The FDA
COVID-19 Drug Approval Process

Remdesivir *vs* Ivermectin

How Greed and Negligence Likely Killed 600,000+ Americans

9-2-21 (revision 4-16-23)

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Note 1: *All of this Report's Table of Contents sections above, are clickable links.*
In the Report, all of the underlined blue text are all also clickable links.

Note 2: *To quickly return to where you were reading, when clicking on a link, hold down the* ***Command/Control Key.*** *This will open the link on a separate page (behind this document).*
When done reading the link, put that document away, and you will still be where you left off here...

Note 3: *Physicist John Droz, jr is the author of this report. Email him with any questions.*

Cover graphic credit.

Important: This Report is a living document as several of its components are moving parts. For example the number (and results) of Remdesivir, Ivermectin and Vitamin D studies changes every few days. As time permits, these numerous references (esp. on pages 4, 6, 8, 11, 12, & 13) will be updated. In the meantime, the data totals and percentages cited herein are a snapshot view as of the report date.

Chapter 1: Introduction

The COVID-19 situation has made citizens much more aware of the Medical Establishment's control of our health decisions. (*The Medical Establishment is the WHO, FDA, CDC, AMA, etc.*)

One interesting aspect of this bureaucracy, is how the FDA gives its approval (e.g., on a vaccine, a pharmaceutical, etc.). This report is focused on the area of possible COVID-19 **drug therapies**, and specifically compares the Science behind the FDA's handling of Remdesivir and Ivermectin**.**

When we say COVID-19 drug "therapies" we mean what pharmaceutical does the FDA recommend that a patient just diagnosed with COVID-19 should immediately start taking, to minimize the likelihood of them getting sick enough to have to be hospitalized — which might also lead to death. A therapy successful at preventing hospitalization would be called **effective**.

This 2020 NIH Study compared Remdesivir and Ivermectin. The study concluded that they have a lot of similarities, and that both are repurposed drugs that have good promise as COVID-19 therapies. That said, Ivermectin has **not** been given the FDA's approval as an effective treatment of COVID-19, whereas the FDA **has** given its approval to Remdesivir.

So advocates of Ivermectin (and other drug therapies) who aspire to get FDA approval, should make sure that their treatment meets or exceeds the standards set by Remdesivir.

One would think that would mean that: **a)** there were many scientific studies supporting Remdesivir, *plus* **b)** the conclusions in multiple Remdesivir studies strongly endorsed it as being a very effective therapy — from early COVID-19 infection on. *But is that the case?*

Before we get into that, we need to understand the FDA Approval Process for Drugs. This infographic provides a helpful overview of this process.

The NIH is generally acknowledged as a premier source for applicable scientific studies that are used in the FDA approval process. Here is the key summary page for COVID-19: Antiviral Drugs That Are Approved or Under Evaluation for the Treatment of COVID-19.

(Note the title of that NIH page, and that Ivermectin is listed as an *antiviral*. Now compare that to an unscientific FDA claim here, where they say: "Ivermectin is not an antiviral!")

Note that nothing in this report should be misconstrued as giving medical advice. We recommend that for all medical issues that citizens consult with a licensed physician.

For all medical decisions patients should be well-educated — including getting information from different perspectives — so that with their physician they can make informed health decisions. This is essentially what is spelled out in the Nuremberg Code.

Chapter 2: Remdesivir and COVID-19

As a brief background, Remdesivir (patented by Gilead Sciences) is administered as an infusion, and requires "70 raw materials, reagents, and catalysts" to make, with approximately “twenty-five chemical steps." Some of the ingredients are extremely toxic, like trimethylsilyl cyanide.

Reportedly, the original end-to-end manufacturing process required 9 to 12 months to go from raw materials to finished product, but after restarting production in January 2020, Gilead was able to find ways to reduce the production time to six months. The complexity involved here explains why “the price could be $3,000 to $5,000 per treatment.”

That said, the question is: **what are the scientific studies that convinced the FDA that Remdesivir was an effective COVID-19 treatment that earned their official approval?**

Briefly, the NIH Remdesivir COVID-19 Clinical Data site *originally* said —

1 - There were five (5) identified studies that had the “greatest impact” on their decision:

- **a)** This study (541 patients received Remdesivir) concluded that “Remdesivir was superior to placebo in shortening the time to recovery in adults who were hospitalized with COVID-19…” This study indicated an effectiveness of only 27%.
- **b)** This study (158 patients received Remdesivir) concluded: “In this study of adult patients admitted to hospital for severe COVID-19, Remdesivir was **not** associated with statistically significant clinical benefits.”This study indicated an effectiveness of - 9%!
- **c)** This WHO study (2750 patients received Remdesivir) concluded: “Remdesivir, had little or no effect on hospitalized patients with COVID-19, as indicated by overall mortality, initiation of ventilation, and duration of hospital stay.” *NOTE: Studies “b” and “c” contradict study “a”, essentially negating it.* This study indicated an effectiveness of 5%.
- **d)** This study (584 patients received Remdesivir) concluded: “Among patients with moderate COVID-19, those randomized to a 10-day course of Remdesivir did **not** have a statistically significant difference in clinical status compared with standard care at 11 days after initiation of treatment. Patients randomized to a 5-day course of Remdesivir had a statistically significant difference in clinical status compared with standard care, but the difference was of uncertain clinical importance.” *NOTE: This study was overseen by a scientist who has received funding from the manufacturer of Remdesivir, Gilead Sciences.* This study had the most positive result: but only an effectiveness of 35%.
- **e)** This study (397 patients received Remdesivir) concluded: “At baseline, patients randomly assigned to the 10-day group had significantly **worse** clinical status than those assigned to the 5-day group… In patients with severe COVID-19 not requiring mechanical ventilation, our trial did **not** show a significant difference between a 5-day course and a 10-day course of Remdesivir. With no placebo control, however, the magnitude of benefit cannot be determined.” *NOTE 1: A clinical trial like this is not considered strong without a control group. NOTE 2: This study was funded by the manufacturer of Remdesivir.*

2 - Some conclusions from reviewing the five original NIH Remdesivir studies:

a) Not a single one of the five NIH listed studies addressed how effective Remdesivir was in *preventing* hospitalization and/or subsequent death — which is a reasonable definition of therapeutic effectiveness.

