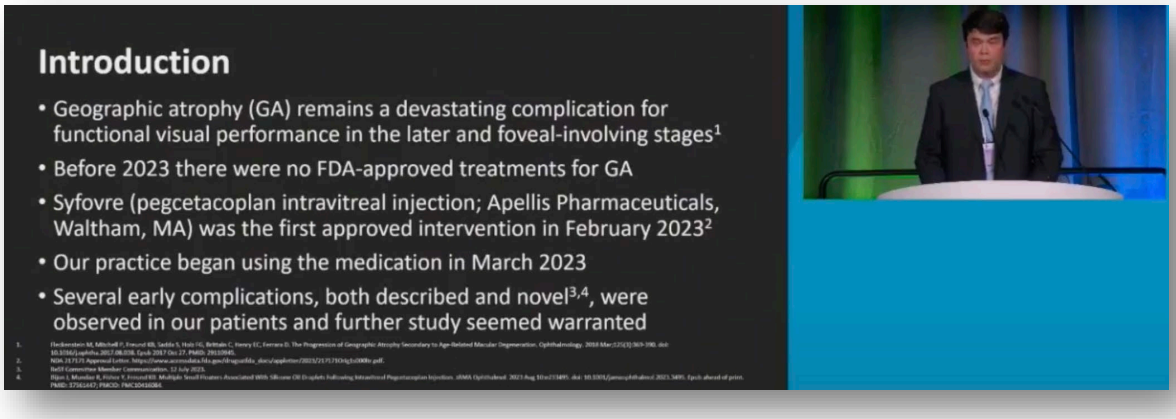
But Wait….It Gets Worse

In a presentation later in the day entitled "Late Breaking Developments" Dr. William Johnson of the Wolfe Eye Clinic presented a critical analysis of Syfovre entitled,

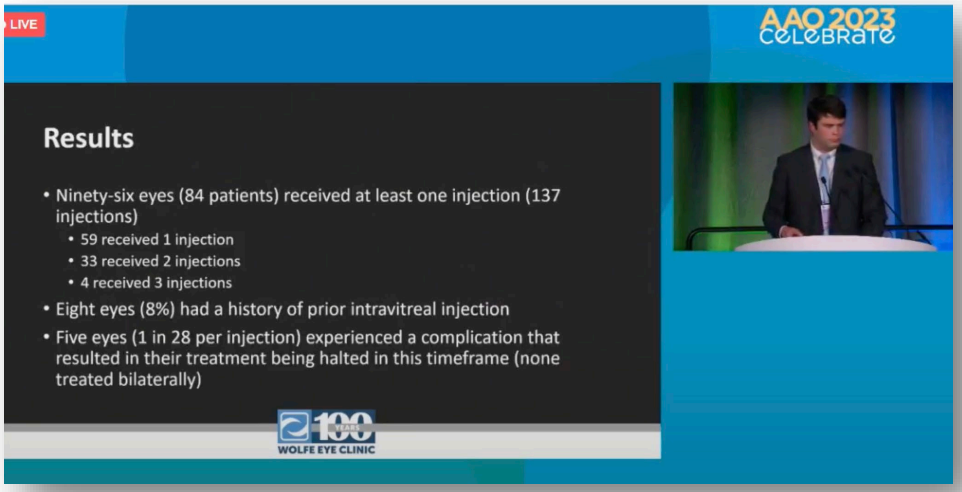
"Syfovre Initial Complication Experience"

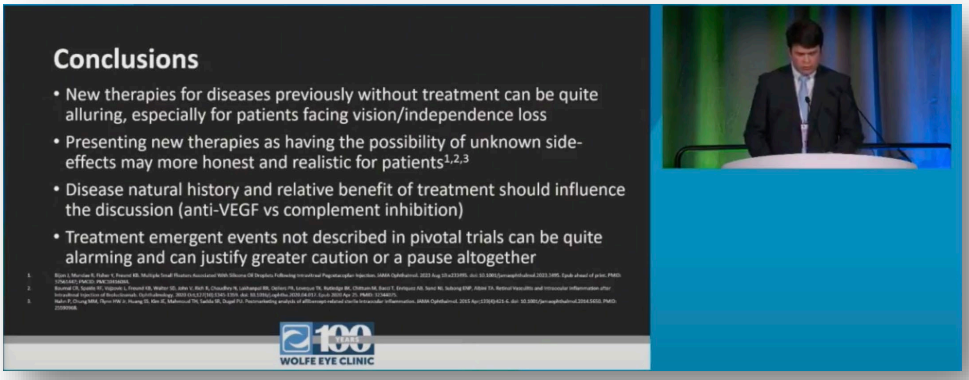
It should be noted that Wolfe Eye Clinic has participated in 18 different clinical trials for GA and are experts in the field.

