

U.S. Senate Committee on Homeland Security

Full Committee Hearing, Early Outpatient Treatment: An Essential Part of a COVID-19 Solution, November 19, 2020

Statement for the Official Record, by:

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Summary

Research and development of medicine is now a matter of national security. Prior to COVID-19, medicine was generally left to the pharmaceutical industry and a few agencies (“Big Pharma”). Big Pharma relies on an economic incentive model that prioritizes fiduciary duty to shareholders over public benefit, resulting in expensive, proprietary, patented drugs that take significantly more time to develop. This incentive model is leading to a mortality count that may be greater than the civil war - historically the most deadly war for the USA.

The cure to COVID-19 is a combination therapy of generic drugs and supplements that must be administered within the first four (4) days of symptoms. It was the fastest a cure for any disease has ever been developed (months), using open source Real World Evidence data exchange at global scale, of non-patented drugs for public benefit – this is the opposite of the Big Pharma incentive model.

The development of new medicines in this way is an elegant solution which provides extreme value to society, dramatically reduces load to healthcare system and allows for overall greater production in economy. This can be done for many other diseases and conditions if the proper resources were allocated – so that a COVID-19 like situation never happens again. There must be an organization that functions as an intelligence agency for medicine whose exclusive duty is to the people, not shareholders – building on this solution. Significant funds must be allocated to implement this - a gap which can be filled by an organization funded by Homeland Security similar to how the TSA was created in response to 9/11. COVID-19 must be swiftly ended and a situation like this must never happen again.

Background

The 21st Century Cures Act (the “Cures Act”) is a law that was passed in 2016. Section 3022 of the Cures Act is titled Real World Evidence. The Cures Act defines Real World Evidence as:

“ data regarding the usage, or the potential benefits or risks, of a drug derived from sources **other than randomized clinical trials** ... including

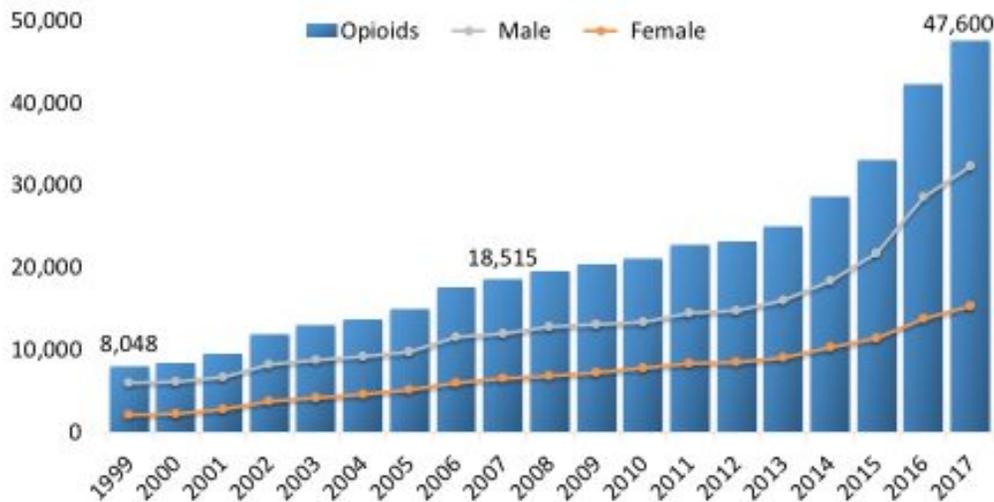
Vladimir Zelenko MD is a board certified physician in the state of New York. He is the inventor of the Zelenko Protocol. He has treated over 3,000 COVID-19 and suspected COVID-19 patients as well as consulting with peer physicians that have treated over 10,000 COVID-19 patients on four (4) different continents. 100% of Dr. Zelenko's patients that are high risk have fully recovered if they received the Zelenko Protocol within the first 4 days of symptoms, and took it for at least 5 days. Dr. Zelenko's work has been peer reviewed and published. He publishes his findings in real time on twitter @zev_dr.

ongoing safety surveillance, **observational studies**, registries, claims, and patient-centered outcomes research activities...”