b) Additionally, as noted above, there was no agreement between these studies about Remdesivir having any beneficial effect even on more severely ill patients hospitalized with COVID-19. The **net** conclusion of these studies appears to be that Remdesivir has little benefit for severely ill patients hospitalized with COVID-19.

c) Only two out of the five "greatest impact" Remdesivir studies were double-blind.

d) None of the five "best" Remdesivir studies was identified as having been peer-reviewed.

e) Since Remdesivir is a patented drug, there is an advocate for its approval: the large (annual revenue $23± Billion) American pharmaceutical company Gilead Sciences. (Note that the FDA drug approval process shows that a drug "sponsor" is required.)

f) For some reason the NIH list does **not** include several other, equally **unimpressive**, studies. For example, this superb collection identifies forty-seven (47) Remdesivir late-treatment studies. [For instance, this study of 6000± veterans — which resulted in **longer** hospital stays.] Comparing all studies (pooled effects, all stages), Remdesivir rates as the **near the bottom as an effective therapy (out of dozens of alternatives)**.

g) It's unfortunate that the FDA did not include in any of their Remdesivir studies (or subsequently), some that warned about serious safety matters (e.g., here and here).

h) This is latest revision of the NIH Remdesivir list of studies is (where they have added two additional studies since 2/22/21)! It would seem (considering that we are in a pandemic) that the FDA would be *continuously* updating this list, to make absolute sure that its recommendations reflect the latest scientific research. *August material is not consistent with that view.*

3 - Despite the lack of scientific evidence of benefits, Remdesivir is a **fully approved** FDA drug for the late treatment of COVID-19. See here. *How can this be, when its **effectiveness** is only about 11%? [Note Paxlovid and molnupiravir are EUA approved, not fully.]*

4 - Despite "approving" Remdesivir, the NIH "Hospitalized Adult Patients Treatment Plan" recommends a LOT more than Remdesivir for COVID-19 treatment.

Note: Remdesivir is administered as an *infusion* (not an injection). An infusion is a drug being given in an IV line, and it could take one to two hours for the process to be completed. Also, it appears that essentially all Remdesivir infusions are in a hospital setting.

Chapter 3: Ivermectin and COVID-19

Ivermectin's lineage was unearthed in Japan, by Dr. Satoshi Ōmura. Ivermectin has been categorized as one of the all time wonder drugs, on a par with aspirin! Ivermectin has proven to be so safe and effective, that the discoverer was given the 2015 Nobel Prize in Medicine.

However, when Dr. Ōmura subsequently spoke about the *possible* benefits of using Ivermectin for COVID-19, his video was censored by YouTube! Clearly their censors have more medical expertise than Dr. Ōmura, as he has only discovered almost 500 medical compounds.

Ivermectin was initially patented and then produced by Merck. The Merck Ivermectin patent expired in 1996, so there is no current patent holder. What that means is that there is no self-interested "sponsor" to shepherd Ivermectin through the FDA drug approval labyrinth.

Let's continue to the NIH/FDA analysis on Ivermectin regarding COVID-19:

1 - Briefly, the Ivermectin: Selected COVID-19 Clinical Data says that there were sixteen (16) studies that the FDA's panel said had the "greatest impact" on their decision to **not** approve Ivermectin. See Appendix C details on these limited FDA-found studies, particularly in light of the fact that Ninety-five (95) Ivermectin studies have now been published.

2 - Some observations after reviewing the *sixteen* Ivermectin studies, found by the FDA:

a) Not one of the sixteen NIH listed studies indicated any safety concerns with Ivermectin. (This is a sample pre-COVID-19 study (2018) about Ivermectin safety, plus a sample post-COVID-19 study (2021). See what *Medscape* lists about Remdesivir safety, compared to what they indicate about Ivermectin safety! To date there have been in excess of 3.7 Billion human doses of Ivermectin, and these have resulted in an enviable safety record.)

b) There are **seventeen** recent studies that showed that Ivermectin is a highly successful (83%) **preventer** of COVID-19. This is an inexpensive option, with minimal side-effects. However, no prophylaxis (preventative) studies are included in the NIH's sixteen "greatest impact" Ivermectin studies. (*Note: there are zero similar studies about Remdesivir*.)

c) There are **thirty-seven** studies that show that Ivermectin is a very successful (62%) **early treatment** for anyone diagnosed with COVID-19 — i.e., that it *prevents* hospitalization and worse. Of the NIH sixteen "greatest impact" Ivermectin studies, only six of these were about *preventing* hospitalization. (*There are no such studies about Remdesivir!*)

d) There are **thirty-seven** studies that concluded that Ivermectin is a moderately successful treatment for **hospitalized patients**. (Ten of these were in the NIH sixteen "greatest impact" studies list.) The Ivermectin success rate for such a situation is **39% — over three times as good as the "approved" drug Remdesivir's late treatment effectivity (11%)!**

e) For some reason this NIH list (dated 3-6-23) does **not** include over **THIRTY** other Ivermectin RCT studies. These are all publicly identified here, so why can't the NIH find them also? (See Appendix C for some details.)

f) One of the items on the "greatest impact" list is not a clinical study, since there was no control group (#20: see Appendix C). Additionally two others (#25 & #27: see Appendix C) are not scientifically strong, as they administered only one dose of Ivermectin — far below what is recommended. It's hard to understand how these three studies were considered better than forty-seven other non-cited Ivermectin clinical studies.

g) Although there are 80 peer-reviewed Ivermectin studies, only twelve of the sixteen "greatest impact" studies were peer-reviewed. (*Note: not sure how many of the five "best" Remdesivir studies selected by the FDA, were peer-reviewed*.)

3 - Despite the overwhelming scientific evidence of benefits (45 controlled studies — with very favorable results) Ivermectin is **not** an FDA approved drug for the treatment of COVID-19. The FDA's excuse is that there is "insufficient evidence." *How can this be? [Note: The amount of misleading/inaccurate material on this FDA Ivermectin page is telling.]*

4 - A federal condition of an Emergency Use Vaccines is that it **cannot** be granted if there are effective therapies for the situation at hand ("no adequate, approved, and available alternatives" — see here, Appendix B for details). The appearance is that the FDA denied approval of Ivermectin, to pave the way for emergency, experimental COVID-19 vaccines (e.g., mRNA) that are very profitable to large, influential pharmaceutical companies.

