Goodman Institute
Turning Ideas Into Policy

In Pandemics, Old Drugs May Save Us

Imagine that a new pandemic hits and, sadly, you test positive. Luckily, we're better prepared this time and a widely used, safe, convenient pill priced at only $1 is available and can reduce your risk of death by 56%. Would you take it?

The FDA needs to stop being the roadblock to using older drugs for off-label therapies.

Actually, such a drug was available during this pandemic. It has been on the market for decades.

This drug and others like it were available at the start of COVID-19. Yet few of us knew about them or had them easily available as therapeutic choices. Why? These life-saving drugs were purposely and systematically ignored and, when not ignored, denigrated by the U.S. Food and Drug Administration, making them generally unavailable. If they had been widely available, and encouraged, hundreds of thousands of Americans might not have died unnecessarily.

While newer drugs are often better than older drugs, older drugs have something that newer drugs don't: they are cheap and widely available today. When a pandemic starts, they are all we have.

Since the pandemic started, some older drugs, vitamins, and minerals have been widely tested for therapeutic activity against COVID-19. Table 1 shows some of the key results. Mortality rates are shown because death is the most serious outcome, and yet these pills also prevent infections, help keep patients off mechanical ventilators, keep them out of the ICU and the hospital

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Table 1: Drugs, Vitamins, and Minerals Not FDA-Approved for COVID-19

Drug	Clinical Trials	Patients in Trials	Mortality Reduction	Price	Uses Before Pandemic	Available (Days into Pandemic)
Melatonin	6	1,730	67%	$1	Millions	1
Curcumin	5	485	59%	$5	Billions	1
Probiotics	5	889	59%	$5	Millions	1
Ivermectin	40	114,635	56%	$1	Billions	1
Colchicine	23	20,305	41%	$1	Billions	1
Vitamin D	42	31,987	37%	$1	Trillions	1
Zinc	13	12,308	35%	$1	Trillions	1
Vitamin C	22	15,816	29%	$1	Trillions	1
Hydroxychloroquine	199	303,887	23%	$1	Billions	1
Famotidine	11	68,556	16%	$5	Billions	1
Aspirin	31	59,333	15%	$1	Trillions	1

altogether, foster faster recoveries, and improve viral clearance. Their utility against this deadly virus has been tested in hundreds of clinical trials involving hundreds of thousands of patients. Moreover, their other attributes are clearly known after decades of use and many millions of doses.

The mortality reduction results in Table 1 are for treatment with these products at all stages of the disease. As can be expected, some drugs work better when given early while others work better when given later. For instance, aspirin prevented 15% of deaths but, when given to patients later, the number jumps to 27%. Vitamin D's 37% benefit jumps to 76% when taken early in the disease. Ivermectin appears to work best when consumed before people ever contract the disease so that its 56% benefit jumps to 90% when given prophylactically. If these results could be extrapolated to the entire American population, 90% of those who died from COVID in the last two years—hundreds of thousands—could have avoided that fate had they taken ivermectin before becoming infected.

Study the results for the drugs in Table 1, keeping in mind that the FDA will vigorously tell you *not* to use them. Table 2 lists the drugs that the FDA *will* tell you to consider.

Bamlanivimab/etesevimab and Regen-Cov do not work for the Omicron variant, which now accounts for virtually all current COVID-19 infections, and the FDA has withdrawn its approval except in those cases where patients are infected with older variants. Lagevrio is potentially unsafe.

The drugs in Table 1 are far cheaper, they had widespread use before the pandemic, and they were available from day 1. During the first 235 days of the pandemic, in fact, the choice was between the drugs in Table 1 and nothing.

Why does the FDA steer us away from the older drugs in Table 1? A bureaucratic mindset. The FDA doesn't have processes in place to evaluate older drugs for new uses in a timely manner, and so instead of coming clean, it fluctuates between ignoring the older drugs and actively disparaging them while threatening helpful companies that publish promising clinical results.

Table 2: Drugs FDA Approved for COVID-19

Drug	Clinical Trials	Patients in Trials	Mortality Reduction	Price	Uses Before Pandemic	Available (Days into Pandemic)
Paxlovid (nirmatrelvir)	1	2,085	96%	$700	Limited	661
Bamlanivimab & etesevimab	10	22,988	56%	$1,250	Limited	345
Lagevrio (molnupiravir)	3	1,901	50%	$700	Limited	662
Regen-Cov (casirivimab & imdevimab)	7	32,895	48%	$2,100	Limited	265
Xevudy (sotrovimab)	2	1,417	46%	$2,100	Limited	451
Veklury (remdesivir)	27	118,153	18%	$3,120	Limited	235

The FDA grants approval to a drug only after it judges the drug to be both safe and efficacious for a particular use. Once approved, that use is considered "on-label" for that drug. How does this work in practice? The drug's "sponsor" must give the FDA a comprehensive report that includes information about every aspect of the product, most notably clinical trial results. These reports are very expensive and take years to compile and, for drugs long since generic, no sponsor is likely to step forward. If one company goes through that expense, people could just as easily take another generic and so the expense is typically not worth bearing. With no sponsor, there is no FDA-approved indication, and no official recognition of effectiveness against COVID-19.

Worse, the FDA actively dissuades doctors and patients from using these older drugs for unapproved, "off-label" uses by saying that such usage could be dangerous. Why would they be dangerous? Because while the FDA approved them as safe for other conditions, it hasn't yet approved them as safe for COVID-19. Never mind that these drugs are legally marketed and have been used safely billions or even trillions of times. By what logic does a safe drug become dangerous when it's used for a new purpose? By the FDA's bureaucratic logic.

We have nothing against newer drugs; we are thrilled that Eli Lilly, Gilead, GlaxoSmithKline, Merck, Pfizer, and Regeneron, among others, have developed successful new drugs. We support old and new drugs alike. The more drugs on the market, the better the therapeutic choices for doctors and patients. However, there's an obvious and powerful point that has been missed: Early in any pandemic, our *only* hope is repurposed older drugs, discussed openly and prescribed off-label. For that to be done in a medically prudent and expedited manner—in other words, to save American lives better than we did during the last two years—the FDA needs to get out of the way. We need to change the FDA's rules in two primary ways: (1) prohibit the FDA from publishing dire warnings for the use of drugs for off-label uses unless that usage is clearly dangerous (in other words, follow the principle of innocent until proven guilty); and (2) allow all pharmaceutical companies to exercise their First Amendment rights and discuss information about off-label prescribing without fear of expensive FDA penalties.

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Pandemics, by nature, move quickly. Drug and vaccine development, especially when highly regulated, are slow. The problem moves faster than the solution. However, there's one good solution that's hidden in plain sight: older drugs. The first place to look for useful therapies during a pandemic is older, generic drugs. These drugs offer Americans the prospect of reduced morbidity and mortality while simultaneously being very cheap. We just need the FDA to cease being a roadblock.

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