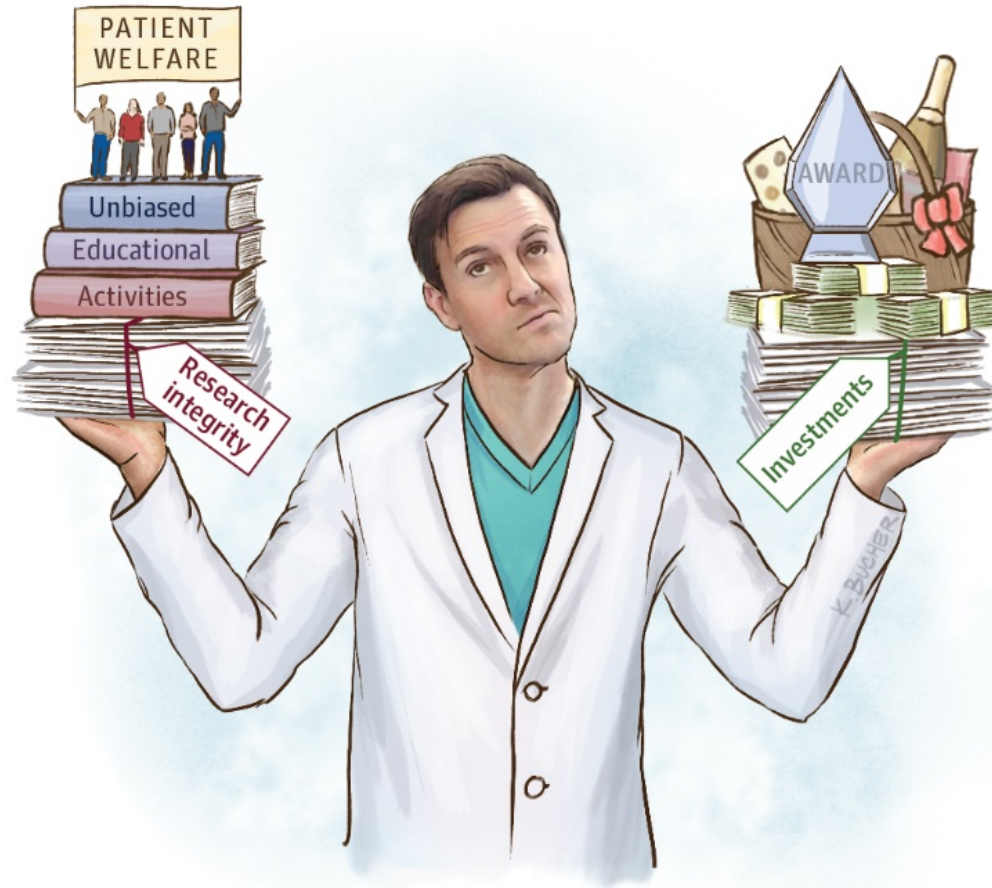


# COVID-19: A Focus on Remdesivir

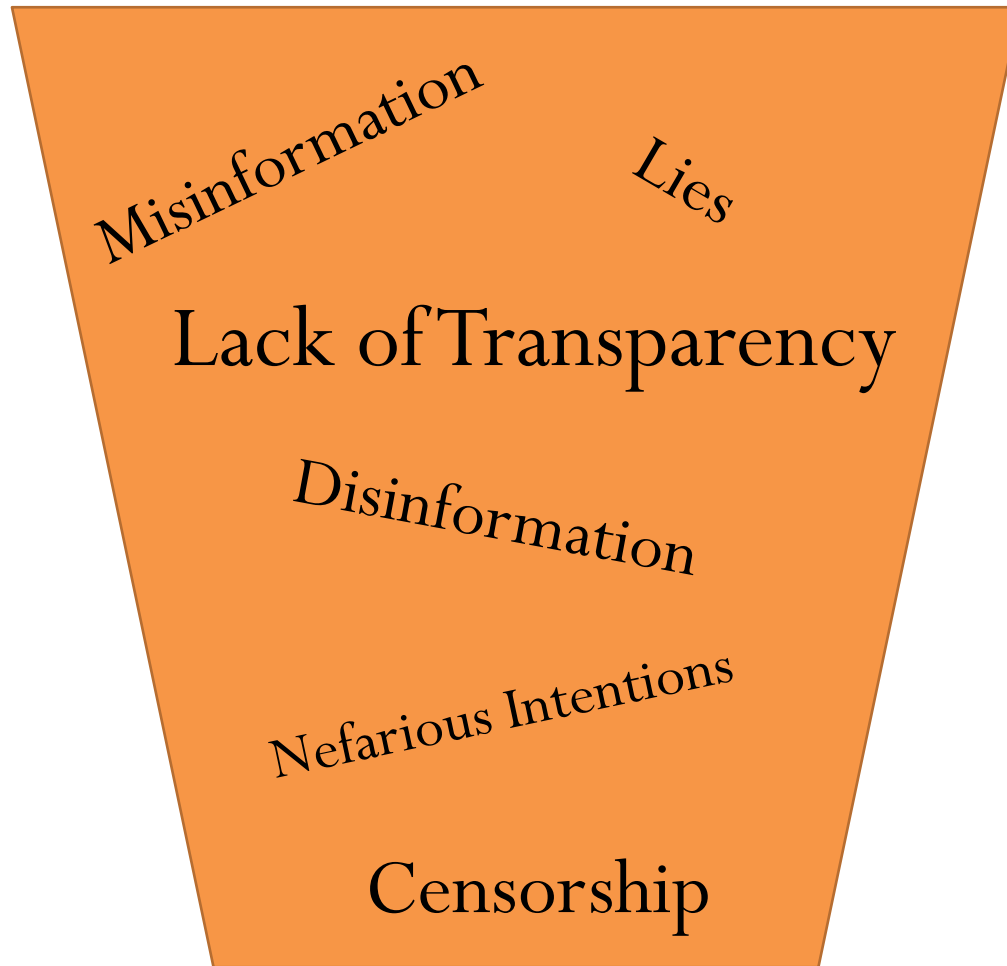


Paul Marik MD, FCCM, FCCP

# Conflicts of Interest



# The Vacuum of Truth





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# Covid-19 vaccines and treatments: we must have raw data, now

Data should be fully and immediately available for public scrutiny

Peter Doshi, Fiona Godlee, Kamran Abbasi

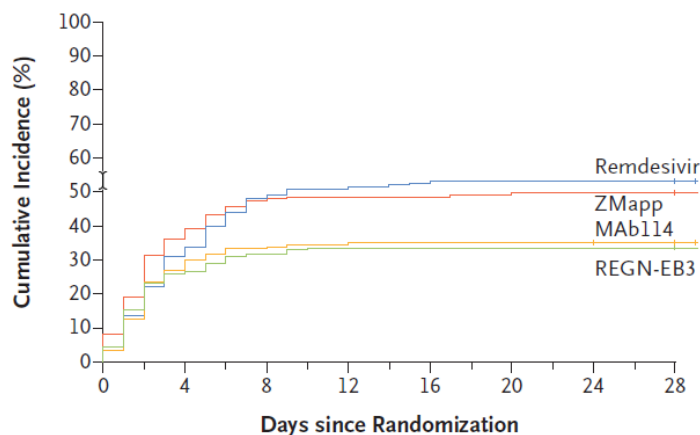
Figure 2. Therapeutic Management of Hospitalized Adults With COVID-19 Based on Disease Severity