5 - This WHO website lists their latest (as of January 13, 2023) comments about COVID-19 therapies. Its official position is a Recommendation Not To Use Ivermectin as a COVID-19 preventative, or a therapy for patients with COVID-19. Note that WHO's latest IVM report is **March 31, 2021**!!! (See Appendix C for more details on this conflicted conclusion.)

6 - Other countries are catching on (e.g., here), how long before the US will?

Here is an excellent Science-based summary about Ivermectin:

"Ivermectin is an effective treatment for COVID-19. Treatment is more effective when used early. Meta analysis using the most serious outcome shows 62% [51-70%] and 82% [73-88%] improvement for early treatment and prophylaxis, with similar results after exclusion based sensitivity analysis, for primary outcomes, for peer-reviewed studies, and for RCTs. Statistically significant improvements are seen for mortality, ventilation, ICU admission, hospitalization, recovery, cases, and viral clearance. All remain significant after exclusions. 59 studies from 53 independent teams in 23 different countries show statistically significant improvements in isolation (41 for primary outcomes, and 39 for the most serious outcome). Results are very robust — in worst case exclusion sensitivity analysis 60 of 95 studies must be excluded to avoid finding statistically significant efficacy."

This is the type of official statement that we would expect from the Medical Establishment — *if* their primary concern was the health, safety and welfare of citizens, *and* the primary basis of their actions was genuine Science. Unfortunately, neither of those appear to be true.

Chapter 4: Head-To-Head Comparison

Factor	Remdesivir	Ivermectin
FDA approved as a COVID-19 Therapy	Yes (5-1-20)	No
Is the drug currently patented?	Yes	No
Sponsor of drug for the FDA COVID-19 approval process	Gilead Sciences (Mfg & Patent Holder)	No One
Number of current relevant COVID-19 Studies	52	95
# of Peer-Reviewed COVID-19 Studies	44	80
# of Random Controlled COVID-19 Studies	9	45
Number of COVID-19 Studies the FDA found	"Over Five" (but not specified)	32
# of COVID-19 Studies considered by the FDA in their approval process	5	16
# of FDA considered COVID-19 Studies concluding that the drug is a real benefit	1	8
# of FDA considered Studies that analyzed results from onset of COVID-19	0	6
SAFETY: Number of studies that found that there were serious safety issues	0 (But see Note 1)	0
Number of global doses given	Unknown	4± Billion
EFFICACY: # of Studies (average effectiveness for all stages of COVID-19 illness)	52 (avg 11%)	95 (avg 62%)
# of Studies about drug as an effective preventer of COVID-19 (effectiveness)	0	17 (avg 82%)
# of Studies about drug as an effective early therapy for COVID-19 (effectiveness)	6 (avg 44%)	37 (avg 62%)
# of Studies about drug as an effective late therapy for COVID-19 (effectiveness)	47 (avg 11%)	41 (avg 42%)
How drug is administered	Infusion (Hospital Only)	Pill (Patient Given)

Note 1: Sample studies that identify Remdesivir as having serious safety concerns are here & here.
Note 2: Many of the statistics here are found at real-time analysis of 2700+ COVID-19 studies.

Chapter 5: The Medical Establishment — Driven by Science or Profits?

To answer this extraordinarily important question, this Report has focused on the **scientificness** of a pivotal part of the pandemic: *the FDA's approval of COVID-19 therapies*.

For those closely following along, it should be clear that in this situation, the FDA's drug approval process has basically been devoid of real Science. The result is not just a small miss of the target, but it actually got things 100% wrong: the drug that should have been approved was not, *and* the drug that should have not been approved, was.

How is this explainable? Is the Medical Establishment scientifically ignorant? Based on credentials and other evidence, that doesn't seem likely. The more probably explanation is that something else has taken priority — and blinded otherwise scientifically competent people to jump the track. That something else appears to be **greed**.

This *amazing* short video hits the nail directly on the head. It explains some history about Ivermectin, the connection to Remdesivir, and what happened with each regarding being a COVID-19 therapy — with an emphasis on **economics**. Everything in that insightful video is consistent with the research for this Report revealed.

What are the consequences of the Medical Establishment allowing pharmaceutical profits to dictate scientific decisions? Based on statistical approximations, some of these would be:

- 600,000± American citizens died unnecessarily (see Appendix A)
- 3,000,000± global citizens died needlessly
- $11 Trillion of worldwide financial consequences
- Numerous personal freedoms have been threatened or lost
- Incalculable suffering from these avoidable tragedies

(It's hard to put these consequences into perspective. Just one example is that the number of unnecessary American deaths is about the same as the total US casualties in World War II…)

What is glaringly obvious is that none of these COVID-19 results are consistent with the mission statements of the main members of the Medical Establishment (e.g., here).

At what point do we conclude: ***when faced with national medical emergencies, we need to follow real Science — with economics a distant secondary consideration?***

At what point do we learn our lesson and say: ***we need to fix the Medical Establishment?***

At what point do we say: ***some of the parties responsible for this carnage, need to be indicted?***

Chapter 6: Some Key Takeaways

In no particular order, here are some of the conclusions that might be drawn from the information in this COVID-19 Report:

1 - In all of the published studies, there were no safety concerns expressed about Remdesivir or Ivermectin — so the FDA approval decisions should come down to **effectiveness**.

2 - Not a single one of the five Remdesivir studies cited by the FDA as the basis for their approval, concluded that it was effective for **early onset COVID-19 treatment**.

3 - The majority of the five Remdesivir studies cited by the FDA, concluded that it was **not** an effective treatment for severely ill (hospitalized) COVID-19 patients. Yet despite the scientific conclusions in their own cited studies, the FDA approved Remdesivir as a treatment for severely ill (hospitalized) COVID-19 patients.

4 - It's likely that Remdesivir received FDA approval because it had a powerful sponsor — pharmaceutical giant *Gilead Sciences* (which holds the patent on Remdesivir).

5 - It appears that the FDA has no meaningful provisions for having influential sponsors for the approval process of drugs with no patent (like Ivermectin). A permanent **Citizen Advocate** position is strongly recommended, and long overdue.