Dr. Johnson opens his presentation admitting that his clinic was early adapters of Syfovre, until it went real bad



Wolfe Clinic recognized complications in 1 in 28 per injection. His conclusion that Syfovre should immediately get a warning label or get paused altogether.





Dr. Johnson's presentation was so impactful that immediately after Dr. Suber Huang, former President of the American Society of Retina Specialists, Chair of the Foundation of the ASRS, AAO Associate Secretariat of Federal Affairs, and Chair of the Research, Regulatory, and External Scientific Affairs Committee commented

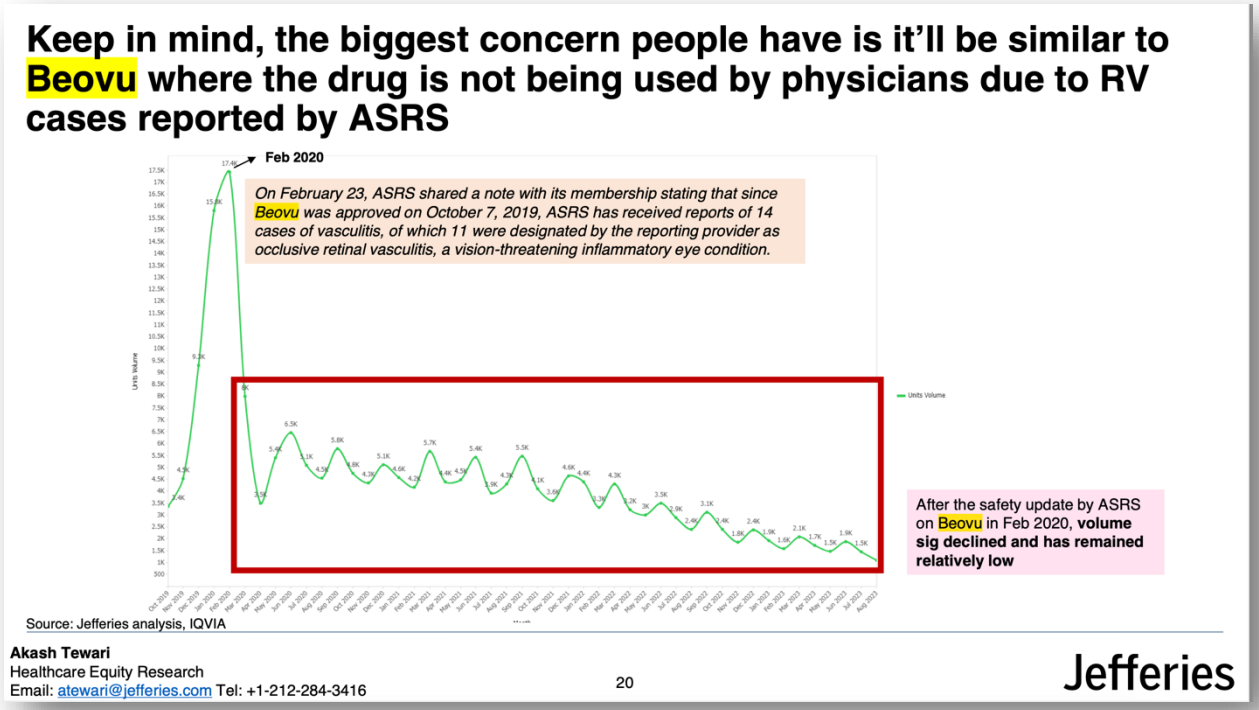
"Kudos to your practice for putting together such a detailed summary of this unexpected and devastating complication."
https://www.asrs.org/find-a-specialist/profile/991/Suber-S-Huang

He went on to call the presentation "one of the most important papers in the entire meeting."
https://www.managedhealthcareexecutive.com/view/syfovre-complications-discussed-in-late-breakers-session-aao-2023

What happens next to Syfovre?

