House Select Subcommittee on the Coronavirus Crisis

"Combating Coronavirus Cons and the Monetization of Misinformation"
November 17, 2021

Witness Testimony

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Short Biographical Summary of the Witness:

Dr. Aeschlimann has been an Infectious Diseases Pharmacist and an Associate Professor at the University of Connecticut (UConn) School of Pharmacy for 23 years. His clinical practice and research site is located at UConn Health John Dempsey Hospital in Farmington, Connecticut.

Since the COVID-19 pandemic's early weeks, Dr. Aeschlimann has served as an expert advisor within the UConn community for a variety of initiatives. He is a member of the UConn Health John Dempsey Hospital COVID-19 "Think Tank" Committee, serves as its COVID-19 pharmacotherapy expert, and plays a primary role in the development and ongoing revisions of its COVID-19 Treatment Guidance Document. Dr. Aeschlimann has been a member of the Committee/Working Group for the use of COVID-19 Monoclonal Antibodies and COVID-19 Vaccines at UConn Health. Early in the pandemic, he developed and delivered presentations for UConn's "COVID-19 Pandemic: Impacts on Health, Business, and Society" online course, which was offered for the education of UConn students, faculty, staff, and University alumni.

Dr. Aeschlimann's other clinical practice, teaching and research activities include: (1) the development and implementation of antimicrobial stewardship initiatives and the evaluation of their impact on patient care, and (2) clinical and laboratory investigations of gram-positive and gram-negative bacterial resistance.

Witness Verbal Testimony

Members of the House Select Subcommittee on the Coronavirus Crisis, it is my honor to be called as a witness to provide testimony at today's hearing.

My name is Dr. Jeffrey Aeschlimann. I have been an Infectious Diseases Pharmacist and faculty at the UConn School of Pharmacy for 23 years. In that time, I've helped to manage thousands of patients with a variety of infectious diseases collaboratively with my trusted healthcare colleagues.

Since the pandemic's early weeks, I've been immersed in all things related to COVID-19 infection treatment and prevention. I am a prominent member of my clinical site's COVID-19 "Think Tank" committee, where we discuss new research on COVID-19 treatments and use high-quality science to improve the outcomes of our patients. I'm honored to have participated in UConn's efforts to train new vaccinators and to directly vaccinate the citizens of Connecticut against COVID-19.

Today, I'd like to speak to you because I have seen first-hand evidence of how the spread of misinformation about COVID-19 treatments can adversely impact the health and personal finances of people with COVID-19 infection.

Here is one example:

A few months ago, an unvaccinated patient was admitted to our hospital with severe COVID-19 infection. I discovered that this patient had prescriptions filled for both ivermectin and hydroxychloroquine prior to admission.

As outlined in more detail in my full written testimony, both drugs currently do not have clear benefits for the prevention or treatment of COVID-19. Neither are recommended for routine use in reputable COVID-19 treatment guidelines. In fact, both drugs can cause significant harms to patients if used incorrectly.

My patient began to take ivermectin and hydroxychloroquine once their diagnosis of COVID-19 infection was confirmed. After over one week of worsening symptoms despite treatment with these medications, they eventually sought care at our hospital. The patient was admitted and was finally discharged after more than 7 days of hospitalization.

This patient's severe COVID-19 infection and costly hospitalization could have been prevented in at least two ways: either by vaccination before the illness occurred, or by the prompt administration of proven-effective therapies such as monoclonal antibody infusions.

I noted that the drugs were prescribed from a practitioner in a southwestern state, and that the prescriptions were processed and filled by a "Tampa Specialty Pharmacy" in Florida. Although I know that the pandemic has required increased use of telehealth and online/mail-order pharmacies, the locations of both these providers seemed odd to me.

With a little "Google sleuthing", I found that the practitioner's address mapped to a nondescript office building, and there did not appear to be any obvious medical practitioners there. Tampa Specialty Pharmacy's address mapped to a warehouse building--which would make sense for a mail-order pharmacy. Interestingly, the sign on the building said "Benzer Pharmacy". Things clearly weren't passing the "smell test" for legitimacy.