The Cures Act goes on to state Real World Evidence may support the approval of new indications for generic drugs. There is very significant Real World Evidence that support the approval of using generic drugs to effectively treat COVID-19 in the outpatient setting.

While formal clinical trials can provide significant insight into a drug’s safety and efficacy in a patient population, it may also provide misleading data - as was the case with the opioid clinical trials which resulted in a fatal epidemic. Reliance on these clinical trials has led to over 200,000 deaths from opioids in the USA - which only started to decrease recently as of 2016 - 2017, because of use of Real World Evidence. To clarify, the clinical trials for some opioids did not show how addictive the drugs actually were. These clinical trials were used to push opioids prescriptions, which has significantly increased the demand for heroin in the USA. Below is a chart of opioid based deaths over time.

Figure 3. National Drug Overdose Deaths Involving Any Opioid, Number Among All Ages, by Gender, 1999-2017



Source : Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death 1999-2017 on CDC WONDER Online Database, released December, 2018

It was only use of Real World Evidence by physicians in the clinic that showed their true effect - how dangerous opioids can be. Why? Because patients in the clinic is an actual real world setting, with real clinicians and patients whereas clinical trial data is generally paid for by a pharmaceutical company who has an economic incentive to optimize data presentation for FDA approval. For example, details from “failed” clinical trials are often not published.

This has been the case for COVID-19 big pharma drugs. For remdesivir - an alleged COVID-19 drug that was given emergency use authorization, there is clinical trial data which shows no statistically significant benefit in mortality, yet it

has received emergency use authorization by the FDA. The World Health Organization has even stated that remdesivir should not be used to treat COVID-19 due to lack of efficacy in mortality. A significant amount of data has not been published for remdesivir. This is generally the case with Big Pharma clinical trial drugs, a significant portion of the data is not published because of economic incentives.

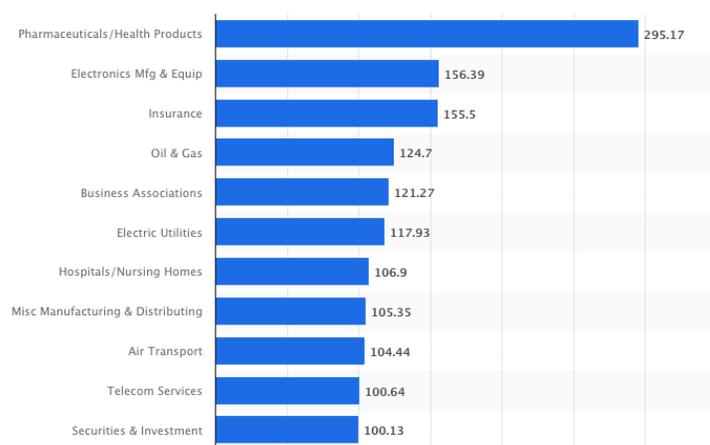
Reliance on clinical trials as the only evidence to support the use of medicines in the market has led to significant problems such as COVID-19 and the opioid epidemics.

Incentives - No one can serve two masters

The financial interests in drug development are significant. Specifically, pharmaceutical companies and biotech's are generally publicly traded and therefore owe a fiduciary duty to their shareholders. This means that the standard Big Pharma corporation has a special duty to act in the best interest of the parties that hold their stock. Notably, these Big Pharma companies do NOT owe a fiduciary duty to patients nor the general public. Big Pharma owes the same duty to their shareholders that any publicly traded company owes to their shareholders - make as much legal profit as possible to make the stock price go up. If a CEO does not do this, he/she will be replaced. Big Pharma's total market capitalization is over \$2 trillion USD, which is larger than 90% of all country's GDP and is approximately 10% of the USA's GDP.

In the USA, because of the fiduciary duty, Big Pharma spends significant funds on lobbying. The pharmaceutical industry as a whole spends more on lobbying U.S. government agencies and officials than any other industry by over \$100 million USD, per year.