Where there is smoke there must be fire and the metaphorical smoke in hallways of the AAO conference is obvious. The clinical trials are not matching the real-world profiles in safety and efficacy and the FDA should at a minimum put a warning label on Syfovre.

It is the opinion of Citron that Syfovre follows the steps of Novartis's Beovu. We will plagiarize this page from analyst Akash Tewari from Jeffries who laid out the worst-case scenario.



Securities Fraud?

Citron has reason to believe that CEO Cedric Francois is not being honest with Wall St. about the report cases of vasculitis. This believe would coincide with conclusions from Favus and Wolfe, but now we can prove it.

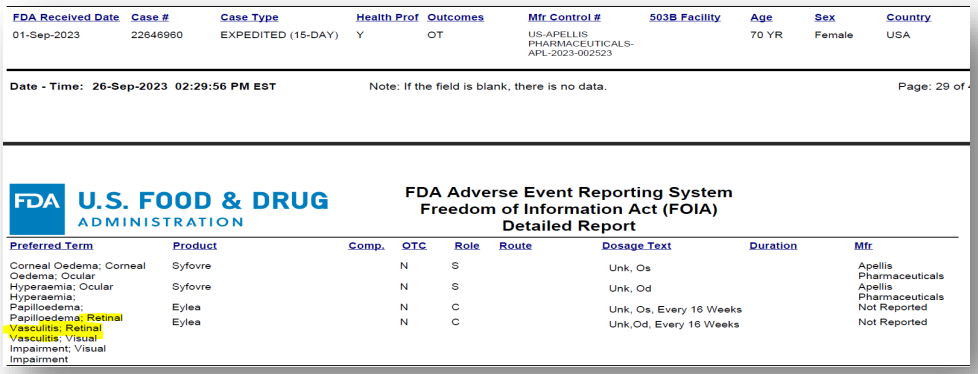
On the recent call Francois stated

> "So we're going to stop talking about individual cases because frankly that's not an effort that we think is fruitful. To put this in perspective, the last case of a patient with geographic atrophy that was reported to us with vasculitis is already from September first, right."

https://seekingalpha.com/article/4645993-apellis-pharmaceuticals-inc-apls-q3-2023-earnings-call-transcript

Contrary to the CEO's claim of a solitary case of vasculitis, a Freedom of Information Act (FOIA) request reveals at least 12 cases reported in the last month. Should this data be accurate, it raises the possibility of securities fraud on top of the reported adverse events from the past two months.

*Look at the FOIAs below. Medicare pays 25k to put a needle in the eye of a 96 year old man to slow down vision problems.



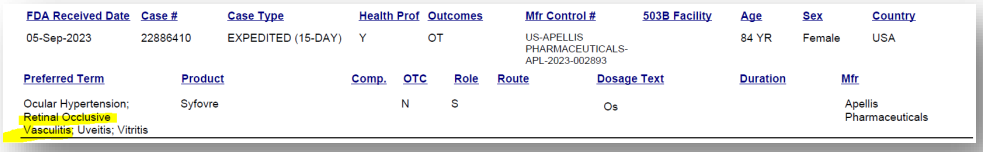
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
01-Sep-2023	22646960	EXPEDITED (15-DAY)	Y	OT	US-APELLIS PHARMACEUTICALS-APL-2023-002523		70 YR	Female	USA

Date - Time: 26-Sep-2023 02:29:56 PM EST Note: If the field is blank, there is no data. Page: 29 of

U.S. FOOD & DRUG ADMINISTRATION

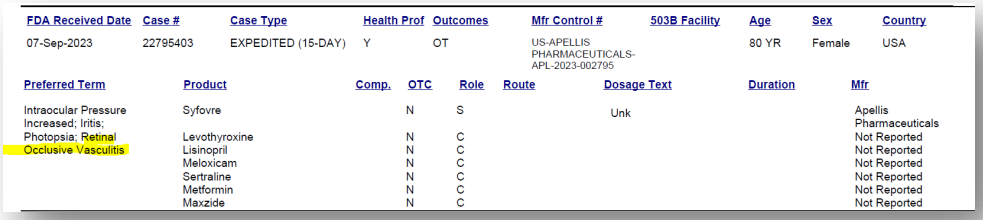
FDA Adverse Event Reporting System
Freedom of Information Act (FOIA)
Detailed Report

