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Playing Favorites? Patentholder's FDA Strategy for Remdesivir Pushes Cat Owners to the Black Market

By Paige Hardy

"The veterinarian gave us two options: Either euthanize our cat before the disease became too painful, or join a Facebook page and pay \$6,000 for unmarked vials of black market experimental medication that has to be injected for 90 days with a massive needle. The vet couldn't give us any information beyond that."^[1]

This quote comes from a confidential source, whose kitten was recently infected with feline infectious peritonitis (FIP). The disease mainly impacts kittens; about 70% of cats that develop FIP are less than a year and a half old.^[2] FIP is degenerative and without treatment, "the disease will eventually result in death in almost every case."^[3] Most estimates place the FIP mortality rate between 95 and 100%.^[4] Many cats are exposed to feline enteric coronavirus (FeCV), as the virus is widespread. Usually, FeCV causes no symptoms; however, in about 10% of cases, FeCV mutates within the body into FIPV, the virus that causes FIP.^[5] Though FIP has been devastating the feline population since the 1960s, it has garnered significant media attention in the past year.^[6] This renewed focus is partially due to the fact that FIP is caused by a coronavirus. Though the virus is unrelated to the one that causes Covid-19, expression of both diseases can result in an extreme immune response and multiorgan failure.^[7]

What's another common thread between this cat coronavirus and our human coronavirus? Gilead Sciences. Gilead Sciences is the patentholder of the antiviral drugs GS-441524 and remdesivir. The two drugs combat viral replication in the same way.^[8] The drugs have the same base molecular structure, but remdesivir has an added prodrug portion to facilitate cell permeation. In theory, remdesivir essentially becomes GS-441524 once it is inside the cell.^[9] Though initially created for Ebola, remdesivir has been used to moderate success in Covid-19 treatment. A study of 1,062 Covid-19 patients demonstrated that patients treated with remdesivir had a shorter average recovery time (10 days compared to 15 days for the placebo group) and a reduced rate of serious adverse events (24.6% compared to 31.6% for the placebo group).^[10] The results of GS-

441524 in treating cat coronavirus are even more striking. A 2019 field study co-authored by researchers from UC Davis and Gilead successfully treated 25 out of the 31 FIPV-infected cats that participated in the study.^[11] Moreover, of the cats that received the full 12 weeks of treatment, 25 out of 26 recovered, a 96% cure rate.^[12] In an interview, Dr. Niels Pedersen, the lead researcher, said that he “thought this was a good capstone for [his] career.”^[13] GS-441524 represented the opportunity to flip the FIP script: from a more than 95% mortality rate to a more than 95% cure rate.

Despite these remarkable initial results, the drug is not legally available for veterinary use or for commercial development by any other company. Why? According to some, the answer is simple—to push remdesivir through the FDA. Pedersen believes that because GS-441524 and remdesivir are so chemically similar, any negative effects of GS-441524 in cats could prompt further scrutiny in remdesivir.^[14] Other observers are even less generous. Representatives of Public Citizen insinuate that Gilead is promoting remdesivir over GS-441524 because the remdesivir patent may prove more profitable. In a letter urging Gilead to develop GS-441524 for Covid-19, Public Citizen remarked that:

"It is unclear why Gilead and federal scientists have not been pursuing GS-441524 as aggressively as remdesivir, but we cannot help but note that there are significant financial incentives tied to Gilead's current patent holdings. Specifically, Gilead holds patents on both agents, but the earliest patent approval date on remdesivir is 2015 whereas the earliest on GS-441524 is 2010. Thus, Gilead's monopoly power over remdesivir may have at least five additional years of enforceability beyond that of GS-441524."^[15]

Gilead has been nearly silent on the matter. A search on the Gilead Sciences website for “FIP” yields zero results. Gilead declined to comment on the Atlantic article cited in this post.^[16] Interestingly, Dr. Merdad Parsey, the Chief Medical Officer of Gilead Sciences, answered a question about FIP and GS-441524 in a talk he gave with University of Maryland on September 25, 2020.^[17] When an attendee asked whether Gilead Sciences has any plans to advance an Investigational New Drug Application (IND) with the FDA, Dr. Parsey gave several inaccurate statements. First, he claimed that “the FDA does not regulate animal medicines.”^[18] They do.^[19] Additionally, he said that “those aren’t trials that we’ve run and they’re not data that we have access to other than the publications that are out there.”^[20] The initial field study, led by Pedersen, listed Gilead employees as 2 of its 7 named authors. Additionally, Gilead provided the GS-441524 used in the research.^[21] Lastly, Dr. Parsey claimed that “we’re not in the way of getting that approved or available...to people who want to use it for veterinary uses.”^[22] On the contrary, Gilead has steadfastly refused to license GS-441524 to the many companies that wish to purchase a license, in a move that Pederson said, “hits you very hard, especially when you didn’t see any reason for it.”^[23] In fairness, Dr. Parsey did state that he did not “know the details here because we’ve been so focused on human disease.”^[24] Gilead leadership leaves much to be desired in its communication about FIP and GS-441524; messaging spans from nonexistent to false.