Leading lobbying industries in the United States in 2019, by total lobbying spending (Source: statista) *(in million U.S. dollars)*



The amount spent on lobbying is directly correlated to deaths by opioids. A recent 2020 JAMA Internal Medicine article, “analyzed publicly available data on campaign contributions and lobbying in the US from 1999 to 2018 and found

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that the pharmaceutical industry spent \$4.7 billion, an average of \$233 million per year, on lobbying the US federal government; \$414 million on contributions to presidential and congressional electoral candidates, national party committees, and outside spending groups; and \$877 million on contributions to state candidates and committees. Contributions were targeted at senior legislators in Congress involved in drafting health care laws and state committees that opposed or supported key referenda on drug pricing and regulation.”

The government agencies that execute the policy, regulations and/or pricing that flows from this lobbying are Food and Drugs Administration (“FDA”), the Centers for Disease Control (“CDC”), the National Institutes of Health (“NIH”). All three (3) of these agencies have significant financial interests aligned with Big Pharma - as outlined below.

FDA

The FDA budget for 2019 was approximately \$6 billion. Approximately 50% comes from tax payers while the other 50% is paid for by industry user fees. User fees are paid by industry, e.g. Big Pharma for drug approvals such as a PDUFA fee. A PDUFA fee is \$2 - \$10 million USD paid for by a drug sponsor to the FDA to allow a drug on the market, after the drug has been approved. The FDA does not receive PDUFA fees when new indications or uses for generic drugs are discovered or invented.

Additionally, it is quite customary for FDA employees to go work for industry. This is the case of former high ranking FDA officials working for Big Pharma companies after they finish at the FDA. Throughout the COVID-19 epidemic, these former FDA officials regularly go in the media and “update” the country as to the state of the COVID-19 epidemic. To date, they have generally not advocated for the use of Hydroxychloroquine or Ivermectin drug combinations (e.g. Hydroxychloroquine or Ivermectin, Zinc, Doxycycline or Azithromycin).

The FDA has warned against the use of Hydroxychloroquine in both the hospital and outpatient setting. It is unlikely the FDA has received fees for generic drugs to treat COVID-19 in the outpatient setting. It is very likely the FDA has received fees for patented Big Pharma drugs and vaccines.

It is known that the combination therapy of Hydroxychloroquine, Zinc and antibiotic (azithromycin or doxycycline) is a cure to COVID-19 if administered within the first 4 days of symptoms. This has been proven with real world evidence. There is no clinical trial that refutes this. The data is overwhelming. The FDA has not removed their restrictions on hydroxychloroquine nor supported the use of this drug combination.

CDC

Established by Congress as an independent, nonprofit organization, the CDC Foundation is the sole entity authorized by Congress to mobilize philanthropic partners and private-sector resources to support CDC’s critical health protection mission. Although the CDC Foundation was chartered by Congress, it is not a government agency nor is it a division of CDC. It is a private, nonprofit organization classified as a 501(c)(3) public charity. Donors to the CDC

Foundation include the top Big Pharma companies. The CDC Foundation then funds the CDC's work and becomes a partner.

NIH

The NIH budget is approximately \$40 billion per year, paid by tax payers. This is the biggest bio R&D operation in the world. The NIH is financially involved with almost every Big Pharma company. A significant portion of Big Pharma drugs originate at the NIH, generating approximately \$100 million a year in royalties paid to the NIH and NIH employees. According to End Points, "from 1988 to 2004, NIH entered into almost 2,500 license agreements and generated more than \$500 million in royalty revenues. More recently, royalties have amounted to more than \$100 million per year."

The NIH is paid for by tax payers but is incentivized with Big Pharma's fiduciary duty to shareholders. As such this can have a significant effect on research and markets as support for one drug may increase or decrease sales of a competing drug therefore affecting economic flow (royalties, relationships, etc.). Such a model favors research and support to patented drugs over generics and supplements. The NIH budget allocated towards drug repurposing (generics) is approximately .015% of the budget.

A significant amount of NIH research data is generally not publicly available for collaborative data mining. Notably, from 2013 - 2019, the NIH spent over \$250 billion USD in research and US life expectancy actually decreased. How can this be?