As I would later discover, the Pharmacist/owner of this company has had a long-standing history of shady business practices, prescription filling fraud, and illegal billing practices.

My personal experience seeing the hazards of misuse of off-label drugs for COVID-19 is not isolated.

I know that there are groups on social media platforms that promote ivermectin and other inadequately studied medications for COVID-19 infection. I also know that online pharmacies will dispense prescriptions for these potentially harmful medications.

Three such groups that I describe in greater detail in my written testimony are **America's Frontline Doctors** (also known as the AFLD) the **Front Line COVID-19 Critical Care Alliance** (also known as the FLCCC), and **Ravkoo Pharmacy**.

Both the AFLD and the FLCCC aggressively promote the use of unproven therapies for COVID-19 infection through their internet websites and various social media platforms. They directly enable people to get these prescription medications, and both organizations have recently been verbally attacking pharmacies and pharmacists on social media for refusing to fill prescriptions for unproven COVID-19 drugs—even though it is legal and a professional and ethical obligation for a pharmacist to do this in the interests of patient safety.

The AFLD sets up $90 telehealth visits for prescribing drugs like ivermectin. A recent two-part investigation published by TIME (in which I was sourced) revealed that in many cases, patients' credit cards were charged the $90 fee but no telehealth visits ever occurred. Some people became sick enough to require ICU care while waiting for their ivermectin.

Tens of thousands of patients paid nearly $7 million dollars in aggregate for telehealth consultations, and Ravkoo pharmacies filled over 300,000 prescriptions for unproven COVID-19 therapies at a drug cost of ~$8.5 million dollars.

At this point in the pandemic, many individuals have spent hundreds of dollars and have put their health in jeopardy using unproven therapies over proven-effective therapies. Effective vaccines and therapies would have lowered their risks of developing severe COVID-19 infections, prevented unnecessary and costly hospitalizations, and even prevented COVID infection deaths.

With that, I would like to again thank all the Select Subcommittee members for your time and attention and for the opportunity to speak to you. I am happy to discuss this with you further and answer any questions that you may have.

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Detailed Additional Written Testimony

Guidelines for Management of COVID-19 Infection:

Links to the current guidelines for COVID-19 infection management that have been developed by the **National Institutes of Health (NIH)** and the **Infectious Diseases Society of America (IDSA)**:

NIH Guidelines (last updated October 27, 2021): https://www.covid19treatmentguidelines.nih.gov/

Sections concerning ivermectin and hydroxychloroquine:

https://www.covid19treatmentguidelines.nih.gov/therapies/antiviral-therapy/ivermectin/

