Why You Can’t Trust What the FDA Says About Ivermectin

By Julius Dahne | Covid-19 Up

Most people in the United States have not heard of ivermectin even though it’s been around for more than 30 years and is one of the most distributed drugs on Earth, with more than 2.5 billion doses given out globally over the last 30 years.

Many Americans first started to learn about ivermectin in December 2020 when Dr. Pierre Kory testified in front of the Homeland Security Committee and gave an impassioned testimony about the medicine as a treatment for COVID-19, but the backlash against his position soon arrived.

On March 5, the FDA published a statement online entitled Why You Should Not Use Ivermectin to Treat or Prevent COVID-19.
You may think that the statement would discuss the FDA’s research on the effectiveness and safety of ivermectin, a cheap generic drug whose patent expired in 1996, but instead, their statement was a masterful sleight of hand, as it does not say what most people think it says.

Why Is the FDA Attacking a Safe, Effective Drug? – WSJ

“The Food and Drug Administration claims to follow the science. So why is it attacking ivermectin, a medication it certified in 1996?” https://t.co/8uyMCJRN4k

— David Thunder (@davidjthunder) August 3, 2021

As it turns out, the FDA did no research to investigate ivermectin’s effectiveness, as we will discover.

Many news organizations have parroted the FDA’s statements. For example, a CBS Evening News report broadcast on July 1, called ivermectin a “horse gel,” as reporter David Begnaud stared into the camera and said, “a lot of humans have tried it, and they’ve ended up in the hospital.”

What are the facts? The remarkable thing is that in the FDA’s short statement, the agency included one outright lie, one very interesting act of misdirection, and one very surprising admission—none of which, to my knowledge, has been discussed in the mainstream media so far.

Let’s just call them:

THE THREE MYTHS OF IVERMECTIN

Myth #1) Ivermectin is not an anti-viral, it’s just a horse de-wormer.

Myth #2) Many people are getting sick from using ivermectin when they are trying to use it for COVID-19.
Myth #3) The FDA has researched the effectiveness of ivermectin against COVID-19.

Let’s unpack these myths.

**Myth #1) Ivermectin is not an antiviral, It’s just a horse de-wormer.**

The FDA states in their warning, “Ivermectin is not an antiviral (a drug for treating viruses.)” But ivermectin is a potent antiviral. (By the way, no one besides the FDA uses a hyphen in the middle of the word “antiviral.”)

As recorded in the June 2020 issue of the journal *Antiviral Research*, a single treatment of ivermectin was able to cause a 5,000-fold reduction of SARS-CoV-2 in cell culture within 48 hours. This news was widely reported in the press, everywhere from *The Guardian* in Great Britain to Medscape.com, a top medical news website. So how did the FDA miss it? It seems they weren’t looking very hard.

Beyond COVID-19, ivermectin has been shown to be an antiviral agent against at least 18 other viruses. As reported in 2020 in the journal *Cells*, “cell culture experiments show (ivermectin exhibits) robust antiviral action towards HIV-1, dengue virus (DENV), Zika virus, West Nile virus, Venezuelan equine encephalitis virus, Chikungunya virus, Pseudorabies virus, adenovirus, and SARS-COV-2 (COVID-19.)”

Not only can we point to medical journals to make the case that ivermectin is an antiviral, we can also use the FDA’s own documents. You see, this author filed a Freedom of Information Act (FOIA) request on July 19 to see the documents that the FDA used to make their recommendation to not use ivermectin.

The FOIA memorandum I received states, “Ivermectin has known in vitro antiviral properties, and was initially described in the context of COVID-19 in April 2020. On April 3, 2020, Caly
et al. published in vitro data that demonstrated ivermectin inhibiting SARS-CoV-2 viral replication.”

Thanks, FDA, for admitting you told a whopper of an untruth.

On this point, we can also look to a research paper published June 17 on the website of The Lancet, one of the world’s most respected medical journals, Antiviral effect of high-dose ivermectin in adults with COVID-19: A proof-of-concept randomized trial. The study concluded that higher doses of ivermectin did reduce viral activity at higher rates. In other words, it’s an antiviral—against COVID-19.

