The Paxlovid-only strategy: A “let them eat cake” response to the COVID-19 pandemic

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4 May 2022

“Paxlovid will remain a boutique treatment available to the well-to-do, but the majority of the working class will not be able to access it in time for it to be effective.”—Gregory Travis, health care expert and data scientist

If one thing characterized the annual dinner of the White House Correspondents’ Association that brought together 2,600 rich and famous people—establishment journalists, high-level politicians, including President Joe Biden, and Hollywood celebrities—it was their utter contempt for the impact of the pandemic on the American population. COVID-19 has killed more than one million, left more than 200,000 children orphaned, and has caused millions more to suffer from the debilitating post-acute sequelae of SARS-CoV-2 infection, better known as Long COVID.

The derision was most notably affirmed by comedian Trevor Noah, who knowingly quipped, “It is my great honor to be speaking tonight at the nation’s most distinguished superspreader event. No, for real, people. What are we doing here?” And unsurprisingly, CNN has confirmed that dozens of reporters and staffers have since tested positive for COVID-19. Yet, without any contact tracing and testing in place, health officials are relying on text messages, social media and emails being shared among attendees to place an estimate on the number infected.

The net worth of the attendees most likely places every one of them in the top one percent of the financial pecking order. What this means is that they all have premier access to first-rate health care, with their physicians on speed dial should they need various post-infection and anti-viral treatments.

Indeed, Vice President Kamala Harris’ use of Paxlovid after contracting asymptomatic COVID-19 only brought to light the class issues behind Pfizer’s highly effective anti-viral medication that has been touted as a magic bullet by the Biden administration. Some have questioned why Harris was given the medication when she is not deemed a medically high-risk individual. New York University Professor and medical ethicist Arthur Caplan said of the revelation, “It’s what I make of the American health care system— better to be rich and connected.”

Speaking for this layer, celebrity physician and *Washington Post* columnist Dr. Leana Wen recently told the *Wall Street Journal*, “We have many different ways of protecting ourselves at this point. People are going to choose different levels of protection based on their own tolerance of risk and how much they want to avoid COVID-19, and at this point, the role of government needs to be to empower people to use the tools that are readily available.”

The *Journal* said most succinctly, “Health officials are leaving it up to people to assess if they need booster shots, whether to wear a mask and how long to isolate after a positive test. Businesses, schools and other entities are scaling back specific guidelines as they prepare a return to normal.” And to achieve this normality requires the complete abandonment of all public health principles and any effort to enlist them in protecting the life and welfare of the population.

From the perspective of the well-fed and well-financed, it is easy to dispense opinions to the public that are analogous to the infamous saying associated with Queen Marie Antoinette during the French Revolution: “Let them eat cake!” Working people in America are no more likely to have access to high-priced drugs like Paxlovid than the starving population of 1789 Paris could obtain cake.

Over 30 million Americans are uninsured and another 70 million are underinsured, with high deductibles and large out-of-pocket expenses. Many may disregard their symptoms as another flu and risk waiting it out or fear repercussions at work for taking time off. Amazon recently announced that workers will no longer receive paid time off for COVID-19. The company added that it would not be sending out site-wide alerts about positive COVID-19 cases nor require masking at work.

In a report published in 2018 by the Commonwealth Fund, “41 percent of underinsured adults said they delayed needed care because of cost … [and] almost half report medical bill and debt problems.” And these are being compounded by the intensification of the inflationary pressures that are driving up costs for all basic goods and services. And this must be placed in the context that four in 10 adults, or approximately 93 million people, have risk factors for developing serious illness if infected with COVID-19.

Individuals at risk for severe COVID-19 include cancer patients, those with chronic kidney disease, prior stroke, chronic lung or liver disease, diabetes and obesity. Also at risk are those with immune deficiencies, heart conditions, mental health disorders, smokers, transplant patients and those who take corticosteroids or immunosuppressives.

What Dr. Wen fails to take proper account of is how limited the current tools are in fighting COVID-19. They come with major caveats that the mainstream press does little to bring to light, including the failure of current monoclonal antibodies, rapidly waning antibodies from existing vaccines, the continued waves of infection that propel the present versions of the Omicron variants towards even more contagious and immune-evading variants and concerns over development of viral resistance to Paxlovid and other treatments.

Though the immediate goal of holding the White House Correspondents’ Association gala was to disarm the concerns raised by COVID-19, the objective evidence demonstrates that the insane and cavalier policy of ignoring the pandemic, now being pursued by almost every country across the globe, is only exacerbating the dangers posed by allowing the virus to persist in human populations.

From vaccine-only to Paxlovid-only

One of the last elements in the shutdown of pandemic measures by the Biden administration has been the promise to ensure that post-infection

treatments and anti-viral medications are made readily available to the general public. This might be termed the "Paxlovid-only" strategy, a revival in even more threadbare form of the pragmatic vaccine-only strategy that has guided the Biden administration.

A recent study published in the *Lancet Respiratory Medicine* on the durability of Pfizer's mRNA vaccines against hospital and emergency department admissions for Omicron found that nine months after the original course of two doses, the vaccine was only 41 percent effective in preventing hospitalization and 31 percent effective in preventing death. A third dose raised effectiveness to 85 percent for both. But only three months after the third dose, effectiveness fell to 55 percent.