Recommendation

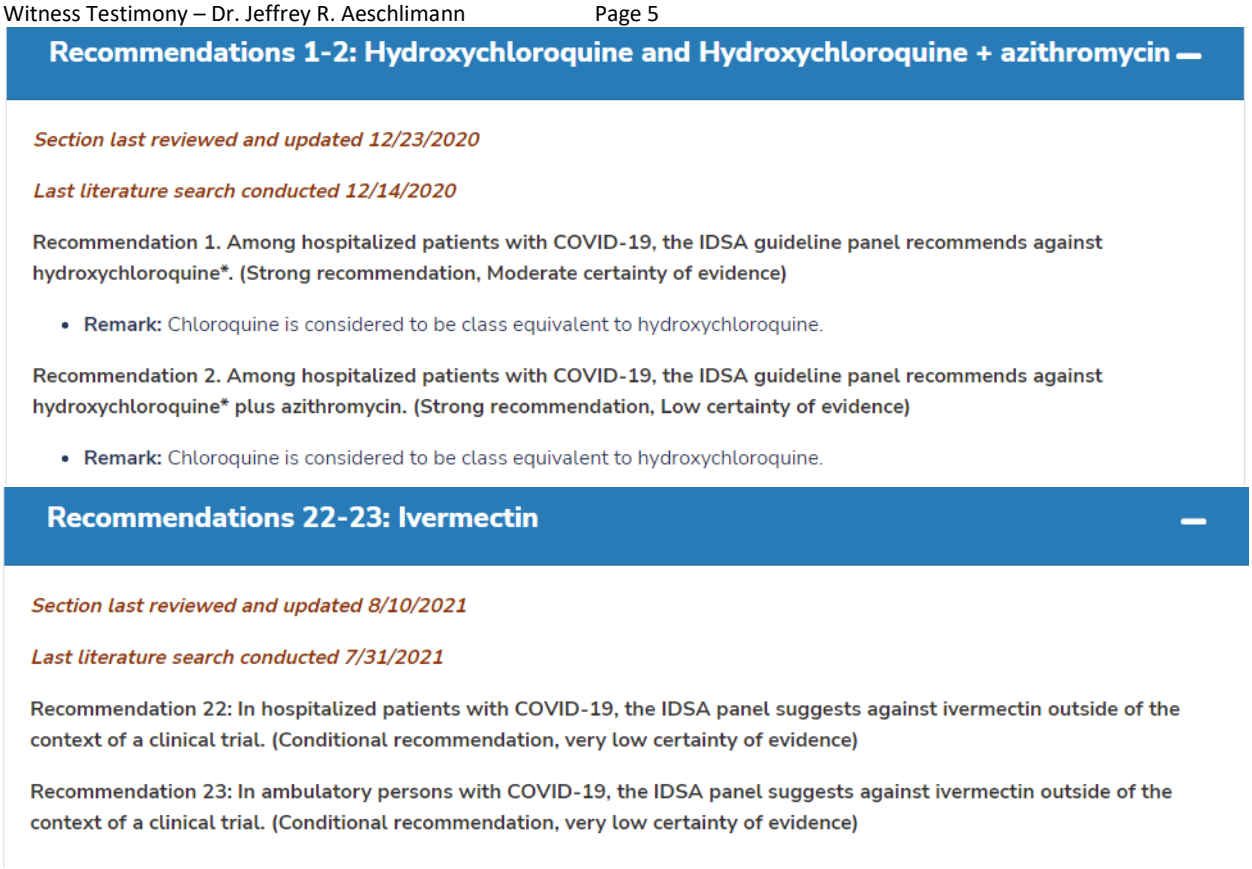
- There is insufficient evidence for the COVID-19 Treatment Guidelines Panel (the Panel) to recommend either for or against the use of ivermectin for the treatment of COVID-19. Results from adequately powered, well-designed, and well-conducted clinical trials are needed to provide more specific, evidence-based guidance on the role of ivermectin in the treatment of COVID-19.

Recommendation

- The COVID-19 Treatment Guidelines Panel (the Panel) **recommends against** the use of **chloroquine** or **hydroxychloroquine** and/or **azithromycin** for the treatment of COVID-19 in hospitalized patients **(AI)** and in nonhospitalized patients **(AIIa)**.

IDSA Guidelines (last updated November 9, 2021):
https://www.idsociety.org/practice-guideline/covid-19-guideline-treatment-and-management/

Sections concerning ivermectin and hydroxychloroquine:



Recommendations 1-2: Hydroxychloroquine and Hydroxychloroquine + azithromycin

Section last reviewed and updated 12/23/2020

Last literature search conducted 12/14/2020

Recommendation 1. Among hospitalized patients with COVID-19, the IDSA guideline panel recommends against hydroxychloroquine*. (Strong recommendation, Moderate certainty of evidence)

- **Remark:** Chloroquine is considered to be class equivalent to hydroxychloroquine.

Recommendation 2. Among hospitalized patients with COVID-19, the IDSA guideline panel recommends against hydroxychloroquine* plus azithromycin. (Strong recommendation, Low certainty of evidence)

- **Remark:** Chloroquine is considered to be class equivalent to hydroxychloroquine.