6 - An unsafe use of Ivermectin (or *any* drug) is for people to use an animal-grade version. The reason that people would do that in this case, is if they are not able to get a prescription from their primary physician. Many physicians are resistant to prescribe Ivermectin (for legal concerns) due to the fact that the FDA has not approved it (as they did Remdesivir).

7 - Regarding getting support from the Medical Establishment (e.g., FDA approval) it appears that Ivermectin was doomed from the start, as it had three strikes against it:

a) **Elitism is in play.** Ivermectin was discovered in Japan, and most of its human usage and success has been in Africa, not the US.

b) **It's generic and inexpensive.** There is no major pharmaceutical giant pushing it through the FDA approval process, as no one stands to make a financial killing from its approval.

c) **It's too effective a treatment.** Once the FDA acknowledges Ivermectin's well-documented effectiveness, they no longer have an EUA basis for authorizing very profitable vaccines.

8 - By ignoring real Science (and capitulating to financial profits), the Medical Establishment's not approving Ivermectin (etc.) in 2020, likely led to a loss of 600,000± American lives (3± million globally), plus incalculable other hardships and financial losses ($11± Trillion to date).

9 - Once the pharmaceutical bias of the Medical Establishment is understood regarding their resistance to a drug with strong scientific evidence, it should be quite clear that their other recommendations (e.g., injections) should be very critically analyzed in that light.

10-The conclusions in this Report should be integrated with the earlier Report: Scientific Observations of the Medical Establishment's handling of the COVID-19 Matter.

Appendix A: Estimating the Number of Unnecessary Deaths

Using the scientific data found in this report, the estimate of 600,000 Americans who died unnecessarily can be arrived at from more than one perspective.

For example, as of 4-16-23 there were 1,124,000± reported US COVID-19 fatalities. Let's say that the FDA had Fast Tracked Ivermectin, Zinc and Vitamin D by June 1, 2020, with the same "warp speed" that they had approved Remdesivir (on May 1, 2020).

There were 105,000± reported American COVID-19 deaths by June 1, 2020. If all subsequent US citizens had been prescribed a proper dose of Ivermectin at the onset of their getting COVID-19, the results of **37 scientific studies** are that there was an ***average*** early treatment success (recovery) rate of **62%**.

Multiplying (1,124,000-105,000)± x .62 = **613,000**± lives saved (*and counting*).

Another reasonable assumption (that would increase this total) would be not to use the *average* success rate of these 37 studies, but to use just the most appropriate ones (*e.g., exclude those studies that did not have a sufficient dosage of Ivermectin*). Twelve of the 37 Ivermectin early treatment studies had a success rate of **over 80%!**

If US patients were *also* given Zinc and Vitamin D, the studies suggest that even more lives would have been saved. *Is it unreasonable to expect the FDA to have also approved them?* Consider this March 23, 2020 article by the former head of CDC. He explains why Vitamin D would very likely be beneficial for treating COVID-19 patients. Later in 2020, some 220 experts wrote a letter supportingVitamin D as a COVID-19 therapy.

There have now been a grand total of 109 **Vitamin D** COVID-19 related studies, done by over 1099 **scientists**, with over 183,000 patients. **94% of 109 Vitamin D *treatment* studies report** positive effects. More specifically, 11 studies concluded that the effectiveness of Vitamin D for early treatment of COVID-19, is 60%. (*See also next page.*)

Yet despite this mountain of positive evidence, the official FDA/NIH position *still* is:

> "Currently, data are insufficient to support a recommendation for or against the use of Vitamin D supplementation to prevent or treat COVID-19."

Reasonable people can disagree about what assumptions to make here. However, the scientific evidence strongly indicates that if the FDA had been as aggressive with their approval of Ivermectin, Zinc and Vitamin D as they had been with Remdesivir, then hundreds of thousands of American lives would have been saved.

Comparing FDA/NIH approval factors of Remdesivir to Vitamin D

Factor	Remdesivir	Vitamin D
FDA approved as a COVID-19 Therapy	Yes (5-1-20)	No
Is the drug currently patented?	Yes	No
Sponsor of drug for the FDA COVID-19 approval process	Gilead Sciences (Mfg & Patent Holder)	No One
Number of current relevant COVID-19 Studies	52	109
# of Peer-Reviewed COVID-19 Studies	44	102
# of Random Controlled COVID-19 Studies	9	27
Number of COVID-19 Studies the FDA found	"Over Five" (but not specified)	39?
# of COVID-19 Studies considered by the FDA in their approval process	5	10 (1 was COVID-19)
# of FDA considered COVID-19 Studies concluding that the drug is a real benefit	1	9 (0 was COVID-19)
# of FDA considered Studies that analyzed results from onset of COVID-19	0	0
SAFETY: Number of studies that found that there were serious safety issues	0 (But see Note 1)	0
Number of global doses given	Unknown	Many Billions
EFFICACY: # of Studies (average effectiveness for all stages of COVID-19 illness)	52 (avg 11%)	109 (avg 36%)
# of Studies about drug as an effective preventer of COVID-19 (effectiveness)	0	56 (avg 30%)
# of Studies about drug as an effective early therapy for COVID-19 (effectiveness)	6 (avg 44%)	11 (avg 60%)
# of Studies about drug as an effective late therapy for COVID-19 (effectiveness)	47 (avg 11%)	42 (avg 46%)
How drug is administered	Infusion (Hospital Only)	OTC Tablets (Patient Given)

Note 1: Sample studies that identify Remdesivir as having serious safety concerns are here & here.
Note 2: Many of the statistics here are found at real-time analysis of 2700+ COVID-19 studies.
Note 3: The sole Vitamin D COVID-19 study listed by the NIH, only gave patients one dose(!).

Appendix B: WHO and Ivermectin

The table below is from the WHO website (dated 3-31-21 !!) where they compare Ivermectin to "Standard Care" (which is not clearly defined, but appears to be not to provide any proven medication to COVID-19 patients). Their table clearly indicates that Ivermectin is *far better on most counts!* (See the section that we've outlined in red.)