The share of fully vaccinated people in the US has remained static at 66 percent. Half the population was vaccinated back in mid-July 2021. By mid-January 2022, four months ago, 25 percent had received a booster. Vaccination has appeared to have reached an insurmountable barrier.

Concerns regarding the declining effectiveness of vaccines are intersecting with evidence of reduced efficacy of the current monoclonal antibodies against the subvariants of Omicron.

Presently, Evusheld's long-acting antibody combination—tixagevimab and cilagavimab—remains active against Omicron and is given as an intramuscular injection. Manufactured by AstraZeneca, it is authorized only as a prevention of COVID-19 for vulnerable populations who have medical conditions or are receiving immunosuppressive treatments and would not be able to mount an immune response with a COVID-19 vaccination. Additionally, individuals for whom COVID-19 vaccinations are not recommended for other reasons can receive the treatment.

In April the FDA removed its authorization for Sotrovimab, as it was found ineffective against the dominant BA.2 subvariant ending its nationwide distribution. Similarly, in January, both REGEN-COV and the combination treatment of Bamlanivimab and etesevimab were shown to be ineffective against BA.1, with the announcement by the FDA that they "were not currently authorized for use in any US region because of markedly reduced activity against the Omicron variant."

Only Eli Lilly's Bebtelovimab, authorized by the FDA in February, has been shown in-vitro to work against BA.1 and BA.2. However, real world data in the form of placebo-controlled trials is lacking.

This leaves Paxlovid as one of the main choices for treatment after mild to moderate infection to block the risk of severe disease. Remdesivir also remains in the limited arsenal, although it has proven over the course of multiple studies to be suboptimal.

Paxlovid is the brand name for Pfizer's anti-viral treatment for COVID-19. It contains two medications—Nirmatrelvir and Ritonavir—and was given emergency use authorization by the US Food and Drug Administration (FDA) for patients infected with the SARS-CoV-2 virus with mild to moderate symptoms at risk for severe disease or hospitalization.

Though the medication is taken orally, it requires a prescription by a licensed provider due to its extensive potential drug interactions. If taken within five days of symptom onset, it has shown to reduce the chance of hospitalization or death by about 88 percent. It is approved for those weighing over 40 kilograms (88 pounds) and aged 12 or more. Of note, recent prevention trials (involving exposure to someone with COVID-19 at home) did not significantly reduce infection rates.

The rollout of Paxlovid and "test-to-treat"

Last week the Biden administration said it had secured 20 million treatment courses of the Pfizer antiviral COVID-19 pill. Dr. Ashish Jha, the new White House COVID-19 Response Coordinator, told NPR, "Now we've got to turn those pills into prescriptions and into the things that patients can get so that they can get better if they get infected." However, a senior White House administrator said that without further funding, "We will not be able to purchase more."

Nearly all those seeking testing in the US are symptomatic. (Health expert and data scientist Gregory Travis said that 95 percent of the 70 million documented infections in the CDC database were listed as symptomatic.) This means, in the context of a very unhealthy population, most of those infected even mildly could derive some benefit from the anti-viral treatment.

But the supply is entirely inadequate for that purpose. And considering the scale of the effort to deliver these treatments to such a large population, with the tight time limits prescribed—five days or less from test to treat—and with the current rise in cases in the US, the only outcome that can be expected will be disorganization, chaos or even the abandonment of the effort entirely.

Speaking on the issue of access, *Politico* said, "Only physicians, physician assistants and certain registered nurses—not pharmacists—can prescribe the drug. That means patients may have to visit a testing site, a doctor's office and, in the worst-case scenario, visit a participating pharmacy just to get the pills." Added to this is the five-day window between symptom onset, testing and actual taking of the antiviral.

However, about a quarter of Americans do not have a primary care physician. And if they do, a return call can take several days when time is of the essence. Though the test-to-treat initiative sounds cogent on paper, a service map of nationwide locations by the Department of Health and Human Services shows many of them are concentrated in major metro regions.

And despite attempts to claim that treatments are plentiful, according to Travis there are roughly only 660,000 courses available. Because of lack of any real metric on the amount held at pharmacies across the country, Travis designed a tracker to list pharmacies' supplies of Paxlovid and other treatments, which can be accessed through this link. Based on the state and county, it provides an address to pharmacies in the region and the number of courses available to the antiviral treatment.

With Omicron BA.2 and its sub-lineage BA.2.12.2 rapidly spreading across the US, and with hospitalization rates climbing, even the *New York Times* has acknowledged that Paxlovid and other drugs are sitting on shelves because people do not know how to access them due to the inefficiencies in the process and inadequate messaging. People infected with COVID-19 do not know they are eligible, and overworked providers oftentimes read the eligibility guidelines very narrowly or raise concerns about the drug interactions as listed in the FDA packaging.

And though Paxlovid is currently free, there are consultation fees that customers must be able to pay at test-and-treat sites that are not included in the Biden program. Public health officials have also noted that appointments are difficult to get and can often require long drives to reach an available site.