Recommendations 22-23: Ivermectin

Section last reviewed and updated 8/10/2021

Last literature search conducted 7/31/2021

Recommendation 22: In hospitalized patients with COVID-19, the IDSA panel suggests against ivermectin outside of the context of a clinical trial. (Conditional recommendation, very low certainty of evidence)

Recommendation 23: In ambulatory persons with COVID-19, the IDSA panel suggests against ivermectin outside of the context of a clinical trial. (Conditional recommendation, very low certainty of evidence)

History of the Use of Ivermectin for Infectious Diseases and for COVID-19 infections

There are many examples where misinformation is adversely affecting the optimal management of the COVID-19 pandemic. In my testimony, I would like to use the case of Ivermectin as one illustration of the harms that are occurring on both an individual and societal level because of misinformation related to this medication.

I have provided a short background on the history of Ivermectin use in infectious diseases. Note: some of this information is excerpted from a recent article I wrote for The Conversation (https://theconversation.com/ivermectin-is-a-nobel-prize-winning-wonder-drug-but-not-for-covid-19-168449)

Ivermectin is a Nobel-prize winning drug that has been available for use in humans for over 30 years. It was originally discovered in the 1970s, and early research showed that it had powerful activity against a variety of parasitic infectious diseases. The infections included “River Blindness” (also known as Onchocerciasis), which predominantly occurs in Africa and Latin America. River blindness is caused by a parasitic worm (called *Onchocerca volvulus*), and it is the second leading cause of preventable blindness in the world. Since Ivermectin’s approval in 1987, it has been distributed free of charge through the Mectizan Donation program. The effectiveness of Ivermectin for River Blindness has essentially eliminated the disease in many Latin American countries and has prevented over a half of a million cases of blindness.

Ivermectin also is a highly effective first-line therapy for another parasitic infection called **Strongyloidiasis**. This infection is an intestinal worm infection that affects between 30-100 million people throughout the world. In most people, infections are generally mild. However, in people who have weak immune systems, the infection can spread throughout their body, cause severe symptoms, and can even be fatal if not treated promptly.

Now, for information about the evolving story of Ivermectin use for COVID-19 Infection:

In the field of infectious diseases, we frequently attempt to **repurpose** FDA-approved medications to help treat infections for which there are no effective and safe options available for use. The **benefits of repurposing during a pandemic** are that the drug is already is **immediately available** for use, and that we usually will have a fairly good understanding of the safety profile of that medication over a certain range of dosages.

Early Reports of Ivermectin for COVID-19 infections

Ivermectin had previously been shown to have some activity against various types of viruses before the Coronavirus pandemic began. In April 2020, a laboratory study from researchers in Australia was published that claimed an "~5000-fold reduction of viral RNA" against SARS-CoV-2 virus in an experimental cell-culture system. (https://www.sciencedirect.com/science/article/pii/S0166354220302011?via%3Dihub)

Several media outlets began to report on these results but often **did not present an important context**: the amounts of Ivermectin that were needed to produce that result could be **as much as 2,000 times higher than those that will be achieved with usual doses** of the drug when given to humans.

Preprints are preliminary reports of research that have not been certified by peer review. A preprint report was uploaded to the SSRN preprint server (https://www.ssrn.com/index.cfm/en/) in April 2020 by Sapan Desai, the founder of Surgisphere, and other researchers. The preprint claimed that Ivermectin significantly reduced mortality in patients with COVID-19 infection. Several Latin American countries that were being ravaged by the pandemic—for example, parts of Brazil, Peru, & Bolivia--took that early non-peer reviewed data on Ivermectin and used it as a justification to add Ivermectin to various clinical guidelines for prevention and treatment of COVID-19 in May 2020. Unfortunately, Surgisphere was ultimately determined to have fabricated large data sets on treatment of COVID-19 infection; articles published by the group in the journals *New England Journal of Medicine* and *Lancet* were both retracted; it's Ivermectin pre-print was removed from the SSRN server soon thereafter. Some links to articles discussing this in more detail are provided below:
(https://www.nature.com/articles/d41586-020-02958-2)
(https://www.nature.com/articles/d41586-020-01695-w)
(https://www.the-scientist.com/news-opinion/surgisphere-sows-confusion-about-another-unproven-covid19-drug-67635)