During the Covid-19 pandemic, approximately \$10 billion was committed by the federal government to big pharma companies for patented drugs and vaccines. Less than 1% of this was allocated to researching generic drug combinations - even after the cure was announced in March 2020. The cure to COVID-19 is a combination of safe generic drugs and supplements administered in the outpatient setting. NIH started a clinical trial for a combination outpatient therapy of hydroxychloroquine and azithromycin - but terminated the clinical trial after only two (2) months due to "lack of enrollment." It is known that such trials can take significantly longer than just two (2) months.

The NIH funded the development of Remdesivir in a \$37.5 million grant to the University of Alabama at Birmingham - with the grant's principal investigator being a board member of Gilead Sciences. Remdesivir is Gilead's drug. On April 29 2020, Anthony Fauci MD, the leader of the National Institute for Allergy and Infectious Disease at the NIH, declared Remdesivir as the "standard of care" for COVID-19 treatment. On April 30, 2020 Gilead's stock reached its annual high of \$84 per share. On November 20, 2020, the World Health Organization recommended "against the use of remdesivir ... regardless of disease severity, as there is currently no evidence that remdesivir improves survival and other outcomes in these patients." As of November 30, 2020, Gilead's stock is trading at approximately \$60 per share. A drop of 40%, and a loss of over \$20 billion in market capitalization.

Markets

Stock markets have moved considerably on positive COVID-19 research news, e.g. advance of treatment, vaccines, etc. In February and March 2020, the stock market had decreased the most in the shortest period of time, ever, likely due to COVID-19 fear. This is despite significant injections of capital by government and institutions. It was only on March 19, 2020 when President Trump announced the combination therapy of Hydroxychloroquine and Azithromycin that the trend started to reverse. President Trump even stated that this combination therapy is expected to provide most benefit early in treatment, e.g. outpatient, before hospital. On this news, Gilead's stock went down and the entire market went up. The exact bottom of Tesla stock was the day before, on March 18.

As stated by the hearing witnesses, there is not consensus amongst medical professionals regarding effective outpatient treatment. This lack of consensus is due to an incentive model that has led to faulty message propagation, controlled by shareholder value as opposed to public benefit. If the generic drug combination therapy was promoted as the cure, it would take profit away from the patented Big Pharma drugs and likely eliminate the mass panic and state of emergency, which would reduce funding to Big Pharma. The economic incentives are misaligned at the expense of tax paying American citizens.

The cure to COVID-19 did not come from large pharmaceutical companies nor the government - it came from private citizens engaged in open source R&D at global scale. According to Harvey Risch, MD, PhD of Yale University, to date the generic combination therapy is better than anything that the pharmaceutical industry or government has put out, including Remdesivir and monoclonal antibodies. It is clear that generic drug and supplement research can provide significant benefit.

The Zelenko Protocol

I have treated over 3,000 COVID-19 and suspected COVID-19 patients in a unique orthodox Jewish setting in New York. Additionally, I have consulted physicians who have treated over 10,000 patients in total. 100% of my patients that are high risk have fully recovered if they received the triple combination therapy of Hydroxychloroquine + Zinc + Antibiotic (Azithromycin or Doxycycline) within the first 4 days of symptoms, and take it for at least 5 days. This triple combination therapy administered immediately in the outpatient setting has gained international acclaim and has become known as the Zelenko Protocol. High risk patients that have been cured include the elderly including Holocaust survivors that are over 90 years old, cancer patients, diabetics, etc. This group should have a fatality rate between 5% - 20%. The fatality rate of these patients that follow the Zelenko Protocol in the first four (4) days of symptoms is 0.00%.

To my knowledge, I am the first person to publicly integrate a high dose of Zinc into the combination therapy as of March 2020. Zinc has proven to be extremely efficacious when used in combination with a zinc ionophore such as Hydroxychloroquine or Quercetin. These combinations have proven to be very safe in the outpatient setting. The Zelenko Protocol calls for risk stratifying patients into high risk and low risk group and treat empirically the high risk group within the first 4 days of symptoms.