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Corneal Oedema; Corneal Oedema; Ocular Hyperaemia; Ocular Hyperaemia; Papilloedema; Retinal Vasculitis; Retinal Vasculitis; Visual Impairment; Visual Impairment	Syfovre		N	S		Unk, Os		Apellis Pharmaceuticals
	Syfovre		N	S		Unk, Od		Apellis Pharmaceuticals
	Eylea		N	C		Unk, Os, Every 16 Weeks		Not Reported
	Eylea		N	C		Unk,Od, Every 16 Weeks		Not Reported



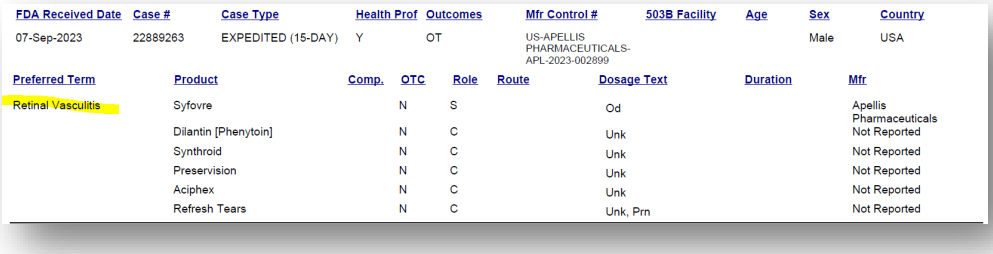
FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
05-Sep-2023	22886410	EXPEDITED (15-DAY)	Y	OT	US-APELLIS PHARMACEUTICALS-APL-2023-002893		84 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Ocular Hypertension; Retinal Occlusive Vasculitis; Uveitis; Vitritis	Syfovre		N	S		Os		Apellis Pharmaceuticals



FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2023	22795403	EXPEDITED (15-DAY)	Y	OT	US-APELLIS PHARMACEUTICALS-APL-2023-002795		80 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intraocular Pressure Increased; Iritis; Photopsia; Retinal Occlusive Vasculitis	Syfovre		N	S		Unk		Apellis Pharmaceuticals
	Levothyroxine		N	C				Not Reported
	Lisinopril		N	C				Not Reported
	Meloxicam		N	C				Not Reported
	Sertraline		N	C				Not Reported
	Metformin		N	C				Not Reported
	Maxzide		N	C				Not Reported



FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
07-Sep-2023	22889263	EXPEDITED (15-DAY)	Y	OT	US-APELLIS PHARMACEUTICALS-APL-2023-002899			Male	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Retinal Vasculitis	Syfovre		N	S		Od		Apellis Pharmaceuticals
	Dilantin [Phenytoin]		N	C		Unk		Not Reported
	Synthroid		N	C		Unk		Not Reported
	Preservision		N	C		Unk		Not Reported
	Aciphex		N	C		Unk		Not Reported
	Refresh Tears		N	C		Unk, Prn		Not Reported

FDA Received Date	Case #	Case Type	Health Prof	Outcomes	Mfr Control #	503B Facility	Age	Sex	Country
22-Sep-2023	22913880	EXPEDITED (15-DAY)	Y	OT	US-APELLIS PHARMACEUTICALS-APL-2023-002918		72 YR	Female	USA

Preferred Term	Product	Comp.	OTC	Role	Route	Dosage Text	Duration	Mfr
Intraocular Pressure Increased; Iridocyclitis; Retinal Haemorrhage; Retinal Vasculitis	Syfovre		N	S		Unk, Os	1 DAY	Apellis Pharmaceuticals
	Baby Aspirin		N	C		Unk		Not Reported
	Vitamins Nos		N	C		Unk		Not Reported
	Prolia		N	C		Unk		Not Reported
	Iron		N	C		Unk		Not Reported
	Metoprolol		N	C		Unk		Not Reported
	Simvastatin		N	C		Unk		Not Reported
	Preservision		N	C		Unk		Not Reported

