

Two items of significance occurred after the Briefing was sent earlier which I did not think should wait until after Christmas.

Ed

Paxlovid FDA EUA Approval

As predicted, FDA gave EUA for approval for Paxlovid. The authorization today permits doctors to prescribe the medicine to high-risk patients age 12 and older early in the course of disease. Paxlovid is expected to be available at pharmacies and hospitals in the coming week, however, initial supplies will be limited, until Pfizer can ramp up production.

Pfizer will ship tens of thousands of treatment courses in the U.S. before the end of this year, and hundreds of thousands at the start of 2022. . The US government has agreed to pay \$5.29 billion to purchase 10 million treatment courses that Pfizer will deliver by the end of next year.

The authorization comes after studies found Paxlovid was safe and cut the risk of hospitalization or death by about 89% if people at high risk of severe Covid-19 took the pill within three days of diagnosis. To remind everyone Paxlovid is taken with another drug ritonavir. Drug interactions will need to be reviewed.

Comment: This is great news, but it will take a while to get supplies to match demand and you will need a positive test in a timely manner. Given current testing capabilities, this is easier said than done.

Two Studies Show Hospitalization Risk with Omicron Significantly Lower

New data from Scotland and South Africa suggest people infected with Omicron are at lower risk of hospitalization than those who contracted earlier variants of the virus including Delta.

The Edinburgh study, reviewed the health records of 5.4 million people in Scotland, found the risk of hospitalization with Covid-19 was two-thirds lower with Omicron than with Delta. In a separate study published online by investigators at South Africa's National Institute for Communicable Diseases similarly found people infected with Omicron were 70% to 80% less likely to need hospital treatment than people infected with earlier variants, including Delta. [medRxiv 12.21.21] The risk of severe complications in those who were admitted to hospital, such as needing oxygen or intensive care, was also reduced with Omicron compared with other variants.

Comment: These new studies shed light on the severity of illness Omicron causes. Both Scotland and South Africa's infected population arose in people between 20 and 59 years old and is younger on average than the US and Europe. The combination of increased risk of transmission and immune evasion of Omicron mean that even reduced hospitalization could potentially still be impacted by increased rates of infection in the community. More data is needed to confirm these findings.