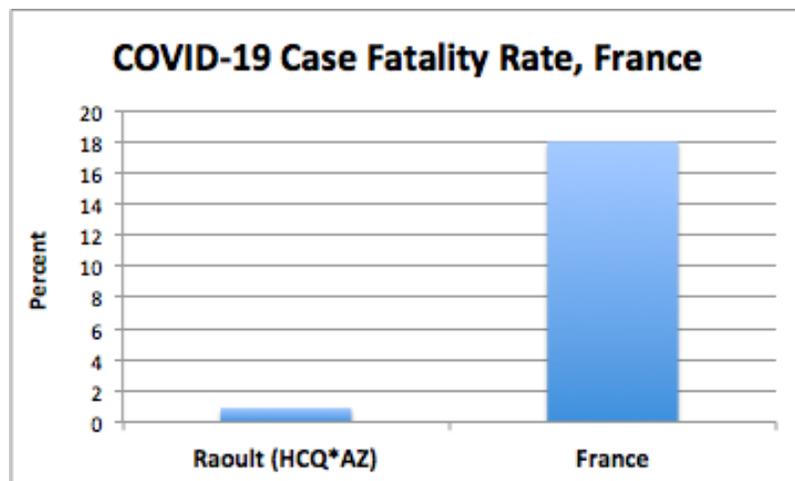
I have published an initial study of my findings with two prominent German researchers, Dr. Roland Derwand of Alexion Pharma and Dr. Martin Scholz of Heinrich-Heine University in Dusseldorf Germany, which can be found here: <https://www.sciencedirect.com/science/article/pii/S0924857920304258?via%3Dihub> . Further publications are currently in process.

In addition, patients that have been successfully treated with the Zelenko Protocol have gone on to develop antibodies to COVID-19. We have provided a cure and immunity quickly and inexpensively.

The Zelenko Protocol was developed based on the work of Didier Raoult MD PhD at the main COVID-19 hospital in Marseille, France - the IHU. Dr. Raoult is known as one of the top infectious disease doctors in the world and the most widely cited microbiologist in Europe.

Incredibly, the French government decided to place a ban on the use of Hydroxychloroquine to treat COVID-19. Dr. Raoult ignored the ban and continued to treat his patients with the combination therapy, while the rest of France abided by the ban. As of July 2020, the case fatality rate of Dr. Raoult's patients (3000 +) was less than 1% where as the rest of France had a case fatality rate of more than 15%. Dr. Raoult has been a strong proponent to early treatment.

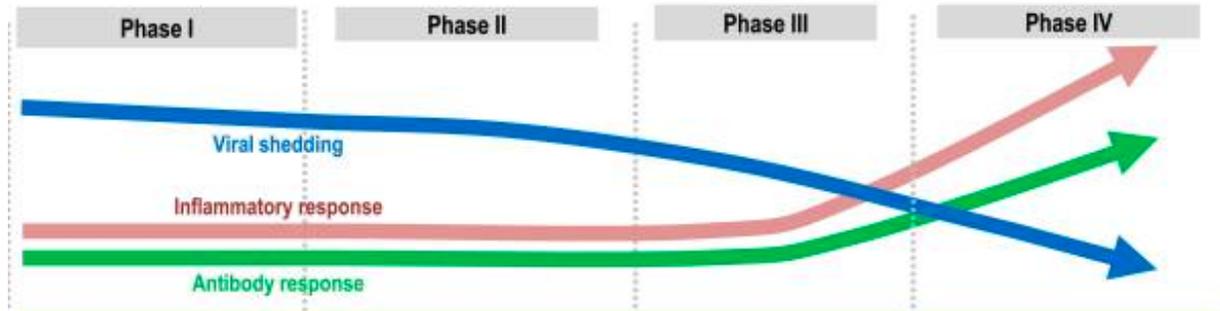
Any professional who states this combination therapy does not work must explain the below difference in COVID-19 fatality in France as of July 2020. (Source: Worldometer, IHU website)



Dr. Raoult and his team have been rapidly publishing throughout the pandemic, for which this recent publication conveys their results from 3,737 COVID-19 patients which is consistent with my results: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7315163/>

The reason why it is so important to engage in early treatment is because COVID-19 is effectively two different diseases. The first being a replicating virus

and the second being respiratory inflammation including pneumonia in the lungs. If the virus replication is stopped early, the respiratory inflammation can be limited in which patients can be back to normal quickly. If the virus is not effectively treated early on, it can be difficult to treat the respiratory inflammation especially in high risk patients - as their lungs may become severely infected. This visual was created by Dr. Raoult and his team to illustrate the stages of COVID-19.