Despite this powerful data, they choose **not** to recommend Ivermectin…

Their apparent main excuse for not recommending Ivermectin is that they arbitrarily decided that the limited studies they show (**far** fewer than are available) only provide "very low certainty." Just as with the FDA, WHO has also chosen not to find the 95 relevant Ivermectin COVID-19 studies ferreted out by some dedicated volunteers. (See Appendix C for more details.) *If this isn't scientific incompetence, what is?*

Ivermectin vs Usual care
Patients with COVID-19 infection (all disease severities)

8 Outcomes

Outcome Timeframe	Study results and measurements	Absolute effect estimates Standard care	 Ivermectin	Certainty of the Evidence (Quality of evidence)	Plain language summary
Mortality	Odds Ratio 0.19 (CI 95% 0.09 — 0.36) Based on data from 1419 patients in 7 studies	**70** per 1000	**14** per 1000 Difference: **56 fewer per 1000** (CI 95% 63 fewer — 44 fewer)	**Very low** Due to serious risk of bias and very serious imprecision	The effect of ivermectin on mortality is uncertain. Uncertainty
Mechanical ventilation	Odds Ratio 0.51 (CI 95% 0.12 — 1.77) Based on data from 687 patients in 5 studies	**20** per 1000	**10** per 1000 Difference: **10 fewer per 1000** (CI 95% 18 fewer — 15 more)	**Very low** Due to very serious imprecision and publication bias	The effect of ivermectin on mechanical ventilation is uncertain. Uncertainty
Viral clearance 7 days	Odds Ratio 1.62 (CI 95% 0.95 — 2.86) Based on data from 625 patients in 6 studies	**500** per 1000	**618** per 1000 Difference: **118 more per 1000** (CI 95% 13 fewer — 241 more)	**Low** Due to serious inconsistency and imprecision	Ivermectin may increase or have no effect on viral clearance. No imp. diff.
Hospital admission (outpatients only)	Odds Ratio 0.36 (CI 95% 0.08 — 1.48) Based on data from 398 patients in 1 study	**50** per 1000	**18** per 1000 Difference: **32 fewer per 1000** (CI 95% 47 fewer — 23 more)	**Very low** Due to extreme imprecision	The effect of ivermectin on hospital admission is uncertain. Uncertainty

Appendix C: Ivermectin COVID-19 Studies

The most objective, comprehensive and scientific listing and analysis of Ivermectin COVID-19 studies is found here. It's an amazing database of **95** Ivermectin COVID-19 studies (**80 Peer-Reviewed, 45 are Random Clinical Trials** [RCTs]).

Their exceptional analysis is what scientists, legislators and citizens would expect to have been done by the Medical Establishment (e.g., WHO, FDA, CDC, NIH, AMA). The disparity between a site maintained by a few volunteers, and the Medical Establishment's, are not only extreme, but also very revealing about the commitment and competence of the Medical Establishment.

For example, this NIH website says that they have only been able to find 32 COVID-19 Ivermectin clinical trials (*vs* 63 found by the volunteers). Then they discard (without explanation) *half* of the found studies, and decide to only consider 16 (again, out of 63).

As a further point of comparison, let's look at the results of the two NIH groups:
a) 16 FDA used Ivermectin studies: **8 Positive** and **8 Neutral**.
b) 16 FDA discarded Ivermectin studies: **13 Positive** and **3 Neutral**.

Per the NIH: **The first 16 studies below have limitations that make them less definitive and informative than the second 16 studies (#17 thru #32).**

[Following each study, a relevant conclusion from the study's author(s) is quoted. A Positive Conclusion means that the study found that Ivermectin was effective. A Neutral Conclusion means that little or no benefit was found from taking Ivermectin. A Negative Conclusion is that patients taking Ivermectin were injured by doing that.]

1. Spoorthi V, Sasank S. Utility of Ivermectin and doxycycline combination for the treatment of SARS-CoV-2. Int Arch Integr Med. 2020;7(10):117-182.

   Positive Conclusion: "Our study supports the benefits of utilization of combination of Doxycycline and Ivermectin in mild to moderate COVID-19 infection in terms of early recovery based on the time for symptom resolution and the mean duration of hospital stay."

2. Camprubi D, Almuedo-Riera A, Marti-Soler H, et al. Lack of efficacy of standard doses of Ivermectin in severe COVID-19 patients. PLoS One. 2020;15(11):e0242184.

   Neutral Conclusion: "Ivermectin has recently shown efficacy against SARS-CoV-2 in-vitro. We retrospectively reviewed severe COVID-19 patients receiving standard doses of Ivermectin and we compared clinical and microbiological outcomes with a similar group of patients not receiving Ivermectin. No differences were found between groups."

3. Bhattacharya R, Ray I, Mukherjee R, Chowdhury S, Kulasreshtha MK, Ghosh R. Observational study on clinical features, treatment and outcome of COVID-19 in a tertiary care centre in India - a retrospective case series. *Int J Sci Res.* 2020;9(10).

   Positive Conclusion: "For patients with laboratory confirmed severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection, triple therapy with Ivermectin, N-acetyl-cysteine and Atorvastatin along with standard of care is safe and effective in SARS-coV-2 infection."

4. Morgenstern J, Redondo JN, León A, et al. The use of compassionate Ivermectin in the management of symptomatic outpatients and hospitalized patients with clinical diagnosis of COVID-19 at the Medical Center Bournigal and the Medical Center Punta Cana, Rescue Group, Dominican Rep., from May 1 to August 10, 2020. medRxiv. 2020

   Positive Conclusion: "3,099 patients with diagnosis of COVID-19 were evaluated between May 1st to August 10th, 2020, and all received Ivermectin treatment. A total of 2,706 (87.3%) were discharged for outpatient treatment, all with mild infection. In 2,688 (99.33%) with outpatient treatment, the disease did **not** progress to warrant further hospitalization and there were **no deaths**. In 16 (0.59%) with outpatient treatment, there was subsequent hospitalization, but **without any deaths**. There were 411 (13.3%) patients hospitalized, being admitted at a COVID-19 room with a moderate disease 300 (9.7%) patients of which 3 (1%) died; and with a severe to critical disease were hospitalized in the ICU: 111, 34 of whom died. Total mortality was 37 (1.2%) patients, which is much lower than that reported in world statistics, which are around 3%."

