

Doctor Reveals Remdesivir Is Real Cause Of COVID-19 Maladies

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Dr. Bryan Ardis makes an astounding revelation. He states that Dr. Fauci pushed the use of Veklury® (remdesivir) as a treatment for COVID-19 knowing that it would be unsafe and ineffective for patients.

Veklury® (remdesivir) is a nucleotide analogue RNA polymerase inhibitor. Dr. Ardis reveals that the symptoms of lungs filling with fluid and the other alleged COVID-19 symptoms were actually side effects of kidney poisoning and other organ damage that are known side-effects of Veklury® (remdesivir). Dr. Ardis alleges that the devastating health toll allegedly caused by COVID-19 was actually caused by the NIH recommended treatment of Veklury® (remdesivir).

Dr. Bryan states that the NIH even cited two studies on its website that showed that Veklury® (remdesivir) was ineffective and unsafe to patients. It seems that many doctors just blindly followed the recommendation of the NIH to use Veklury® (remdesivir) without actually reading the cited studies. I tracked down those studies and read them.

NIH Recommends Remdesivir

On May 12, 2020, the NIH recommended the use of Veklury® (remdesivir) for severe cases of COVID-19. At that time, Veklury® (remdesivir) was an unapproved experimental drug made by Gilead Sciences. It was authorized by the FDA for emergency use treatment of COVID-19.

Conflicts Of Interest

In my research I discovered something quite disturbing. The recommendation from the NIH to use Veklury® (remdesivir) to treat COVID-19 came from the *NIH Panel on COVID-19 Treatment Guidelines*. There were nine (9) people on the NIH Panel on COVID-19 Treatment Guidelines with financial ties to Gilead Sciences, the maker of Veklury® (remdesivir).

The following is a list of those people on the *NIH Panel on COVID-19 Treatment Guidelines* who had financial ties to Gilead Sciences, the manufacturer of Veklury® (remdesivir):

Rajesh Gandhi is on the advisory board of Gilead Sciences.

David Glidden is a consultant for Gilead Sciences.

Adaora Adimora is a consultant for Gilead Sciences and received research support from Gilead Sciences.

Eric Daar is a consultant for Gilead Sciences and receives research support from Gilead Sciences.

Judith Aberg received research support from Gilead Sciences.

Jason Baker received research support from Gilead Sciences.

Susanna Naggie received research support from Gilead Sciences.

Pablo Tebas received research support from Gilead Sciences.

Roger Bedimo received an honoraria from Gilead Sciences.

Steering Doctors Away From Hydroxychloroquine

The panel tried to steer doctors away from Hydroxychloroquine, by stating that “[t]here are insufficient clinical data to recommend either for or against using chloroquine or hydroxychloroquine for the treatment of COVID.”

The panel, of course, had an interest in undermining inexpensive and effective treatments: “[T]he Panel recommends against the use of the following drugs for the treatment of COVID-19: The combination of hydroxychloroquine plus azithromycin because of the potential for toxicities.” That was not true. Indeed many subsequent studies have shown that the hydroxychloroquine plus azithromycin “combination is safe and may avoid worsening, virus persistence, and subsequent contagiousity.”

This author previous wrote an article explaining the extreme efforts taken to discredit hydroxychloroquine. Doctors conducting studies purposely administered toxic levels of hydroxychloroquine to falsely show that it was dangerous to patients.

Remdesivir Adverse Events

Many of the studies cited in support of NIH's recommendation to use Veklury® (remdesivir) were *in vitro* studies or animal studies. A couple of the human studies were at best a mixed bag. Two of the most authoritative studies showed Veklury® (remdesivir) to be ineffective and unsafe.