Because it is impossible to get GS-441524 legally, a black market for the medicine has ballooned. A number of companies in China have been producing GS-441524 for sale to cat owners, both in China and in the United States.^[25] The cat owners pay thousands of dollars for

unmarked vials, usually disguised as dietary supplements to pass through customs.^[26] Many of these cat owners find medication through a private Facebook group with tens of thousands of members.^[27] Though the administrators of the group help struggling individuals as much as they can, there is only so much they can do. As with other medical black markets, there is no oversight or testing for the biological activity of the medication.^[28] Additionally, since the medication is unapproved by the FDA, many veterinarians believe that it is illegal and unethical to aid cat owners beyond the initial diagnosis of FIP.^[29] The source cited at the beginning of this post remarked that “as helpful as the FIP Warriors admin were, it was terrifying to do everything on our own without a real veterinarian. I had never given a shot to anyone or anything in my life.”^[30]

On October 22, 2020, the FDA announced that it had approved remdesivir for the treatment of Covid-19 requiring hospitalization.^[31] With that FDA approval in hand, will Gilead finally be ready to take GS-441524 off of the sidelines?

Footnotes

[1] Confidential source.

[2] <https://www.vet.cornell.edu/departments-centers-and-institutes/cornell-feline-health-center/health-information/feline-health-topics/feline-infectious-peritonitis>

[3] <https://vcahospitals.com/know-your-pet/feline-infectious-peritonitis>

[4] <https://pets.webmd.com/cats/cat-fip-feline-infectious-peritonitis#1>

[5] Feline Infectious Peritonitis, *supra* note 2.

[6] <https://onlinelibrary.wiley.com/doi/10.1111/tbed.13856>; <https://www.theatlantic.com/science/archive/2020/05/remdesivir-cats/611341/>

[7] Feline infectious peritonitis (FIP) and coronavirus disease 19 (COVID-19): Are they similar?, *supra* note 6.

[8] A Much-Hyped COVID-19 Drug Is Almost Identical to a Black-Market Cat Cure, *supra* note 7.

[9] <https://pubs.acs.org/doi/10.1021/acsmedchemlett.0c00316>

[10] <https://www.nejm.org/doi/full/10.1056/NEJMoa2007764>

[11] <https://journals.sagepub.com/doi/full/10.1177/1098612X19825701>

[12] Id.

[13] A Much-Hyped COVID-19 Drug Is Almost Identical to a Black-Market Cat Cure, *supra* note 7.

[14] *Id.*

[15] <https://www.citizen.org/wp-content/uploads/2535.pdf>

[16] A Much-Hyped COVID-19 Drug Is Almost Identical to a Black-Market Cat Cure, *supra* note 7.

[17] <https://www.youtube.com/watch?v=uRY5EHUuD4U> at (1:09:02-1:10:37).

[18] *Id.*

[19] <https://www.fda.gov/animal-veterinary/animal-health-literacy/what-fda-does-and-does-not-regulate#:~:text=Animal%20Drugs%E2%80%9393%20The%20Federal%20Food,the%20drug%20approved%20by%20FDA.>

[20] The Challenges of Drug Development During COVID-19, *supra* note 18.

[21] <https://journals.sagepub.com/doi/10.1177/1098612X19825701>.

[22] The Challenges of Drug Development During COVID-19, *supra* note 18.

[23] A Much-Hyped COVID-19 Drug Is Almost Identical to a Black-Market Cat Cure, *supra* note 7.

[24] *Id.*

[25] <https://ccah.vetmed.ucdavis.edu/sites/g/files/dgvnsk4586/files/inline-files/Black%20market%20production%20and%20sale%20of%20GS.pdf>.

[26] *Id.*

[27] <https://abc7.com/cats-covid-coronavirus-cure/6253361/>.

[28] Blackmarket production and sale of GS-441524 and GC376, *supra* note 25.

[29] *Id.*

[30] Confidential source.

[31] <https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-covid-19>.

Feline Infectious Peritonitis