To be fair, it is not used widely as an antiviral medication, except where it is being used around the world right now against COVID-19.

How does it work in connection with coronavirus? Without getting too technical, it binds with the viral RdRP, which are enzymes needed to help the virus reproduce itself, and it disrupts this RdRP. In other words, it stops the virus from making copies of itself.

And there are about 60 other studies that show ivermectin works well against the virus of COVID-19 which can be found at C19ivermectin.com.

Let’s move on.

**Myth #2) Many people are getting sick**
from using ivermectin when they are trying to use it for COVID.

The main argument that the FDA makes in their statement is that people are getting sick from using ivermectin. They focus on the fact that there is a version of ivermectin that is meant for animals.

They say, “The FDA has received multiple reports of patients who have required medical support and been hospitalized after self-medicating with ivermectin intended for horses.” They have a sub-headline that reads “Ivermectin Products for Animals Are Different from Ivermectin Products for People.”

Yes, veterinary drugs are different from human drugs.

Yes, it could be dangerous to ingest veterinary drugs as they may have ingredients not safe for human use as well as vastly different potencies.

And yes, ivermectin is also used as a horse dewormer.

Did you know that Viagra was originally developed for heart issues? Did you know that remdesivir, the drug touted by Dr. Anthony Fauci for COVID-19, was originally developed for hepatitis?

Oddly, while there are many headlines mocking the use of ivermectin as an “animal dewormer” there are no headlines mocking remdesivir as a hepatitis drug.

What about the ivermectin that is FDA-approved? Is anybody getting sick taking that? The FDA is strangely silent on this point.

Their main headline is Why You Should Not Use Ivermectin to Treat or Prevent COVID-19, but really their headline should read Why You Should Not Use Animal Ivermectin to Treat or Prevent COVID-19. They don’t bring any evidence at all that
anyone has been injured by using the FDA-approved version to treat COVID-19.

So that’s misdirection. In the many months that I have been intently following this story, I cannot remember reading about or seeing a single doctor recommending animal ivermectin for human consumption. But there are many doctors, such as the doctors in the Front Line COVID-19 Critical Care Alliance, who are recommending the off-label use of FDA-approved ivermectin for patients because they have seen it work, both in reducing hospitalizations and deaths significantly, especially when it is used early.

Safety of Ivermectin

Is ivermectin safe for humans to use? You might get the feeling, reading the FDA statement, that it is quite dangerous. That was certainly the impression that CBS News wanted to leave their viewers with when they reported that “a lot of humans have tried it, and they’ve wound up in the hospital.” That was also clearly the impression that ScienceAlert.com wanted to share when they ran the story: People Are Accidentally Poisoning Themselves Trying to Treat COVID With a Horse Drug.

You may be surprised to learn that 300 million people use ivermectin every year, mostly in Africa and Latin America, because it very effectively fights river blindness. It is distributed for free by non-profit organizations such as the Carter Center and even the US government organization USAID. It is donated by the pharmaceutical company Merck. To put that number of 300 million in perspective, that’s about equal to the populations of England, France, Germany, and Australia put together.

The Nobel-prize-winning scientist (he won his prize for developing ivermectin) Satoshi Omura reports that the rate of Serious Adverse Events for ivermectin is one per million
doses. It is an extremely safe medicine. However, like any drug, there exists the potential for drug interactions. In addition, it should not be taken by people with an impaired blood-brain barrier, pregnant women, and women who have just given birth. There is limited evidence on its safety for children under age 5 and for those who weigh less than 15 kg or 33 pounds.

Who else is on record saying that ivermectin is safe?

How about the New York Times? In June 2019, the New York Times ran an article about ivermectin saying, “the drug is considered safe enough to give to almost everyone except the youngest infants and pregnant women.”

Or how about the National Capitol Poison Center, which has upon its website at Poison.org: “To date, ivermectin has been shown to be a safe and well-tolerated drug.”

In fact, what about the World Health Organization? While they have been funding laudable programs globally to distribute ivermectin to fight river blindness, they funded public relations materials such as this poster, which states, “Mectizan Is For Everybody.”

