TWO NEW COVID-19 TREATMENTS IN PERSPECTIVE

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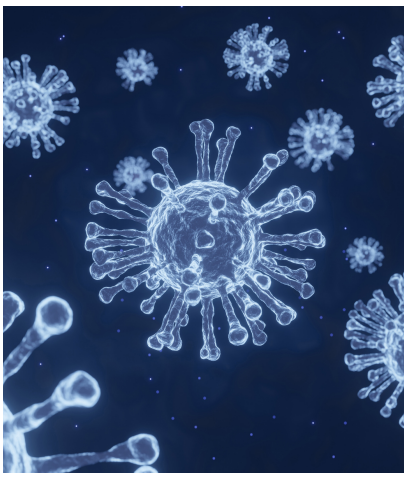

COVID-19

NEW TREATMENTS

Last month, the FDA gave its blessing (an EUA: Emergency Use Authorization) to two different COVID-19 early treatment, oral drugs. This is a major milestone, as to-date, there have been zero FDA endorsed pharmaceutical pill options that anyone diagnosed with COVID-19 could take. The standard medical therapy for a newly diagnosed person has been for them to: go home, rest, drink water, and go to the hospital if things get dire. *Now, **after almost two years**, people diagnosed with early stages of* COVID-19, *can be prescribed a pill!*

As background, there are two primary considerations before the FDA will support authorizing an EUA for medications: **effectiveness** and **safety**. The two drug companies involved (Pfizer and Merck) oversaw clinical trials that attempted to answer both of those concerns.

Here are the FDA official EUA authorizations for Paxlovid (Pfizer) and Molnupiravir (Merck). In those documents, the FDA outlines what tests were done, what the results were, what some of the limitations and concerns are, etc.

The FDA then generated more detailed advisories to healthcare providers (doctors) for Paxlovid and Molnupiravir. These documents give more specifics about use restrictions (*e.g., not to children*), potentially adverse effects of each drug (*e.g., not to be used by pregnant women, etc.*), potential conflicts with other drugs (*quite a few)*, etc.

FOUR KEY POINTS TO CONSIDER

1) the tests were conducted by the pharmaceutical companies trying to get an FDA blessing [*not some unbiased source*],

2) no long-term testing was done on either of these drugs [*the trials lasted a few months*],

3) the effects on patients with many other diseases [*e.g., Parkinson's*] were **not** evaluated, so are unknown, and

4) the reported effectiveness of each drug [*hospitalization or death*: **88%** and **30%]** are *relative* **not** absolute. (See this explanation about this *important* point.)

OK, kudos to the FDA for giving consumers some early-treatment options for dealing with COVID-19. It's especially good that they are non-hospital, take-at-home therapies.

However, the question is: how do these FDA endorsed drugs compare to OTCs (Over-The-Counter) and non-patented drugs — **especially Ivermectin (IVM) and Hydroxychloroquine (HCQ)** — that are reported to have some early treatment effectiveness against COVID-19?

As a scientist (physicist) I try to be careful in analyzing data, to not only be accurate, but to present it objectively and understandably. In that light, see this table where I juxtapose Paxlovid & Molnupiravir to IVM, HCQ and three OTCs. The comparison is on about **twenty COVID-19 factors** (effectiveness, safety, cost, etc.).

KEY TAKEAWAYS

1) Pfizer's Paxlovid is reported to have very high effectiveness,

2) HCQ and the Curcumin have effectiveness comparable to Paxlovid,

3) Merck's Molnupiravir has very low effectiveness,

4) IVM, Vitamin D and Zinc have effectiveness far superior to Molnupiravir,

5) Paxlovid & Molnupiravir have more serious side effects than the others, and

6) Paxlovid & Molnupiravir cost considerably more than the non-patented options.

TWO MAJOR QUESTIONS

A) Are the Pfizer and Merck oral treatment EUAs legal?

Note that federal law (e.g., here and here) stipulates that an EUA can **not** be granted *unless*:

"There is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating the disease or condition."

The data in this analysis seem to indicate there **are** "adequate and available alternatives for treating" COVID-19. If that is accurate, then these EUAs have questionable legality. [Note: *The only apparent reason IVM, etc. are not "approved" is that the FDA has arbitrarily and unscientifically chosen not to do that. See "B" to the right.*]

Further, if these FDA issued drug EUAs violate federal statutes, a closer examination of the FDA's COVID-19 vaccine EUAs seems warranted.

B) If yes, then why haven't HCQ and IVM also been given EUAs?

Considering the six takeaways on the prior page (plus the fact that there have been successful HCQ and IVM studies much larger (~10x) than those done for Paxlovid and Molnupiravir), *exactly why has the FDA not issued EUAs for IVM and HCQ?*

[Comparing the information on the table, there does not seem to be a scientific or health reason to justify the FDA not granting EUAs to both IVM and HCQ.]

If the FDA *had* granted EUAs for HCQ and IVM, a year ago, **literally hundreds of thousands of Americans would likely not have died.**

What FDA policy, procedure or precedent took priority over preventing hundreds of thousands of American deaths???