

COVID Scandal: Feds Ignored 2016 Law Requiring Use of Real World Evidence

Exclusive: Joel S. Hirschhorn cites hypocrisy of Fauci et al. for spurning HCQ and ivermectin

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Here is the scandal. In 2016 under the Obama administration, Congress with strong bipartisan support passed the [21st Century Cures Act](#). It required the Food and Drug Administration to use “Real World Evidence,” or RWE, for approval of drugs. During the Trump administration, this statute was not invoked by the White House task force under Dr. Fauci. But it should have been used early in the pandemic.

Starting a year ago, courageous front-line doctors generated RWE because they were curing COVID patients with protocols that kept patients out of hospitals. Real world data showed the effectiveness of cheap generics like hydroxychloroquine and ivermectin to cure and prevent COVID-19. Dr. Vladimir Zelenko used RWE language early on and this February, in light of over 2 million COVID deaths globally, [noted](#): “The problem is that the medical world and governments ignored REAL WORLD EVIDENCE.”

Other physicians and the organizations leading the cause did not invoke RWE, namely America’s Frontline Doctors, the Association of American Physicians and Surgeons, and the Front Line COVID-19 Critical Care Alliance. Nor have conservative and liberal media informed the public about the legal mandate to use RWE.

In my recent book, [“Pandemic Blunder,”](#) I used RWE to conclude that 70 to 80% of COVID deaths could have – and still can be – prevented by using the cheap and effective protocols.

This, too, was noted: “In a December 2016 article in the [New England Journal of Medicine](#) titled ‘Real World Evidence – What Is It and What Can It Tell Us?’ all twelve authors were from the FDA. A big point was that RWE would come from clinical care and home or community settings as opposed to research-intensive or academic environments. ... In order to assess patient outcomes and to ensure that patients get treatment that is right for them, real-world data needs to be utilized.” Perfectly applicable for supporting use of hydroxychloroquine and ivermectin protocols.

Outrageously, despite huge numbers of hospitalizations and deaths, the government did not use RWE to support use of documented protocols for early home/outpatient COVID

treatment and prophylactic use.

Just the opposite, in fact. NIH and FDA created blocks to wide use of these protocols. The emphasis was on contagion controls, like masking and shutdowns, and expensive medicines for hospitalized patients and vaccines.

The ubiquitous Fauci in endless media appearances never invoked the 2016 law and RWE. He ignored it. Worse, he often dismissed observational studies using clinical data. But the European Medicines Agency [concluded](#): “Real-world evidence generated by observational studies is fundamental to understanding the benefits and risks of medicines when used in clinical practice for the prevention and treatment of COVID-19.”

[Joy Pullmann](#) got it exactly right: “What Fauci does is not science. It is public manipulation in the name of science. His entire professional history has not been one of testing observable phenomena and accurately reporting the results. It has been in wearing a lab coat while playing politics.”

To be clear, there is no conflict between following the science and using RWE. Public confidence in the “follow the science” mantra has surely fallen because “experts” and politicians have only followed selected data and ignored a whole lot more.

RWE is so important because formal, expensive randomized clinical trials do not fully account for the entire patient population of a particular disease. FDA [said](#): “RWE can be generated by different study designs or analyses, including but not limited to, randomized trials, including large simple trials, pragmatic trials, and observational studies (prospective and/or retrospective).” All the latter supported use of hydroxychloroquine and ivermectin.

“The FDA is approaching the generation of real-world evidence for Covid-19 with a sense of urgency to learn what we can, as soon as we can, from patients who are receiving care right now,” [said](#) a senior FDA official in early 2020. But not for early treatment protocols.

The Department of Health and Human Services [emphasized](#) that “the Cures Act places focus on the use of real-world data to support regulatory decision-making, including the approval of new indications for existing drugs.” And RWE “is a key priority for the Department of Health and Human Services (HHS).” Another broken promise.

Hydroxychloroquine and ivermectin had many decades of wide, safe use for a variety of illnesses and under the law deserved approval early in the pandemic for COVID treatment. But it did not happen.

Now, we see pandemic hypocrisy because articles are appearing promoting use of COVID vaccines by invoking RWE.

Days ago, this was a [headline](#): “Real-World Evidence Confirms Efficiency of mRNA COVID-19 Vaccines.” The article notes, “A CDC study used real-world evidence to find that both Pfizer and Moderna’s COVID-19 vaccines reduced risk of infection 90% two or more weeks after the second dose.”

Every time you see data on COVID deaths remember that most could have been prevented if the government had honored the statutory mandate to use RWE. Following the science legally means using RWE.

Now, some “experts” are calling for more shutdowns, mask mandates and school closing. Congress should hold a hearing and put Fauci and other officials on the spot. How can they justify not obeying the 2016 law? How can they ignore all the RWE for protocols proven to cure COVID patients when given early to them?

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