What is Mectizan? It’s simply a trading name for ivermectin. The World Health Organization was on board with the safety of ivermectin, at least until it was recommended for COVID-19.

Here’s a close-up of the bottom of this poster:
What about the poisonings that the FDA say are happening? Didn’t the FDA say there were “multiple reports of patients who have required medical support and been hospitalized after self-medicating with ivermectin intended for horses”?

My FOIA documents from the FDA say that “evidence that people are misusing ivermectin products for prevention and treatment of COVID-19 has emerged. This may be in part due to the ease of procurement (e.g. via Amazon or pet stores) and availability of veterinary topical ivermectin products to the general public.” Again, we are talking about veterinary ivermectin, not that which is FDA-approved for human use.

The FDA’s Department of Pharmacovigilance retrieved 400 cases of exposure to ivermectin products. Of these, 92 were labeled “intentional,” and the rest were presumably accidents. Of these 92 there were only five in the category of deaths and “major effects.” Among these were one death and four outcomes labeled “major effect.” However, two of these were related to psychiatric medical problems (for example, a suspected suicide attempt).

When you take out the cases of people with psychiatric problems, you are left with three people with either death or what the FDA terms a “major effect.”

The FDA also reported that there were four other cases of intentional misuse related to using ivermectin for COVID-19 that led to what the FDA classifies as a “moderate or potentially toxic effect.”

So that’s seven cases altogether.

For some reason, in this new FOIA document dump, only six of these are described in depth. Four out of the six were people ingesting animal ivermectin, which to the best of my knowledge is not recommended by any doctors promoting the use of ivermectin for COVID-19.
That leaves only two cases described involving human FDA-approved ivermectin. One is the case of a person feeling light-headed, which soon resolved. And finally, we have a case of an 80-year-old man who experienced a racing heart rate, but he was also taking oxycodone, an opiate drug, along with ivermectin. His high heart rate may have been caused by oxycodone. He was released from the hospital after two days of treatment.

So as far as can be seen in these FOIA documents, there are no known cases of people taking FDA-approved ivermectin for COVID-19 and suffering severe and lasting ill effects. None.

That’s a slim basis to tell people not to take ivermectin that they could get a prescription for. Especially when many meta-analyses now show that it would dramatically reduce deaths from COVID-19.

**Myth #3) The FDA has researched the effectiveness of ivermectin against COVID.**

This is the easiest one to prove, as the FDA states it outright in their statement, although it’s not clear anyone was really paying attention.

To quote the FDA, “The FDA has not reviewed data to support the use of ivermectin in COVID-19 patients to treat or prevent COVID-19. However, some initial research is underway.” What?

Let me repeat that one more time, a little slower.

“The FDA has …. not…. reviewed… data….to support use of ivermectin in COVID-19 patients to treat or prevent COVID-19.”
So, just to get this straight, there have been more than 100 trials involving ivermectin, including 60 peer-reviewed studies. Those studies have involved almost 600 scientists and nearly 25,000 patients. Pooling studies together, it is estimated that ivermectin reduces the risk of death by 66%. And yet by March 2021, the FDA, with its nearly 15,000 employees and a budget exceeding $3 billion, couldn’t be bothered to review the data to support the use of ivermectin, a drug that has been used against COVID-19 in more than 30 countries around the world.

On their website, the FDA states, “FDA is responsible for advancing the public health by helping to speed innovations that make medical products more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medical products and foods to maintain and improve their health.”

“Speed innovations?” It is now August 2021, five months after this statement, and still there is no word from the FDA on whether they have deigned to “review the data” on ivermectin.

The FDA Gets Their Money for Drug Oversight …. From the Drug Companies
Oh, never mind. I think it’s clear that even if the FDA ever decides to “review the data” on ivermectin, they will be doing so from a position of bias against this very safe drug.

Maybe it has something to do with the fact that many of the people who work for the FDA go on to work for big pharmaceutical companies, so maybe it’s not best to promote cheap generic drugs at the FDA.