On or about May 12, 2020, the FDA reported the following summary for study GS-US-5773:

*In a randomized, open-label clinical trial (Study **GS-US-540-5773**) of remdesivir in 397 subjects with severe COVID-19 treated with remdesivir for 5 (n=200) or 10 days (n=197), adverse **events** were reported in 71 percent and 74 percent of subjects, respectively, serious adverse **events** were reported in 21 percent and 35 percent of subjects, respectively, and Grade=3 adverse **events** were reported in 31 percent and 43 percent of subjects, respectively. Nine (5 percent) subjects in the 5-day group and 20 (10 percent) subjects in the 10-day group discontinued treatment due to an adverse **event**. All cause mortality at Day 28 was 10 percent vs 13 percent in the 5- and 10-day treatment groups, respectively.*

Please do not miss the fact that there were reported **71 percent adverse events** in the 5-day study and **74 percent adverse events** in the 10-day study for patients taking Veklury® (remdesivir). **21 percent** suffered **serious adverse events** in the 5 day study and **35 percent** of the patients suffered **serious adverse events** in the 10-day study. Below is the chart of adverse events published in the study.

Table 3. Summary of Adverse Events According to Remdesivir Treatment Group. ^a		
Event or Abnormality	5-Day Group (N = 200)	10-Day Group (N = 197)
Any adverse event — no. of patients (%)	141 (70)	145 (74)
Nausea	20 (10)	17 (9)
Acute respiratory failure	12 (6)	21 (11)
Alanine aminotransferase increased	11 (6)	15 (8)
Constipation	13 (6)	13 (7)
Aspartate aminotransferase increased	10 (5)	13 (7)
Hypokalemia	10 (5)	12 (6)
Hypotension	9 (4)	12 (6)
Respiratory failure	7 (4)	14 (7)
Insomnia	10 (5)	11 (6)
Acute kidney injury	4 (2)	15 (8)
Adverse event leading to discontinuation of treatment — no. of patients (%)	9 (4)	20 (10)
Any serious adverse event	42 (21)	68 (35)
Acute respiratory failure	10 (5)	18 (9)
Respiratory failure	5 (2)	10 (5)
Septic shock	2 (1)	5 (3)
Acute respiratory distress syndrome	1 (<1)	5 (3)
Hypoxia	2 (1)	4 (2)
Respiratory distress	3 (2)	4 (2)
Dyspnea	4 (2)	1 (1)
Pneumothorax	2 (1)	3 (2)
Viral pneumonia	3 (2)	2 (1)
Aminotransferase levels increased	3 (2)	2 (1)
Any grade ≥3 laboratory abnormality — no. of patients/total no. (%)	53/195 (27)	64/191 (34)
Selected grade ≥3 laboratory abnormalities — no. of patients/total no. (%)		
Creatinine clearance decreased		
Grade 3	13/193 (7)	13/188 (7)
Grade 4	5/193 (3)	23/198 (12)
ALT elevation		
Grade 3	8/194 (4)	11/191 (6)
Grade 4	4/194 (2)	5/191 (3)
AST elevation		
Grade 3	11/194 (6)	7/190 (4)
Grade 4	3/194 (2)	4/190 (2)
Bilirubin increased		
Grade 3	1/193 (1)	3/190 (2)
Grade 4	0	1/190 (1)

^a Adverse events listed are those that occurred in at least 5% of patients in either treatment group, and serious adverse events listed are those that occurred in 5 or more patients.

Hiding Remdesivir Adverse Events

This is where it gets deceptive. In a later published fact sheet dated October 2020, the FDA provided the following summary of that same study:

*Study **GS-US-540-5773** was a randomized, open-label clinical trial in hospitalized adult subjects with severe COVID-19 treated with VEKLURY 200 mg on Day 1 and 100 mg once daily for 5 (n=200) or 10 days (n=197). Adverse **reactions** were reported in 33 (17 percent) subjects in the 5-day group and 40 (20 percent) subjects in the 10-day group. The most common adverse reactions occurring in at least 5 percent of subjects in either the VEKLURY 5-day or 10-day group, respectively, were nausea (5 percent vs 3 percent), AST increased (3 percent vs 6 percent), and ALT increased (2 percent vs 7 percent). Rates of any adverse **reaction**, serious adverse reactions, and adverse **reactions** leading to treatment discontinuation are presented in Table 6. [Chart 6 indicated that 3 percent of the 5 day group and 5 percent of the 10 day group had treatment discontinued due to adverse **reactions**.]*

Notice the differences in reporting. The May 2020 report describes **adverse events**, whereas the October 2020 report changes the reporting to **adverse reactions**.