The *Times* wrote, "test-to-treat is supposed to let people visit hundreds of qualified pharmacy-based clinics, community health centers and long-term care facilities across the country to get tested for the coronavirus and, if positive, receive Paxlovid on the spot. But almost two months later, it is still limited in its reach and has not dramatically sped up access to the drug beyond what its sites were already equipped to do, experts said."

Rebound infections and the limitations of anti-virals

These issues are being compounded by reports of rebound coronavirus levels after COVID-19 patients complete the five-day Paxlovid treatment.

Clifford Lane, the deputy director for clinical research at the National Institute of Allergy and Infectious Diseases (NIAID), told Bloomberg last week, “It is a priority! [The issue] is a pretty urgent thing for us to get a handle on.”

Little is currently understood about rebound cases—how frequently they occur and if the Omicron variant plays a role in it. Dr. Paul Sax, an infectious disease specialist at Brigham and Women’s Hospital, said, “providers who are going to be prescribing this should be aware that this phenomenon occurs, and if people have symptoms worsening after Paxlovid, it’s probably still COVID.” As these experts have noted, such information was not included in the drug labeling.

Immunologist Dr. Michael Mina explained in a Tweet that possibly Paxlovid acts as a crutch for the immune system by preventing the virus from replicating. If the virus rebounds after treatment, the immune system kicks in, leading to the reappearance of the symptoms of infection. He warned that if rebound occurs, then the person should consider himself or herself still infectious.

He wrote, “To be clear, this is not likely because the virus is becoming resistant, but rather an interaction between the immune system not having to work as much to clear the virus while on treatment, and so when treatment ends, the virus grows fast before immunity turns on again. In my view, this is a serious issue and one that may increase chance of a resistant mutation in a virus forming and spreading.” Health officials and Pfizer officials are considering increasing the length of treatment for high-risk individuals to 10 days.

The issue of resistance to Paxlovid was raised in January in *Nature*. The journal wrote about the success of the two antivirals that includes Merck’s less robust Molnupiravir antiviral, which reduced the risk of hospitalization and deaths by only 30 percent. *Nature* continued:

> “It’s too soon to tell whether SARS-CoV-2 is likely to develop any resistance to these first-generation antivirals,” says Tim Sheahan, a corona-virologist at the University of North Carolina at Chapel Hill. Although its sky-high rate of replication is a breeding ground for mutations, he says, the virus also caused acute infections that offer relatively little time for resistance-causing mutations to accumulate.

The journal then added:

> But the threat of resistance is particularly severe for monotherapies such as Molnupiravir and Paxlovid that each target only one part of the virus. That’s why it’s imperative to develop new antivirals aimed at different targets, or ones that can be combined into a single treatment to attack the virus on multiple fronts, says Sheehan.

The article then explains that if the antivirals do not destroy the virus lurking in the body or the medications are not taken as prescribed, the treatment could lead to the virus developing various defenses against the drug. Second generation broad-spectrum treatments will require significant time and investments that simply are lacking, though hundreds of billions are dollars are readily made available for the military destruction of human life and property.

A report from Rutgers in March 2022 on the fears of developing resistance in SARS-CoV-2 against such treatments noted that though Paxlovid still remained effective, “scientists discovered through genetic analysis that the virus is beginning to evolve in ways that may produce strains that can evade present treatments.”

The key protein that Paxlovid targets which jams the virus’s machinery is called Mpro, which the virus uses in replicating. The most common new mutation found in the main protease of the Omicron variant is called the P132H mutation. Though Paxlovid remained effective against Mpro with the P132H mutation, Dr. Jun Wang, author of the study on the P132H mutation, said, “Although this mutation does not cause drug resistance to Paxlovid, this implies that the virus can still evolve to create additional mutations that might cause drug resistance. When a drug gets widespread use, it is just a matter of time before resistance appears.”

BA.2.12.1, a descendent of the BA.2 subvariant of Omicron, now accounts for more than 30 percent of all recently sequenced strains. In New York, where hospitalizations are up, it accounts for 58 percent. Meanwhile, the BA.4 and BA.5 subvariants, more infectious than BA.2, which are causing the fifth wave of infections in South Africa, have also been recently detected in the US.

Deborah Birx, former White House coronavirus taskforce member in the Trump administration, said on CBS’s “Face the Nation,” on Sunday that the US should prepare for another surge in cases this summer due to the natural waning of immunity.

As evidenced by the White House Correspondents’ Association dinner, there is little interest on the issues surrounding the COVID-19 pandemic as all the necessary measures have been put into place to ensure schools, businesses and financial markets operate undisturbed.

The current Paxlovid-only strategy, the latest iteration of the overarching construct of malign neglect, poses serious dangers to the working class population. Entering the third year of the pandemic, the dangers posed by the virus have only been heightened.

As detailed in these findings, without an elimination strategy the war against the pandemic will never end and the current available treatments will be exhausted. These life-saving treatments were never intended nor can they stand alone against a virus that has nimbly evaded every defense put in front of it. The only one that has proven effective has been demonstrated by China in its current effort, and that is Zero-COVID.