The Zelenko Protocol is a cure to the viral shedding phase, not a cure to the respiratory inflammation. Once the virus has replicated too much, the inflammation cascade may not be reversed - hence time is of the essence. This is why outpatient therapy is so important.

Additionally, I put my high risk patients on a prevention protocol which includes use of Zinc and a zinc ionophore (Hydroxychloroquine or Quercetin). To date, none of my patients using prevention have been hospitalized or died.

For a list of studies analyzing the effect of hydroxychloroquine and its use in combination therapy see <https://hcgmeta.com/> as well as <https://c19study.com/>. The great majority of studies show that when used early, it is very effective in treating COVID-19.

This is the Zelenko Protocol for COVID-19 treatment:
<https://docs.google.com/document/d/1TaRDwXMhQHSMsgrs9TFBclHjPHerXMuB87DUXmcAvwg/edit>

This is the Zelenko Protocol for COVID-19 prevention:
https://docs.google.com/document/d/1i7C_6H1Yq0u8lrzmnzt5N1JHg-b5Hb0E3nLixedgwpQ/edit

Despite all of this evidence, the FDA and state pharmacy boards have imposed legal liability on physicians who prescribe these generic drug combinations. Some states have severely restricted the use of hydroxychloroquine - effectively governors telling physicians how to practice medicine. Incredibly, while the FDA and states have imposed legal liability for prescribing generic drugs off-label, Big Pharma companies have been indemnified by the federal government, effectively eliminating their legal liability, for patented treatments and/or vaccines.

Due to the media driven hysteria around these generic drugs which resulted in restrictions, we also use ivermectin in place of hydroxychloroquine

which has also provided outstanding results in the combination therapy. Ivermectin is also a generic drug, safe and inexpensive.

Conclusion

Significant funds must be allocated immediately to research and develop generic medicines under Real World Evidence standard without the influence of the pharmaceutical industry. Research and development of medicine is now a matter of national security. There must be an organization that functions as an intelligence agency for medicine whose exclusive duty is to the people, not shareholders – building on this solution. Significant funds must be allocated to implement this - a gap which can be filled by an organization funded by Homeland Security similar to how the TSA was created in response to 9/11. COVID-19 must be swiftly ended and a situation like this must never happen again.

Without this, the people are reliant on an incentive model that is leading to a mortality count that may be greater than the civil war - historically the most deadly war for the USA. Enemies of the USA are standing by observing how a virus has destabilized the wealthiest nation on the planet.

There is a cure for COVID-19 as well as effective prevention options. The Zelenko Protocol could have saved over 200,000 lives. Implement it immediately for early outpatient use.

Key Points from the Senate Hearing on COVID-19 Outpatient Treatment and Follow up correspondence

Ashish Jha MD stated that he has not treated any COVID-19 patients. Dr. Jha stated several times during the hearing that Hydroxychloroquine does not work to treat COVID-19. Dr. Jha did not mention the combination therapy of Hydroxychloroquine, Zinc and Antibiotic. He also never mentioned Ivermectin. Dr. Jha wrote an opinion piece in the New York Times following the hearing and accused the other witnesses from Yale, Harvard and Baylor as snake oil salesmen.

George Fareed MD (Harvard), Harvey Risch MD, PhD (Yale) and Peter McCullough MD (Baylor) all fully endorsed the combination therapy in the outpatient setting, combining to have treated over 1,000 patients.

George Fareed MD stated that he is seeing a 100% success rate with the combination therapy if it is administered early enough – consistent with my findings as well as Dr. Raoult's findings.

U.S. Senator Ron Johnson, Chairman of the Senate Committee on Homeland Security stated that we should be pouring billions of USD into outpatient

treatment as there are currently no official government approved options for outpatient treatment. Senator Johnson further stated that the risk reward ratio is dramatically in favor of the combination therapy and he used a combination of Zinc and the Zinc ionophore Quercetin to treat his COVID-19 infection. “We can’t wait for the vaccine, we have to take action now.”