5. Cadegiani FA, Goren A, Wambier CG, McCoy J. Early COVID-19 therapy with azithromycin plus nitazoxanide, Ivermectin or hydroxychloroquine in outpatient settings significantly reduced symptoms compared to known outcomes in untreated patients. medRxiv. 2020 (Peer-Reviewed)

   Positive Conclusion: "Apparent benefits of the combination between early detection and early pharmacological approaches for COVID-19 demonstrated to be consistent when when compared to different control groups of untreated patients. The potential benefits could allow a large number of patients prevented from hospitalizations, deaths and persistent symptoms after COVID-19 remission." [Note: they evaluated three different drugs.]

6. Carvallo H, Roberto H, Eugenia FM. Safety and efficacy of the combined use of Ivermectin, dexamethasone, enoxaparin and aspirin against COVID 19. medRxiv. 2020; Preprint. (Peer Reviewed)

   Positive Conclusion: "None of the patients presenting mild symptoms needed to be hospitalized. Only one patient died (0.59 % of all included patients vs. 2.1 % overall mortality for the disease in Argentina today; 3.1 % of hospitalized patients vs. 26.8 % mortality in published data)…. *(continued on next page)…*

IDEA protocol appears to be a useful alternative to prevent disease progression of COVID-19 when applied to mild cases and to decrease mortality in patients at all stages of the disease with a favorable risk-benefit ratio."
[Note: they evaluated four different drugs.]

7. Bukhari KHS, Asghar A, Perveen N, et al. Efficacy of Ivermectin in COVID-19 patients with mild to moderate disease. medRxiv. 2021; Preprint.

   Positive Conclusion: "In the intervention arm, early viral clearance was observed and no side effects were documented. Therefore **Ivermectin is a potential addition to the standard care of treatment in COVID-19 patients**."

8. Elalfy H, Besheer T, El-Mesery A, et al. Effect of a combination of nitazoxanide, ribavirin, and Ivermectin plus zinc supplement (MANS.NRIZ study) on the clearance of mild COVID-19. J Med Virol. 2021;93(5):3176-3183. (Peer-Reviewed)

   Positive Conclusion: "This trial concluded by stating that the combined use of nitazoxanide, ribavirin, and Ivermectin plus zinc supplement effectively cleared the SARS-COV2 from the nasopharynx in a shorter time than symptomatic therapy."

9. Chahla RE, Ruiz LM, Mena T, et al. Cluster randomised trials—Ivermectin repurposing for COVID-19 treatment of outpatients with mild disease in primary health care centers. Research Square. 2021; Preprint.

   Positive Conclusion: "Treatment with Ivermectin in outpatients care with mild disease of COVID-19 managed to slightly reduce PPS. Also, this treatment improved the clinical state to obtain outpatient discharge, even in the presence of co-morbidities. The treatment with Ivermectin could significantly prevent the evolution to serious stages since the EG did not present any patient with referral to critical hospitalization."

10. Tanioka H, Tanioka S, Kaga K. Why COVID-19 is not so spread in Africa: how does Ivermectin affect it? medRxiv. 2021; Preprint.

    Positive Conclusion: "Scientists have so far been unable to determine the reason for the low number of COVID-19 cases in Africa. The community-directed onchocerciasis treatment with Ivermectin is the most reasonable explanation for the decrease in morbidity and fatality rate in Africa. In areas where Ivermectin is distributed to and used by the entire population, it leads to a significant reduction in [COVID-19] mortality."

11. Roy S, Samajdar SS, Tripathi SK, Mukherjee S, Bhattacharjee K. Outcome of different therapeutic interventions in mild COVID-19 patients in a single OPD clinic of West Bengal: a retrospective study. medRxiv. 2021; Preprint.

    Neutral Conclusion: "Mild COVID-19 infection in patients having low-risk to progress can be managed symptomatically without any specific drug intervention."

12. Pott-Junior H, Bastos Paoliello MM, Miguel AQC, et al. Use of Ivermectin in the treatment of COVID-19: a pilot trial. Toxicol Rep. 2021;8:505-510.

    Positive Conclusion: "For patients with laboratory confirmed severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection, triple therapy with Ivermectin, N-acetyl-cysteine and Atorvastatin along with standard of care is safe and effective in SARS-coV-2 infection."

13. Merino J, Borja VH, Lopez O, et al. Ivermectin and the odds of hospitalization due to COVID-19: evidence from a quasi-experimental analysis based on a public intervention in Mexico City. SocArXiv Papers. 2021; Preprint.

    Positive Conclusion: "For patients with laboratory confirmed severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection, triple therapy with Ivermectin, N-acetyl-cysteine and Atorvastatin along with standard of care is safe and effective in SARS-coV-2 infection."

14. Shahbaznejad L, Davoudi A, Eslami G, et al. Effects of Ivermectin in patients w COVID-19: a multicenter, double-blind, randomized, controlled clinical trial. Clin Ther. 2021.

    Positive Conclusion: "A single dose of Ivermectin was well-tolerated in symptomatic patients with COVID-19, and important clinical features of COVID-19 were improved with Ivermectin use, including dyspnea, cough, and lymphopenia."

15. Samaha AA, Mouawia H, Fawaz M, et al. Effects of a single dose of Ivermectin on viral and clinical outcomes in asymptomatic SARS-CoV-2 infected subjects: a pilot clinical trial in Lebanon. Viruses. 2021;13(6). (Peer-Reviewed)

    Positive Conclusion: "Ivermectin appears to be efficacious in providing clinical benefits in a randomized treatment of asymptomatic SARS-CoV-2-positive subjects, effectively resulting in fewer symptoms, lower viral load and reduced hospital admissions."

16. Roman YM, Burela PA, Pasupuleti V, Piscoya A, Vidal JE, Hernandez AV. Ivermectin for the treatment of COVID-19: a systematic review and meta-analysis of randomized controlled trials. medRxiv. 2021; Preprint.

    Neutral Conclusion: "In comparison to SOC or placebo, IVM did not reduce all-cause mortality, length of stay or viral clearance in RCTs in COVID-19 patients with mostly mild disease. IVM did not have effect on AEs or SAEs. IVM is not a viable option to treat COVID-19 patients."

The next sixteen Ivermectin COVID-19 studies studies (#17 thru #32) are those that the FDA said had the greatest impact on the Panel's recommendations.