DISEASE SEVERITY	PANEL'S RECOMMENDATIONS
Hospitalized but Does Not Require Supplemental Oxygen	<p>The Panel <b>recommends against</b> the use of <b>dexamethasone (AIIa)</b> or <b>other corticosteroids (AIII)</b>.<sup>a</sup></p> <p>There is insufficient evidence to recommend either for or against the routine use of remdesivir. For patients at high risk of disease progression, remdesivir may be appropriate.</p>
Hospitalized and Requires Supplemental Oxygen	<p>Use one of the following options:</p> <ul style="list-style-type: none"> <li>• <b>Remdesivir<sup>b</sup></b> (e.g., for patients who require minimal supplemental oxygen) (<b>BIIa</b>)</li> <li>• <b>Dexamethasone plus remdesivir<sup>b</sup></b> (e.g., for patients who require increasing amounts of supplemental oxygen) (<b>BIII</b>)</li> <li>• <b>Dexamethasone</b> (when combination with remdesivir cannot be used or is not available) (<b>BI</b>)</li> </ul>
Hospitalized and Requires Oxygen Delivery Through a High-Flow Device or Noninvasive Ventilation	<p>Use one of the following options:</p> <ul style="list-style-type: none"> <li>• <b>Dexamethasone (AI)</b></li> <li>• <b>Dexamethasone plus remdesivir<sup>b</sup></b> (<b>BIII</b>)</li> </ul> <p>For recently hospitalized<sup>c</sup> patients with rapidly increasing oxygen needs and systemic inflammation:</p> <ul style="list-style-type: none"> <li>• Add either <b>baricitinib (BIIa)</b> or <b>IV tocilizumab (BIIa)</b> to one of the two options above<sup>d</sup> <ul style="list-style-type: none"> <li>• If neither baricitinib nor IV tocilizumab is available or feasible to use, <b>tofocitinib</b> can be used instead of baricitinib (<b>BIIa</b>) or <b>IV sarilumab</b> can be used instead of IV tocilizumab (<b>BIIa</b>).</li> </ul> </li> </ul>
Hospitalized and Requires IMV or ECMO	<ul style="list-style-type: none"> <li>• <b>Dexamethasone (AI)</b></li> </ul> <p>For patients who are within 24 hours of admission to the ICU:</p> <ul style="list-style-type: none"> <li>• <b>Dexamethasone plus IV tocilizumab (BIIa)</b> <ul style="list-style-type: none"> <li>• If IV tocilizumab is not available or not feasible to use, <b>IV sarilumab</b> can be used (<b>BIIa</b>).</li> </ul> </li> </ul>
<p><b>Rating of Recommendations:</b> A = Strong; B = Moderate; C = Optional  <b>Rating of Evidence:</b> I = One or more randomized trials without major limitations; IIa = Other randomized trials or subgroup analyses of randomized trials; IIb = Nonrandomized trials or observational cohort studies; III = Expert opinion</p>	

# A Randomized, Controlled Trial of Ebola Virus Disease Therapeutics

On August 9, 2019, when 681 patients had been enrolled, the data and safety monitoring board conducted an interim analysis on data from 499 patients and, on the basis of two observations, recommended terminating random assignment to ZMapp and remdesivir.

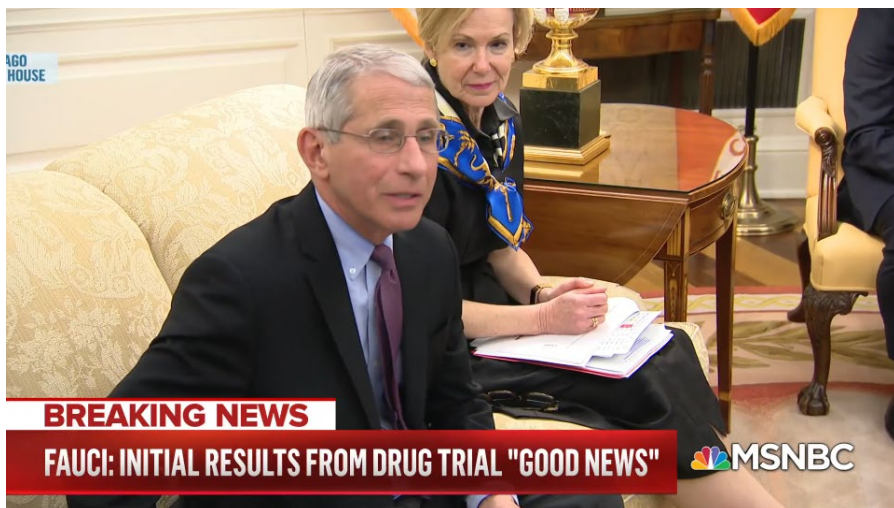
Incidence of Death, Overall



# Remdesivir for the Treatment of Covid-19

ACTT-1 Trial Enrollment Feb 21 to April 19<sup>th</sup> 2020

April 29<sup>th</sup>, 2020 – White House



# Remdesivir for the Treatment of Covid-19 — Preliminary Report

Gilead changed the end-point halfway through study – Scientific Misconduct

## Outcome Measures

### Primary Outcome Measures:

1. Percentage of subjects reporting each severity rating on an 8-point ordinal scale. The ordinal scale is an assessment of the clinical status at the first assessment of a given study day. The scale is as follows: 1) Death; 2) Hospitalized, on invasive mechanical ventilation or extracorporeal membrane oxygenation (ECMO); 3) Hospitalized, on non-invasive ventilation or high-flow oxygen devices; 4) Hospitalized, requiring supplemental oxygen; 5) Hospitalized, not requiring supplemental oxygen – requiring ongoing medical care (COVID-19 related or otherwise); 6) Hospitalized, not requiring supplemental oxygen – no longer requires ongoing medical care; 7) Not hospitalized, limitation on activities and/or requiring home oxygen; 8) Not hospitalized, no limitations on activities.