In the months that followed, additional reports describing the potential use of Ivermectin use for COVID-19 also started to emerge as either (1) preprint publications on websites such as Research Square (https://www.researchsquare.com/) or Medrxiv (https://www.medrxiv.org/)--or as (2) publications in scientific journals of varied--but mostly very low—scientific quality & rigor. These research studies typically included small numbers of treated patients, were typically not randomized nor placebo controlled, and had numerous methodological flaws. However, many of them claimed that Ivermectin could prevent COVID-19 infections, reduce symptoms of infection, and/or reduce mortality from severe infections. Almost a year later, we would learn from the diligent work of a number of independent health scientists that many of these investigations had a high likelihood of being fraudulent, as well. These scientists include: Dr. Kyle Sheldrick (University of New South Wales, Australia), Dr. Nick Brown (Linnaeus University, Sweden), Dr. James Heathers (Chief Scientific Officer, Cipher Skin, CO), Gideon Meyerowitz-Katz, MPH (University of Wollongong in Australia), and Jack Lawrence (a medical student at the University of London).

The links I provide below provide some examples of their rigorous reviews and identification of research errors and/or fraud in a number of Ivermectin research articles:

Data detectives dig into ivermectin studies. Cosmos. https://cosmosmagazine.com/health/covid/data-detectives-ivermectin-studies/ (accessed 11/15/21)
Lawrence, J.M., et al. The lesson of ivermectin: meta-analyses based on summary data alone are inherently unreliable https://doi.org/10.1038/s41591-021-01535-y
Meyerowitz-Katz, G. Is Ivermectin for Covid-19 Based on Fraudulent Research? https://gidmk.medium.com/is-ivermectin-for-covid-19-based-on-fraudulent-research-5cc079278602 (accessed 11/15/21)

Meta-Analyses of Ivermectin for COVID-19 infection:

During this time, several meta-analyses and systematic reviews have been performed on the collective group of Ivermectin research studies. Meta-analyses take outcomes from multiple research studies (typically smaller studies), and then combine the results using well-defined statistical analytical techniques to pool the results to attempt to determine the overall possible effect across multiple investigations. When properly performed, meta-analyses are a powerful tool to help make decisions about whether a treatment may be effective and/or safe to treat a specific disease like COVID-19 infection. Unfortunately, meta-analyses, when not performed properly, can results in inappropriate conclusions about the safety and effectiveness of a given therapy. The researcher performing the meta-analysis needs to be careful to only include the highest-quality investigations with the lowest risks of bias to avoid a "garbage-in, garbage-out" situation.

With highly-rigorous meta-analysis methods, there does not appear to be an overall net positive effect of ivermectin during the treatment or prevention of COVID-19 infection. For example:

Popp, M., et al. Ivermectin for preventing and treating COVID-19 (28 July 2021). https://doi.org/10.1002/14651858.CD015017.pub2

Hill, A., et al. Ivermectin for COVID-19: addressing potential bias and medical fraud. Research Square (preprint). https://doi.org/10.21203/rs.3.rs-1003006/v1 (Accessed 11/15/2021).