17. Lopez-Medina E, Lopez P, Hurtado IC, et al. Effect of Ivermectin on time to resolution of symptoms among adults with mild COVID-19: a randomized clinical trial. JAMA. 2021;325(14):1426-1435. (Peer-Reviewed) *[Early treatment]*

    Mild Positive Conclusion: "The median time to resolution of symptoms was 10 days in the Ivermectin group compared with 12 days in the placebo group… Among adults with mild COVID-19, a 5-day course of Ivermectin, compared with placebo, did not significantly improve the time to resolution of symptoms."

18. Ahmed S, Karim MM, Ross AG, et al. A five-day course of Ivermectin for the treatment of COVID-19… Int J Infect Dis. 2020;103:214-216. (Peer-Reviewed) *[Early treatment]*

    Positive Conclusion: "A 5-day course of Ivermectin was found to be safe and effective in treating adult patients with mild COVID-19."

19. Okumus N, et al. Evaluation of the effectiveness and safety of adding IVM to treatment in severe COVID-19 patients. BMC Infect Dis. 2021;21(1):411. (Peer-Reviewed)

    Positive Conclusion: "According to the findings obtained, Ivermectin can provide an increase in clinical recovery, improvement in prognostic laboratory parameters and a decrease in mortality rates even when used in patients with severe COVID-19. Consequently, Ivermectin should be considered as an alternative drug that can be used in the treatment of COVID-19 disease or as an additional option to existing protocols."

20. Galan LEB, Santos NMD, Asato MS, et al. Phase 2 randomized study on chloroquine, hydroxychloroquine or Ivermectin in hospitalized patients with severe manifestations of SARS-CoV-2 infection. Pathog Glob Health. 2021;115(4):235-242.

    Neutral Conclusion: "Although CQ, HCQ or Ivermectin revealed a favorable safety profile, the tested drugs do not reduce the need for supplemental oxygen, ICU admission, invasive ventilation or death, in patients hospitalized with a severe form of COVID-19."

    Note: This is not a clinical study, since there was no control group.

21. Chachar AZK, et al. Effectiveness of Ivermectin in SARS-COV-2/COVID-19 Patients. Int J of Sci. 2020;9:31-35. (Peer-Reviewed)

    Neutral Conclusion: "Statistically there was no significant difference between case group who were given Ivermectin along with symptomatic treatment and control group who were only given symptomatic treatment without Ivermectin, being asymptomatic on day 7 at follow up."

22. Podder CS, Chowdhury N, Sina MI, Haque W. Outcome of Ivermectin treated mild to moderate COVID-19 cases: a single-centre, open-label, randomised controlled study. IMC J of Med Sci. 2020. (Peer-Reviewed)

    Neutral Conclusion: "Ivermectin had no beneficial effect on the disease course over usual care in mild to moderate COVID-19 cases."

23. Chowdhury ATMM, Shahbaz M, Karim MR, Islam J, Dan G, He S. A comparative study on Ivermectin-doxycycline and hydroxychloroquine-azithromycin therapy on COVID-19 patients. EJMO. 2021;5(1):63-70. (Peer-Reviewed) *[Early treatment]*

    Mild Positive Conclusion: "The combination therapy of Ivermectin-Doxycycline showed a trend towards superiority to the combination of Hydroxychloroquine-Azithromycin for mild to moderate COVID19 disease."

24. Krolewiecki A, et al. Antiviral effect of high-dose Ivermectin in adults with COVID-19: a proof-of-concept randomized trial. Lancet. 2021. (Peer-Reviewed) *[Early treatment]*

    Neutral Conclusion: "No differences in clinical evolution at day-7 and day-30 between groups were observed."

25. Chaccour C, et al. The effect of early treatment with Ivermectin on viral load, symptoms and humoral response in patients with non-severe COVID-19: A pilot, double-blind, placebo-controlled, randomized clinical trial. Lancet. 2021. (Peer-Reviewed) *[Early treatment]*

    Neutral Conclusion: "Among patients with non-severe COVID-19 and no risk factors for severe disease receiving a single 400 mcg/kg dose of Ivermectin within 72 hrs of fever or cough onset there was no difference in the proportion of PCR positives."

    Note: A single dose of Ivermectin is **not** the recommended treatment, so this study should have been excluded from consideration. This should **not** be a top study.

26. Hashim HA, Maulood MF, Rasheed AW, Fatak DF, Kabah KK, Abdulamir AS. Controlled randomized clinical trial on using Ivermectin with doxycycline for treating COVID-19 patients in Baghdad, Iraq. medRxiv. 2020; Preprint. (Peer-Reviewed)

    Positive Conclusion: "Ivermectin with doxycycline reduced the time to recovery and the percentage of patients who progress to more advanced stage of disease; in addition, Ivermectin with doxycycline reduced mortality rate in severe patients from 22.72% to 0%; however, 18.2% of critically ill patients died with Ivermectin and doxycycline therapy. Taken together, the earlier administered Ivermectin with doxycycline, the higher rate of successful therapy."

27. Mohan A, et al. Ivermectin in mild and moderate COVID-19: a randomized, placebo-controlled trial. Research Square. 2021 (Peer-Reviewed) *[Early treatment]*

    Neutral Conclusion: "In patients with mild and moderate COVID-19, a single administration of Ivermectin elixir (either 24 mg or 12 mg) demonstrated a trend towards higher proportion of RT-PCR negativity at day 5 of enrollment."

    Note: A single dose of Ivermectin is **not** the recommended treatment, so this study should have been excluded from consideration. This should **not** be a top study.

28. Gonzalez JLB, Gámez MG, Enciso EAM, et al. Efficacy and safety of Ivermectin and hydroxychloroquine in patients with severe COVID-19. A randomized controlled trial. medRxiv. 2021; Preprint.

    Neutral Conclusion: "In non-critical hospitalized patients with COVID-19 pneumonia, neither Ivermectin nor hydroxychloroquine decreases the number of in-hospital days, respiratory deterioration, or deaths."