[Time Frame: Day 16 ]

### Time to recovery

Day of recovery is defined as the first day on which the subject satisfies one of the following three categories from the ordinal scale: 1) Hospitalized, not requiring supplemental oxygen - no longer requires ongoing medical care; 2) Not hospitalized, limitation on activities and/or requiring home oxygen; 3) Not hospitalized, no limitations on activities.

[Time Frame: Day 1 through Day 29 ]

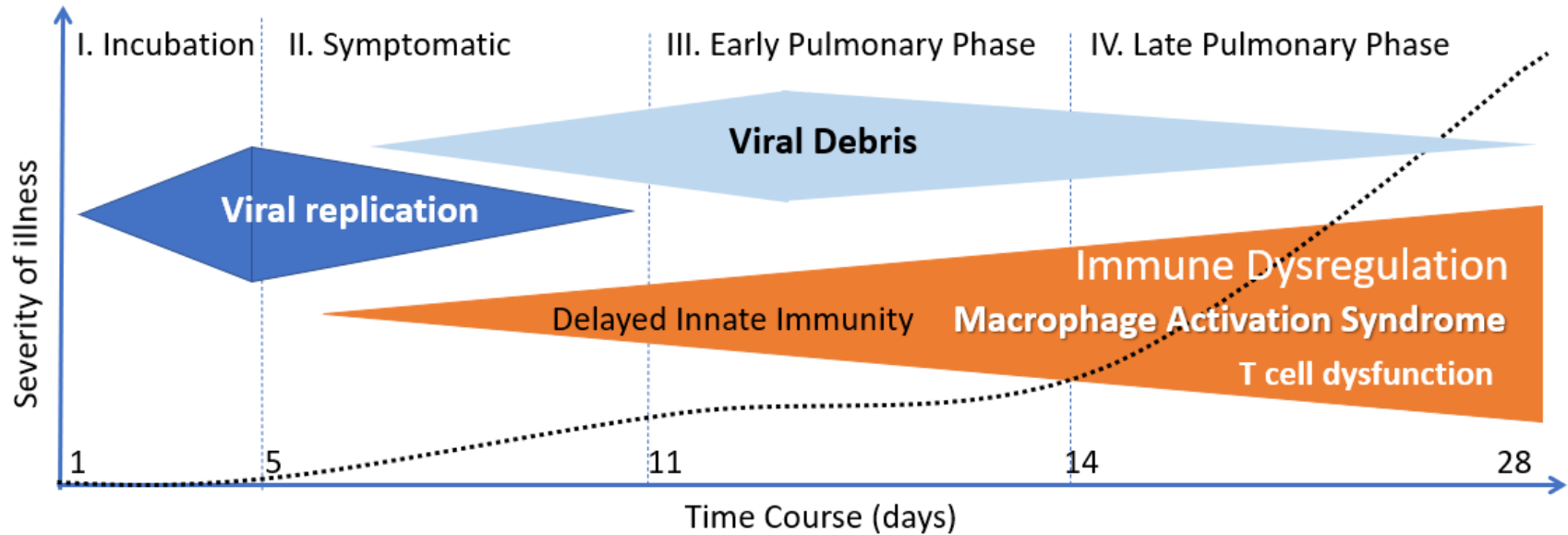
### Secondary Outcome Measures:

## CONCLUSIONS

Our data show that remdesivir was superior to placebo in shortening the time to recovery in adults who were hospitalized with Covid-19 and had evidence of lower respiratory tract infection. (Funded by the National Institute of Allergy and Infectious Diseases and others; ACTT-1 ClinicalTrials.gov number, NCT04280705.)