Or maybe it has to do with the little-known and surprising fact that most of the funding of the FDA’s drug oversight programs comes directly from the drug companies themselves, not taxpayer dollars. In 2015, only 29% of the money for prescription drug oversight came from Congress. The
remaining 71%, almost three-quarters of the funding, came directly from the drug manufacturers. In 2015, that was $796 million straight from Big Pharma to the FDA, under the Prescription Drug User Fee Act (PDUFA).

In the opinion of the nonprofit group the Project on Government Oversight, the “FDA is addicted to drug money.”

And that money comes with strings attached. Every five years, the FDA sits in meetings with drug manufacturers to negotiate a new agreement over how these PDUFA funds are to be used, and often the agreements tie the FDA’s hands. For example, from 1992 to 2002, these PDUFA funds could NOT be used for “postmarketing safety surveillance.”

In other words, these funds could not be used to make sure that the drugs were approved were safe for use. In the next five-year authorization, “a small amount of fee revenues (about 5%) was permitted to be used for post-marketing drug safety activities; however, restrictions on when these funds could be spent (only for drugs approved after 2002, and for up to 2 years after approval, or up to 3 years for “potentially serious drugs”) limited their effectiveness,” according to a report published by the National Academy of Sciences.

In addition to explicitly restricting the FDA from investigating drug safety, the PDUFA negotiations focus on speed. The drug companies want drugs approved as fast as possible, and they negotiate with the FDA for quick target dates for agency action.

In an investigation by the non-partisan non-profit group Project on Government Oversight (POGO), we see that those fast deadlines may have deadly effects.

Former FDA drug reviewer Ron Kavanagh told POGO that, when he was at the agency from 1998 to 2008, PDUFA’s target dates for FDA action left too little time to review drug company submissions, which could total 160,000 pages not counting
supporting data. Reviewers were told not to worry about studying all of the material, Kavanagh said.

“There’s a lot of things I simply didn’t look at,” Kavanagh said. “And even without looking at things I barely made the deadlines.”

Kavanagh shared an internal FDA email from 2007 in which he gave this account: ‘I finally had to stand up and say that I would take being written up for insubordination and would risk a poor performance evaluation, but that I would not curtail my evaluation of a potential safety concern simply to meet a PDUFA goal date.’

He was later fired.

FDA safety official David Graham told a Senate hearing in 2004 that the FDA “views the pharmaceutical industry it is supposed to regulate as its client. It overvalues the benefits of the drugs it approves, and it seriously undervalues, disregards and disrespects drug safety.” Dr. Graham fought to raise an alarm about the arthritis drug Vioxx, which was causing heart attacks within two weeks of its first use. Ultimately, observers believe Vioxx led to the deaths of a minimum of 40,000 people.

And the problem has existed for decades before that. In 1977, a governmental panel reported, “Many current and former FDA employees and consultants had testified to Congressional committees that industry pressure caused FDA officials to approve drugs that did not meet agency safety and effectiveness standards and that those who attempted to oppose industry demands were harshly and improperly treated by senior FDA officials.”

And that circles back to what is perhaps the real reason why ivermectin is suppressed: the Emergency Use Authorization (EUA).
As you may know, the COVID-19 vaccines are not FDA-approved. The only way they can be legally used in the United States today is through a legal “work-around” called the Emergency Use Authorization. The idea being that in a real emergency we need medications that work right away. There must be an “emergency” to justify the Emergency Use Authorization. The way the law works is that “FDA may allow the use of unapproved medical products... when certain statutory criteria have been met, including that there are no adequate, approved, and available alternatives.”

So as the law stands now, if there were “adequate, approved and available alternatives” to a vaccine, the EUA for the vaccine would be invalid. And if the EUA was invalidated, there would be no legal permission to distribute the COVID-19 vaccines. And the billions of dollars of vaccine profits would cease flowing for Pfizer, Johnson & Johnson, etc.

Perhaps that’s the reason, or at least part of the reason, why the FDA has consistently refused to look seriously at any early treatment options.

Maybe that’s why their 14,000 employees haven’t had the time to examine a cheap little generic drug that nobody is going to make billions off of.

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