In contrast, in meta-analyses where all studies are included (including low-quality studies, high-bias studies, and potentially fraudulent studies) and where different outcomes are mixed into the meta analysis (e.g. treatment of mild infection, severe infection, and prevention of infection), there appears to be a possible benefit of ivermectin to prevent or treat COVID-19 infection. For example:
Ivermectin for COVID-19: real-time meta analysis of 65 studies. https://ivmmeta.com/ (Accessed 11/15/2021)

Dr. Nick Mark, an intensivist doctor in Seattle, Washington has produced an elegant, comprehensive, and evidence-based frequently-updated blog post that summarizes the evolution of Ivermectin research during the COVID-19 pandemic (https://onepagericu.com/blog/debunking-ivermectin-a-complete-guide [Accessed 11/15/2021]).

History of the Front Line COVID-19 Critical Care Alliance ("FLCCC", https://covid19criticalcare.com/) and its role in misinformation about COVID-19 infection treatments

The FLCCC was initially formed in April 2020 by Dr. Paul Marik, Dr. Pierre Kory, for what appeared at the time to be a legitimate goal of trying to improve the treatment of people with COVID-19 infection. They developed a protocol of various therapeutic interventions that they dubbed the "**MATH+ protocol**" (https://covid19criticalcare.com/covid-19-protocols/math-plus-protocol/). The protocol initially consisted of methylprednisolone (an anti-inflammatory steroid), ascorbic acid (Vitamin C), Thiamine (a B-complex vitamin), and Heparin (an anticoagulant). The selection of these

products was based primarily on their personal experience and hypotheses about pathophysiology of severe COVID-19 infections. It is worth noting that the use of Vitamin C in critically-ill patients with sepsis was touted and promoted by Dr. Marik in the years prior to the COVID-19 pandemic. High-quality randomized clinical trials have since revealed that the vitamin has no significant beneficial effects in critically-ill patients.

The FLCCC soon developed and implemented an aggressive ongoing social media campaign. According to their own website "*Tens of thousands of people view FLCCC's posts on social media, and many ask where they can go for COVID treatment to be assured of getting the MATH+ protocol*". They continued to expand their media presence throughout the Winter of 2020/2021. To this day, they continue to aggressively market their COVID-19 therapy protocols, do not advocate for use of effective COVID-19 vaccinations, and have managed to appear on several prominent highly-listened-to Podcasts & Talk Shows. These appearances have only served to further amplify the dissemination of their potentially harmful misinformation about the management of COVID-19 infection.

In the Fall & Winter of 2020, the FLCCC began formally promoting the use of Ivermectin for both the prevention and treatment of all levels of COVID-19 infection. Specifically, the FLCCC added the use of Ivermectin to their "**I-MASK+ prophylaxis and at-home treatment**" protocol recommendations, as well as their "**MATH+ protocol**" for hospitalized patients.

At least one of the FLCCC founders (Dr. Fred Wagshul, a Pulmonologist & Medical Director of the "Lung Center of America" (https://www.lungcenterofamerica.org/) appears to directly profit off of telehealth visits for Ivermectin prescriptions, as per the Lung Center of America website (https://www.lungcenterofamerica.org/ivermectin-contact-us), "*The cost of the appointment is $211.00 and is not billable to insurance… If you are a candidate, she will send a prescription to the pharmacy of your choice for a 6-month supply. If you choose to renew at 6 months, you will require an additional phone consult which will cost $75.00*."

America's Frontline Doctors ("AFLD") and its role in misinformation about COVID-19 infection treatments

Another group of Medical practitioners with a strong social media presence known as "**America's Frontline Doctors**" (AFLD, https://americasfrontlinedoctors.org/) emerged during the COVID-19 pandemic. While much of the AFLD's mission & efforts appears to revolve around politics and promoting freedom/autonomy ("*Doctors must have the independence to care for their patients without interference from government, media and the medical establishment*"), the AFLD also began to promote the use of various medications (hydroxychloroquine first, followed by ivermectin and other therapies without proven value), and its views align with the FLCCC and, in fact, they directly reference various publications by the FLCCC group (https://americasfrontlinedoctors.org/covid/ivermectin/).