# Phase Specific Combination Therapy

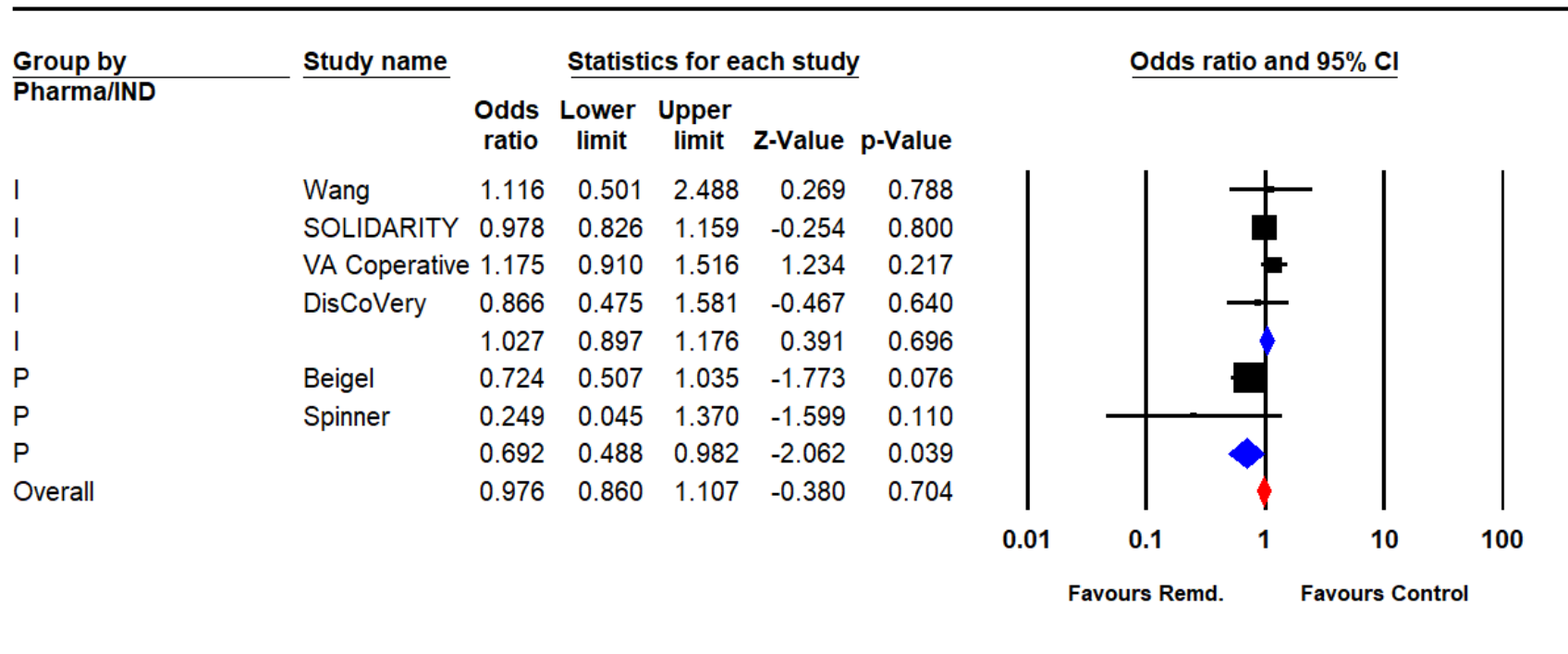


Ground-glass infiltrates	+                      ++                      +++                      ++++			
Clinical Symptoms	Fever, malaise, cough, headache, diarrhea		SOB – Mild hypoxia ≤4 L/min N/C & aSat < 94%	
Treatment approach	Antiviral Rx		Anti-inflammatory Rx	
Potential therapies	Monoclonal Antibodies		Methylprednisolone 40 mg q 12 inc. to 80 - 250 mg if reqd.	
	ASA + Gargle		Enoxaparin 1mg/kg q 12	Enoxaparin 60mg/day
	IVERMECTIN 0.2 -0.4 mg/kg x 2-5 doses		IVERMECTIN 0.4-0.6 mg/kg for 5 doses	
	Fluvoxamine+ Melatonin + Vitamin D + Vitamin C +Flavanoid + Zinc + Omega 3's + Statin			

Remdesivir (antiviral) has no place in the pulmonary phase

# Remdesivir for treatment of COVID-19: Grouped By Pharma Controlled vs Independent

## Meta-analysis of Mortality



### Meta Analysis

Independent Studies: 3% increase in deaths

## Kidney disorders as serious adverse drug reactions of remdesivir in coronavirus disease 2019: a retrospective case–noncase study