FDA Received Date	Case Type	HP?	Outcomes	Age in Years	Sex	503B?	Country	MCN#
05-OCT-2023	DIRECT	Y	DS	84	MALE			FDA-CDER-CTU-2023-73314

FOIA Product Information

Event Preferred Terms (All)	Product Name	Role	Comp.	OTC	Route	Dosage Text	Duration	Manufacturer
1)Haemorrhagic occlusive retinal vasculitis;2)Blindness;	Eylea	C	No	No				
	Pegcetacoplan	S	No	No	Other	15 Mg Q2 Months Intravitreal		Apellis Pharmaceuticals

FDA Received Date	Case Type	HP?	Outcomes	Age in Years	Sex	503B?	Country	MCN#
18-OCT-2023	DIRECT		DS, RI, OT	90	FEMALE			FDA-CDER-CTU-2023-76580

FOIA Product Information

Event Preferred Terms (All)	Product Name	Role	Comp.	OTC	Route	Dosage Text	Duration	Manufacturer
1)Blindness unilateral;2)Eye infection;	Buffered Aspirin	C	No	No				
	Lisinopril	C	No	No				
	Pace Maker	C	No	No				
	Coenzyme Q10	C	No	No				
	Metoprolol	C	No	No				
	Syfovre	S	No	No				
	Multi Vitaman	C	No	No				

FDA Received Date	Case Type	HP?	Outcomes	Age in Years	Sex	503B?	Country	MCN#
20-OCT-2023	15-DAY	Y	OT	72	FEMALE		USA	US-APELLIS PHARMACEUTICALS-APL-2023-002918

FOIA Product Information

Event Preferred Terms (All)	Product Name	Role	Comp.	OTC	Route	Dosage Text	Duration	Manufacturer
1)Retinal vasculitis;2)Visual impairment;3)Iridocyclitis;4)Retinal haemorrhage;5)Intraocular pressure increased;	Simvastatin	C		No		Unk		
	Prolia	C		No		Unk		
	Aspirin	C		No		Unk		
	Minerals\Vitamins	C		No		Unk		
	Metoprolol	C		No		Unk		
	Vitamins Nos	C		No		Unk		
	Syfovre	S		No		Unk, Os	1 DAY	Apellis Pharmaceuticals
	Iron	C		No		Unk		

FDA Received Date	Case Type	HP?	Outcomes	Age in Years	Sex	503B?	Country	MCN#
20-OCT-2023	15-DAY	Y	DS, OT		FEMALE		USA	US-APELLIS PHARMACEUTICALS-APL-2023-002620

FOIA Product Information

Event Preferred Terms (All)	Product Name	Role	Comp.	OTC	Route	Dosage Text	Duration	Manufacturer
1)Retinal occlusive vasculitis;2)Blindness;3)Eye excision;4)Corneal oedema;5)Iris neovascularisation;	Sertraline	C		No				
	Trazodone	C		No				
	Eylea	C		No		Unk		
	Syfovre	S		No		0.1 Milliliter, Qd, Os		Apellis Pharmaceuticals

FDA Received Date	Case Type	HP?	Outcomes	Age in Years	Sex	503B?	Country	MCN#
20-OCT-2023	15-DAY	Y	OT	78	FEMALE		USA	US-APELLIS PHARMACEUTICALS-APL-2023-002390

FOIA Product Information

Event Preferred Terms (All)	Product Name	Role	Comp.	OTC	Route	Dosage Text	Duration	Manufacturer
1)Retinal occlusive vasculitis;2)Retinal oedema;3)Vitreous haemorrhage;4)Macular oedema;5)Chorioretinal disorder;6)Retinal haemorrhage;7)Anterior chamber cell;8)Vitreal cells;9)Intraocular pressure increased;10)Headache;11)Eyelid oedema;12)Conjunctival hyperaemia;13)Sciatica;14)Vision blurred;15)Conjunctivitis;16)Visual impairment;17)Hyphaema;	Preservision Areds 2 + Multivitamin	C		No				
	Betadine	C		No				
	Synthroid	C		No	Oral	75 Microgram, Qd		
	Syfovre	S		No		Unk	1 DAY	Apellis Pharmaceuticals