The AFLD appears to have been using relaxed telehealth laws during the COVID-19 pandemic to generate significant revenues from a variety of medications with unclear benefit for COVID-19 prevention or treatment. (https://americasfrontlinedoctors.org/covid/early-treatment/). They provide a link on their website to set up a $90 telehealth visit (through "Speak with an MD"), which they note will occur "typically within 2-7 days (not counting weekends)". They note that "…the pharmacy will contact you for your payment information and mailing address to send the prescription to you."

In a two-part expose written for Time by Vera Bergengruen (https://time.com/6092368/americas-frontline-doctors-covid-19-misinformation/ , https://time.com/6104407/ravkoo-pharmacy-ivermectin-covid-19-ppp-loan/), she & other investigators discovered and interviewed dozens of people who attempted to use the AFLD telehealth services to get prescriptions for Ivermectin. In many cases, patients' credit cards were charged the $90 fee, no telehealth visits occurred, and attempts to contact the AFLD went unanswered. According to the article, "Some customers described being charged for consultations that did not happen. Others said they were connected to digital pharmacies that quoted

excessive prices of up to $700 for the cheap medication." Alarmingly, "…dozens of people described their or their family members' COVID-19 symptoms worsening while they waited for an unproven "wonder drug" that didn't arrive." According to some testimonies, these people became sick enough to require ICU care while waiting for their Ivermectin.

According to the TIME investigations, electronic prescriptions for drugs like Ivermectin and Hydroxychloroquine that were prescribed through the AFLD were sent to an online pharmacy based in Florida ("Ravkoo") where they are filled and mailed or are sent to a pharmacy near the patient.

Ravkoo is a pharmacy that was rebranded (originally was OHM pharmacy) in part to distance itself from previous cases of fraudulent prescription filling that resulted in a multimillion dollar settlement (https://www.justice.gov/usao-mdfl/pr/us-attorney-s-office-collects-more-2369-million-taxpayers-fiscal-year-2016). Several employees of Ravkoo and its previous embodiments (also as Benzer Pharmacy) had been accused of, prosecuted, and/or convicted of various activities such as defraud of Medicare/Medicaid and illegal dispensing of prescription medications. Data obtained by hackers that was published by the Intercept in October 2021 (https://theintercept.com/2021/09/28/covid-telehealth-hydroxychloroquine-ivermectin-hacked/) revealed that Ravkoo filled over 300,000 prescriptions in 2020-2021 which accounted for ~$8.5 million dollars in drug costs; half of the prescriptions were for either Ivermectin or Hydroxychloroquine, and nearly all of it was paid through cash or credit card transactions.

Hydroxychloroquine Use during the COVID-19 Pandemic

Most people are now quite familiar with the story of the attempt to use Hydroxychloroquine, with or without Azithromycin, to treat or prevent COVID-19 infection. In early 2020, it appeared that these drugs might be able to be repurposed for COVID-19. This was based on some preliminary laboratory studies that suggested possible antiviral activity at dose levels near the high-end of the range considered to be safe in humans. Additionally, press reports from China suggested "success" with use of chloroquine (though specifics were lacking), and then a report from a research group in France claimed that the combination of the two drugs had what appeared to be amazing effectiveness against COVID-19 infection.

News of this potential "miracle cure" spread throughout the world with the help of various social media platforms and endorsements from prominent world leaders.

One of the results of this widespread use of hydroxychloroquine throughout the world was that many patients who relied on these medications for their proven value in treating diseases such as rheumatoid arthritis and other autoimmune disorders could not get their prescriptions filled:

Patients reported international hydroxychloroquine shortages due to COVID-19.
https://www.sciencedaily.com/releases/2020/11/201106103103.htm (accessed 11/15/2021)

Thankfully, it did not take too long for us to learn that hydroxychloroquine was not the "miracle cure" for COVID-19 infection that we had hoped they would be. By late April 2020, there was a large body of well-performed research showing that it had essentially no beneficial effects, while at the same time, it could have severe and potentially life-threatening effects on people's heart rhythms. At that time, we stopped using hydroxychloroquine.