29. Niaee MS, Gheibi N, Namdar P, et al. Ivermectin as an adjunct treatment for hospitalized adult COVID-19 patients: a randomized multi-center clinical trial. Research Square. 2020; Preprint. (Peer-Reviewed)

    Positive Conclusion: "Ivermectin as an adjunct reduced the rate of mortality, low O2 duration, and duration of hospitalization in adult COVID 19 patients. The improvement of other clinical parameters showed that the Ivermectin, with a wide margin of safety, had a high therapeutic effect on COVID-19."

30. Rajter JC, Sherman MS, Fatteh N, Vogel F, Sacks J, Rajter JJ. Use of Ivermectin is associated with lower mortality in hospitalized patients with coronavirus disease 2019: the ICON study. Chest. 2020. (Peer-Reviewed)

    Positive Conclusion: "Ivermectin treatment resulted in lower mortality during treatment of COVID-19, especially in patients with severe pulmonary involvement."

31. Soto-Becerra P, Culquichicón C, Hurtado-Roca Y, Araujo-Castillo RV. Real-world effectiveness of hydroxychloroquine, azithromycin, and Ivermectin among hospitalized COVID-19 patients: results of a target trial emulation using observational data from a nationwide healthcare system in Peru. medRxiv. 2020; Preprint.

    Neutral Conclusion: "Our study reported no beneficial effects of hydroxychloroquine, Ivermectin, azithromycin."

    Note: The study failed to specify the Ivermectin dosage, but it appears to be a single dose. This is not the recommended treatment, so this study should have been excluded from both considerations. It should **not** be a top study.

32. Khan MSI, Khan MSI, Debnath CR, et al. Ivermectin treatment may improve the prognosis of patients with COVID-19. Arch Bronconeumol. 2020; 56(12):828-830.

    Positive Conclusion: "In conclusion, in addition to rapid SARS-CoV-2 clearance, Ivermectin seems to control the course of the disease in patients with COVID-19. The present findings suggest that Ivermectin can be considered as a first-line treatment for containing SARS-CoV-2 to prevent severe irreversible respiratory complications and community transmission."

— End of FDA's Database of Ivermectin COVID-19 Studies —

Referencing the volunteer COVID-19 Ivermectin database, there are **thirty-one (31)** *additional* relevant studies not found by the FDA. Here is a *sample* of these. Note that they are all peer-reviewed — yet another reason the FDA should have included them:

33. Aref, et al., International Journal of Nanomedicine (Peer-Reviewed)

    Positive Conclusion: "Local use of Ivermectin mucoadhesive nanosuspension nasal spray is safe and effective in treatment of patients with mild COVID-19 with rapid viral clearance and shortening the anosmia duration."

34. Babalola et al. QJM: An International Journal of Medicine, 2021, 1–9 (Peer-Reviewed, double-blind)

    Positive Conclusion: "12mg IV regime given twice a week may have superior efficacy over 6mg IV given twice a week, and certainly over the non IV arm of the study. IV should be considered for use in clinical management of SARS-COV2, and may find applications in prophylaxis in high risk areas"

35. Espitia-Hernandez et al. Biomedical Research (2020) Volume 31, Issue 5 (Peer-Reviewed)

    Positive Conclusion: "Recovery rate of the 28 patients that received the combination therapy was 100%, the mean symptomatic recovery duration was 3.6 days and negative PCR was confirmed on day 10… This study found that the combination treatment might mitigate disease progression without significant adverse effects."

36. Mahmud et al., Journal of International Medical Research, doi:10.5061/dryad.qjq2bvqf6 (Peer-Reviewed)

    Positive Conclusion: "Patients with mild-to-moderate COVID-19 infection treated with Ivermectin plus doxycycline recovered earlier, were less likely to progress to more serious disease, and were more likely to be COVID-19 negative by RT-PCR on day 14."

37. Ravikirti et al., Journal of Pharmacy & Pharmaceutical Sciences, doi:10.18433/jpps32105 (Peer-Reviewed, double-blind)

    Positive Conclusion: "All patients in the Ivermectin group were successfully discharged. In comparison the same for the placebo group was observed to be 93%. This difference was found to be statistically significant."

38. Mourya et al., Int. J. Health and Clinical Research (Peer-Reviewed)

    Positive Conclusion: "The treatment with HCQ, azithromycin, and Ivermectin had a better success rate compared to HCQ and azithromycin. Based on the results, Ivermectin could be the potential therapeutic agents for the COVID-19 disease."

39. Loue et al., J. Infectious Diseases and Epidemiology, doi:10.23937/2474-3658/1510202 (Peer-Reviewed)

    Positive Conclusion: Small quasi-randomized (patient choice) study with 25 PCR+ patients in a nursing home offered Ivermectin, of which 10 chose to be treated. The mean age was 83.5 in the treatment group and 81.8 in the control group. There was lower mortality and fewer serious cases with treatment.

40. Faisal et al., The Professional Medical Journal, doi:10.29309/TPMJ/2021.28.05.5867 (Peer-Reviewed)

    Positive Conclusion: "The Combination of Ivermectin and azithromycin was more effective in making patients symptom free than azithromycin alone."

41. Lima-Morales International Journal of Infectious Diseases 105 (2021) 598–605 (Peer-Reviewed)

    Positive Conclusion: " TNR4 therapy (Ivermectin, Azithromycin, Montelukast, and Acetylsalicylic acid) improved recovery and prevented the risk of hospitalization and death among ambulatory COVID-19 cases."

42. Neil et al., *Research Gate*, doi:10.13140/RG.2.2.19703.75680 (Preprint) (meta analysis)

    Positive Conclusion: (This is a different type of meta analysis) "We show that there is strong evidence to support a causal link between Ivermectin, Covid-19 severity and mortality, and: i) for severe Covid-19 there is a 90.7% probability the risk ratio favors Ivermectin; ii) for mild/moderate Covid-19 there is an 84.1% probability the risk ratio favors Ivermectin. Also, from the Bayesian meta-analysis for patients with severe Covid-19, the mean probability of death without Ivermectin treatment is 22.9%, while with the application of Ivermectin treatment it is 11.7%."

Go here for much more scientific information on Ivermectin tests regarding prevention, early *and* late stage treatment of COVID-19. This wonderful site also has powerful scientific data on a variety of other low cost OTC treatments like Zinc and Vitamin D. Those will also likely not garner the Medical Establishment's support, for the same reasons that Ivermectin encountered.