The difference is that an adverse reaction denotes a causal relationship and an adverse event is an event that may or may not be causally related.

A reaction is sometimes defined as the response to a medication where that response is at least reasonably possible to have been caused by the medication.

By concealing the adverse events and only reporting adverse reactions, the October 2020 FDA report conceals the real danger from Veklury® (remdesivir). Keep in mind that an adverse reaction must be established by a reasonable possibility. Such nebulous standards for distinguishing adverse events from adverse reactions are ripe for abuse. An adverse event could be causally related but the reviewer may just decide it is not reasonable to infer it is causally linked, and thus it would not be called an adverse reaction.

May 2020 FDA Publication: “397 subjects with severe COVID-19 treated with remdesivir for 5 (n=200) or 10 days (n=197), adverse **events** were reported in **71 percent and 74 percent** of subjects”

October 2020 FDA Publication: “Adverse **reactions** were reported in **33 (17 percent) subjects in the 5-day group and 40 (20 percent) subjects in the 10-day group.**”

May 2020 FDA Publication: **Nine (5 percent) subjects in the 5-day group and 20 (10 percent) subjects in the 10-day group discontinued treatment due to an adverse event.**

October 2020 FDA Publication: **3 percent of the 5 day group and 5 percent of the 10 day group discontinued treatment due to an adverse reaction.**

May 2020 FDA Publication: **Serious adverse **events** were reported in 21 percent and 35 percent of subjects, [in the 5 day and 10 day groups] respectively.**

October 2020 FDA Publication: **Serious adverse **reactions** were reported in 2 percent and 2 percent of subjects in the 5 day and 10 groups respectively.**

This is where the deception becomes obvious. The study did not measure adverse **reactions**! The study protocols for GS-US-540-5773 published by Gilead states that they were only going to measure adverse **events**. There is no mention of any plan to measure adverse **reactions**.

Indeed, when one read the data from the Gilead study (GS-US-540-5773) itself there is only a recording of adverse **events**. There is no measure or memorialization of adverse **reactions**. So, the question is, if Gilead did not plan to measure adverse **reactions** and there is no record of such measures, where did the adverse **reaction** figures come from?

Majority Of Patients On Remdesivir Suffer Liver Damage

Amazingly, in the May 2020 FDA publication indicated that a majority of the participants in the several remdesivir studies conducted have suffered liver damage.

Transaminase elevations have been observed in the remdesivir clinical development program, including in healthy volunteers and patients with COVID19. In healthy volunteers who received up to 150 mg daily for 14 days, **alanine aminotransferase (ALT) elevations were observed in the majority of patients**, including elevations to up to 10 times baseline values in one subject without evidence of clinical hepatitis.

The FDA report stated that in the GS-US-540-5773 study 5 percent of the patients suffered moderate to severe liver damage. Whereas, 2 percent of the study patients suffered severe liver damage.

Kidney Damage From Remdesivir Is Foreseeable

Another foreseeable side effect of Veklury® (remdesivir) is kidney damage. The FDA publication reveals that “[i]ntravenous administration (slow bolus) of remdesivir to rats at dosage levels of =3 mg/kg/day for up to 4 weeks resulted in findings indicative of **kidney injury and/or dysfunction.**”

Invasive Mechanical Ventilation Required

In another later published study (ACTT-1, NCT04280705) reported in the October 10, 2010 FDA emergency use authorization that alleged to show the benefits of Veklury® (remdesivir), 27 percent of the patients taking Veklury® (remdesivir) “were on invasive mechanical ventilation.” There was no control group in that study. It seems that the ventilation was the result of Veklury® (remdesivir) because the study revealed that “[s]ubjects on mechanical ventilation at screening were excluded” from the study.