FDA Received Date	Case Type	HP?	Outcomes	Age in Years	Sex	503B?	Country	MCN#
24-OCT-2023	15-DAY	Y	OT	43.49315	FEMALE		USA	US-APELLIS PHARMACEUTICALS-APL-2023-003081

FOIA Product Information

Event Preferred Terms (All)	Product Name	Role	Comp.	OTC	Route	Dosage Text	Duration	Manufacturer
1)Retinal vasculitis;2)Retinal vasculitis;3)Intraocular pressure increased;4)Off label use;	Syfovre	S		No				Apellis Pharmaceuticals
	Omeprazole	C		No				
	Ondansetron	C		No				
	Syfovre	S		No		Unk, Os	1 DAY	Apellis Pharmaceuticals
	Izervay	S		No		Unk Od		

FDA Received Date	Case Type	HP?	Outcomes	Age in Years	Sex	503B?	Country	MCN#
23-OCT-2023	15-DAY	Y	OT	84	MALE		USA	US-APELLIS PHARMACEUTICALS-APL-2023-002976

FOIA Product Information

Event Preferred Terms (All)	Product Name	Role	Comp.	OTC	Route	Dosage Text	Duration	Manufacturer
1)Haemorrhagic occlusive retinal vasculitis;	Syfovre	S		No		Unk, Od		Apellis Pharmaceuticals
	Metoprolol	C		No		Unk		
	Losartan	C		No		Unk		
	Atorvastatin	C		No		Unk		
	Eylea	C		No		Unk		
	Prilosec	C		No		Unk		

FDA Received Date	Case Type	HP?	Outcomes	Age in Years	Sex	503B?	Country	MCN#
20-OCT-2023	15-DAY	Y	OT	96	MALE		USA	US-APELLIS PHARMACEUTICALS-APL-2023-002551

FOIA Product Information

Event Preferred Terms (All)	Product Name	Role	Comp.	OTC	Route	Dosage Text	Duration	Manufacturer
1)Retinal vasculitis;2)Blindness;3) Retinal haemorrhage;4)Retinal haemorrhage;5)Corneal oedema;6) Iris neovascularisation;	Syfovre	S		No		Unk		Apellis Pharmaceuticals

Recent Developments Prove Citron Theory- Gale Study

As publicized yesterday by Apellis, a presentation was made by Dr. Charles Wykoff on the "Increasing effects of Pegcetacoplan in Gale Study". This is an add on to the two previous studies.

In the presentation Dr Wykoff discusses diminution in lesion growth that according to numerous physicians, including Dr. Spaide, is statistically negligible. Despite our respect for Dr. Wykoff's perspective, his commentary would make me afraid to be a shareholder in Apellis.

"In the real world, I am using pegcetacoplan and I am a believer in anti-complement therapy. I think it's a conversation to be had with each individual patient, what the risk-benefit ratio looks like,"

Risks…according to Dr. Wykoff

- Asserts that there is a 20% likelihood of a patient developing Wet AMD from Syfovre
- He emphasizes that this is an extended therapy regimen, particularly for an already elderly patient, who will not see benefits from just a few injections.
- Acknowledges the concerns of other clinicians regarding the risks of vasculitis.

Benefits…according to Dr. Wykoff

- Dr. Wykoff clearly states, patients will not see better but Syfovre should slow the progression of the disease.

https://www.hcplive.com/view/charles-wykoff-md-phd-increasing-effects-pegcetacoplan-gale-study

The substantial risk of contracting Wet AMD alone warrants an FDA's decision to mandate a warning label for the drug.

Conclusion

It's highly likely that more will emerge about Apellis and Syfovre. Legal action seems imminent, and it won't be surprising if the FDA steps in with a warning label following a more thorough review of the drug. These developments are expected to have a swift impact on the company's financials.

In the end, Apellis and Syfovre might have the same fate as Henry Winkler last company he did commercial for, One Reverse Mortgages which ended up getting shut down mired by fraud lawsuits….Just another "Fonzi Scheme"

https://www.thestreet.com/personal-finance/are-reverse-mortgages-a-fonzi-scheme-11800245

Cautious Investing To All……Did somebody say 83%???

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