

Rational Vaccines Continues to Battle Herpes, This Time According to the Playbook



By Josh Bloom — July 21, 2020

The company dedicated to discovering vaccines for herpes is back in the news. Rational Vaccines gained notoriety when its founder, the late Dr. Bill Halford, bypassed FDA protocol for vaccine development and set up a small trial on the island of St. Kitts, in the Caribbean, using live attenuated virus on volunteers who were suffering from herpes simplex. Now, three years after Dr. Halford's death, Rational is developing five vaccines for herpes and two for COVID. But his time, by the book.



The story of Rational Vaccines' pursuit of a therapeutic vaccine for genital herpes may go down as one of the strangest and most controversial chapters in the history of drug or vaccine development. Dr. Bill Halford, formerly an Associate Professor at the Southern Illinois University School of Medicine, and virology and immunology expert, knew he was dying from nasal cancer which he had battled for years, but kept working in his lab until shortly before his death in July 2017. (You can read my interview with Dr. Halford [here](#) [1].) But it wasn't Halford's illness or endurance that makes this story so unusual; it was how the vaccine trials were conducted.

The story of Dr. Halford's single-minded quest to demonstrate the effectiveness of his live-attenuated herpes vaccine before he died by bypassing the FDA elicited a huge range of impassioned opinions; he was seen by some as obsessive, or criminal, while others thought him to

be dedicated and heroic.

For what it's worth, I spoke with Bill a number of times and got to know him rather well. You may disagree with his methods (or his judgment may have been clouded by his imminent death), but I saw nothing but a fine man and dedicated scientist trying his best under exceedingly difficult circumstances.

We can all agree that Halford's strategy for demonstrating the safety and efficacy of the Theravax HSV-2 vaccine for treating genital herpes was by any measure unorthodox. Halford's company Rational Vaccines set up trials in St. Kitts & Nevis and had 20 herpes sufferers fly to a clinic on the island to receive a live-attenuated virus injection (for the details of Dr. Halford's quest see [t \[2\]his article \[3\]](#) in Wired.)

After Dr. Halford's death, neither Rational nor Theravax went away. Instead, the company, still led by CEO Agustin Fernandez, continues to believe in Halford's vaccine. This time, however, clinical trials will be run according to FDA requirements. Mr. Fernandez recently told me:

“Rational Vaccines launched a new website this week to share the progress we’re making toward a safe, effective herpes vaccine. We’ve assembled a team of the world’s best scientific minds and have seven vaccine candidates in our pipeline. Our plan is to use [rationalvaccines.com \[4\]](#) to keep the world up-to-date on our progress toward FDA-approved therapeutic and prophylactic vaccines that can help alleviate the suffering of so many and eventually eradicate the herpes pandemic.”

Agustin Fernandez, Rational Vaccines CEO July 16, 2020

We believe a properly attenuated live viral vaccine can be a game changer for the herpes pandemic.

Source: [Rationalvaccines.com](#)

Will a therapeutic vaccine for herpes simplex work? Given the irregular nature of the first trials, there is no way to know. There were reports from some participants that the vaccine was helpful, while others said it caused them harm. One of the participants, Rich Mancuso, author of the book "[Asking For a Friend \[5\]](#)" is in the "helpful" camp (my 2018 interview with Mr. Mancuso can be found [here \[6\]](#).)

I don't think people should be surprised that Rational Vaccines has been working constantly since day one. Unfortunately, the Internet is full of hearsay, conjecture, and assumptions. The same everyday BS that leads people to think the worst of something instead of looking it up. I always knew that one day they would be back

because something that works that well rarely goes unnoticed. Science will say it is cautiously optimistic but for me, I always knew this day was coming. It was just a matter of time.

Rich Mancuso, Private communication. July 17, 2020

No matter what your feelings are regarding "the first time around," you should be rooting for Rational. Although there have been [a number of experimental vaccines](#) [7] from other companies and universities, none has been found to be either prophylactic or therapeutic. Rational is working on both. In fact, the company has seven vaccines in different stages of development, five for HSV-1 and HSV-2, most in the early stages. **(1)**

The most advanced, RVx-201, formerly called TheravaxHSV-2 is approaching Phase I studies where it will be evaluated for safety. Of particular interest is that if successful, RVx-201 will be the *first-ever vaccine* to treat an infectious disease. All other vaccines are prophylactic.

With time COVID-19 will (presumably) be tamed, but there will still be billions of people worldwide who have either HSV-1, HSV-2, or both **(2)**. The unmet medical need is enormous. We wish them well.

NOTES:

(1) Rational is also working on two COVID vaccines.

(2) HSV-1, which causes oral herpes (cold sores) is about 10-times more prevalent than HSV-2, the cause of genital herpes. But it is not that simple. HSV-1 can readily infect the genital area; in some populations, it is the primary infective pathogen. On the other hand, HSV-2 is (mostly) a genital infection. It does not cause significant oral disease in most people.

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[1] <https://www.acsh.org/news/2016/10/17/herpes-vaccines-interview-dr-william-halford-10313>

[2] <https://www.insidehighered.com/news/2018/01/23/late-researchers-work-potential-herpes-vaccine-was-promising-he-used-risky-human>

[3] <http://www.insidehighered.com/news/2018/01/23/late-researchers-work-potential-herpes-vaccine-was-promising-he-used-risky-human>

[4] <https://url.emailprotection.link/?b1kNKFgG2->

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[5] <https://askingforafriend.us>

[6] <https://www.acsh.org/news/2018/02/08/i-met-theravax-herpes-vaccine-patient-and-here-what-he-said-12543>

[7] https://www.acsh.org/search?search_api_views_fulltext=herpes+vaccine