Early Study Termination Due To Adverse Events

In another human study conducted in China, 12 percent of the Veklury® (remdesivir) group participants had to discontinue therapy with Veklury® (remdesivir) due to adverse side effects. That compared to 5 percent in the control group.

Keep in mind that the control group in the Chinese study was not truly a placebo group and the Veklury® (remdesivir) group was not truly a Veklury® (remdesivir) group. Both the control group and the Veklury® (remdesivir) group received corticosteroids, lopinavir/ritonavir, and interferon alfa-2b. The study was terminated early without any conclusions. The NIH admitted that “[t]he use of concomitant medications (corticosteroids, lopinavir/ritonavir, interferon) may have obscured the effects of remdesivir.”

Another human study cited **did not have a control group**, and the NIH, therefore, admitted that “*it is not possible to assess whether the use of remdesivir led to the improvement.*”

Remdesivir Proven Ineffective In Ebola Study

There was only one other human study cited, and the results were devastating for the patients in that study who were administered Veklury® (remdesivir). In that study, Veklury® (remdesivir) was compared to three other treatments for Ebola. The control group was not actually a placebo group. The group was administered a medicine identified as ZMapp (a triple monoclonal antibody agent).

There was something strange about the trial. In another trial study 22% of the study patients died within 28 days using ZMapp on patients with Ebola. But in the comparative study with Veklury® (remdesivir) the mortality rate for the control group using ZMapp shot up to 49.7% during the 28 day study.

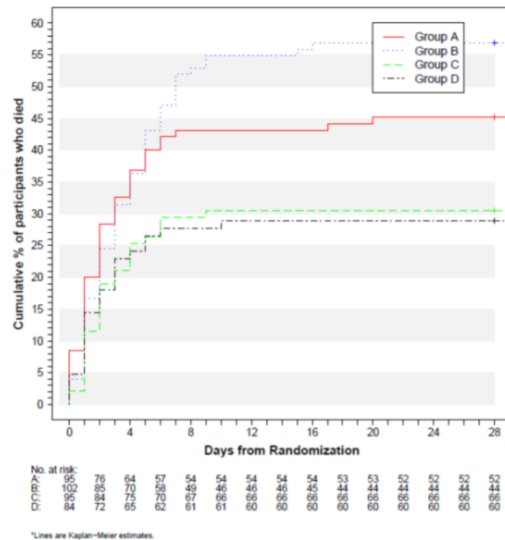
The study administrators could only guess as to why their study patients were dropping like flies. They said: “The reason that mortality among patients who received ZMapp was 22% in the PREVAIL II trial (conducted during the outbreak in West Africa) and 50% in our trial (conducted during the current outbreak in the DRC) is unclear.”

One thing that was clear was that the significantly higher mortality for ZMapp brought the control group closer to the 53.1% mortality rate of the Veklury® (remdesivir) group with the effect that Veklury® (remdesivir) was shown to be merely less effective rather than extremely deleterious. That higher mortality of 49.7% for ZMapp also had the effect of showing that the other two treatment modalities were effective as compared to the control.

In any event, as the chart published in the study below reveals, Veklury® (remdesivir) had the highest mortality of any of the treatment modalities with 53.1 percent of the Ebola patients who were administered Veklury® (remdesivir) dying within 28 days.

S4. Plot of Kaplan-Meier curves for ZMapp, MAb114, REGN-EB3 and remdesivir from Aug 9, 2019 DSMB meeting.

Group A=ZMapp
Group B=remdesivir
Group C=MAb114
Group D=REGN-EB3



Yet, with those studies showing the Veklury® (remdesivir) is unsafe and ineffective, the NIH recommended Veklury® (remdesivir) as the treatment for COVID-19. The results were foreseeable. Its use to treat patients with COVID-19 were predictably ineffective and unsafe.

See more here: jamesfetzer.org

Header image: Greg Nash / Getty Images

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