**Table 1 | Reporting of kidney disorders in remdesivir users among COVID-19 patients, and their RORs within the WHO global pharmacovigilance database**

Type of analysis	Kidney disorder cases <sup>a</sup>	Noncases <sup>b</sup>	ROR (95% CI)
<b>Primary analysis</b>			
Remdesivir users	327	1526	7.2 (5.7–9.0)
Other drug users	107	3572	1 (Reference)
<b>Sensitivity analysis restricted to severe to critical COVID-19 patients</b>			
Remdesivir users	327	1526	3.7 (2.6–5.4)
Dexamethasone, sarilumab, or tocilizumab users	34	591	1 (Reference)
<b>Sensitivity analysis restricted to serious kidney disorders<sup>c</sup></b>			
Remdesivir users	301	1552	6.9 (5.4–8.7)
Other drug users	101	3578	1 (Reference)
<b>Sensitivity analysis restricted to kidney disorders not including concomitant nephrotoxic drugs<sup>d</sup></b>			
Remdesivir users	242	1611	6.1 (4.8–7.9)
Other drug users	88	3591	1 (Reference)

Remdesivir increases OR of Acute Kidney Injury: 6.1 -7.2

Medicine	Year started reporting	Deaths	Adverse events
Ivermectin	1992	18	4 669
Remdesivir	2020	582	8 057
Tocilizumab	2005	786	47 345
COVID-19 vaccines	2021	13 361	2 620 423
Tetanus vaccine	1968	32	14 697
Measles vaccine	1992	35	3 696
Acetaminophen (Tylenol)	1968	3 865	> 146 000

# **WHO recommends against the use of remdesivir in COVID-19 patients**

20 November 2020

# Politics and Economic Greed Define Science

August 21, 2020

 Print This Post

Editors of The Lancet and the New England Journal of Medicine:  
Pharmaceutical Companies are so Financially Powerful They  
Pressure us to Accept Papers

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# Politics and Economic Greed Define Science

August 21, 2020

 Print This Post

## Editors of The Lancet and the New England Journal of Medicine: Pharmaceutical Companies are so Financially Powerful They Pressure us to Accept Papers

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As uncovered by Science Defies Politics: 16 of the [panel members](#) selected by NIH to formulate the official COVID-19 Treatment Guidelines – including two of the three co-chairs – were paid by Gilead.

**At least 7 (seven) members of the Panel on COVID-19 Treatment Guidelines, including 2 out of 3 Co-Chairs, have not disclosed their financial ties to Gilead Sciences (GILD), the patent owner and manufacturer of *remdesivir*.**

# Hospitals' Incentive Payments for COVID-19



The hospital payments include:

- A “free” *required* PCR test in the Emergency Room or upon admission for every patient, with government-paid fee to hospital.
- Added bonus payment for each positive COVID-19 diagnosis.
- Another bonus for a COVID-19 admission to the hospital.
- A 20 percent “boost” bonus payment from Medicare on the *entire hospital bill* for use of remdesivir instead of medicines such as Ivermectin.
- Another and larger bonus payment to the hospital if a COVID-19 patient is mechanically ventilated.
- More money to the hospital if cause of death is listed as COVID-19, even if patient did not die directly of COVID-19.
- A COVID-19 diagnosis also provides extra payments to coroners.



# REMDESIVIR VS IVERMECTIN

COMPARISONS	REMDESIVIR	IVERMECTIN
COST	\$ 3,000.00	PENNIES
LOWER DEATH RATE IN STUDIES	NO	YES 50% +
SIMPLE ACCESS AT HOME	NO	YES
CAUSES ORGAN DAMAGE	YES	NO
STUDIES NEEDED FOR APPROVAL	1 and approved	60 + and not considered
MAJOR CONFLICTS OF INTEREST	YES	NO
SUPPORT OF FDA AND FAUCI	YES	NO

# Here we go again!

How can the FDA Panel Narrowly Back Merck's COVID Pill Molnupiravir when placebo outperformed this known-to-be-mutagenic pill?



Data from the post-interim analysis enrollment, there were fewer placebo patients who were hospitalized or died by day 29 versus patients receiving the intervention (4.7% vs 6.2%, respectively).

# COVID-19 Misinformation...

