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August 15th, 2021

Dear Regina,

Welcome to BioMarketing Insight's monthly newsletter.

With the surge of the Delta variant, health officials are recommending that everyone wear a mask, even the vaccinated when they are indoor or outdoor. This month I will cover "Why Vaccinated People Need to Wear Masks".

Last month's topic was "Why Ransomware Attacks are on the Rise and Are Life Sciences Companies Prepared?" If you missed last month's newsletter, click [here](#) to read my article.

"One Biotech Executive's View on the COVID-19 Vaccine" was published in the *Lioness Magazine* for entrepreneurs. To read my article, click [here](#) to go to the Table of Content.

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difficult time, click on the "[Inspiration](#)" link to give yourself a few minutes to relax and enjoy the music from the Berklee School of Music in their song "What the World Needs Now," other inspirations and ending with Celine Dion and Josh Groban with "The Prayer".

Please read on for other current news in the Table of Content below. The next newsletter will be published on September 15th, 2021.

We encourage you to share this newsletter with your colleagues by using the social media icons below, or by simply forwarding this newsletter or use the link below. Should you or your colleagues want to join my mailing list, click on "join my email list" link below.

Please email [me](#), Regina Au, if you have any questions, comments, or suggestions.



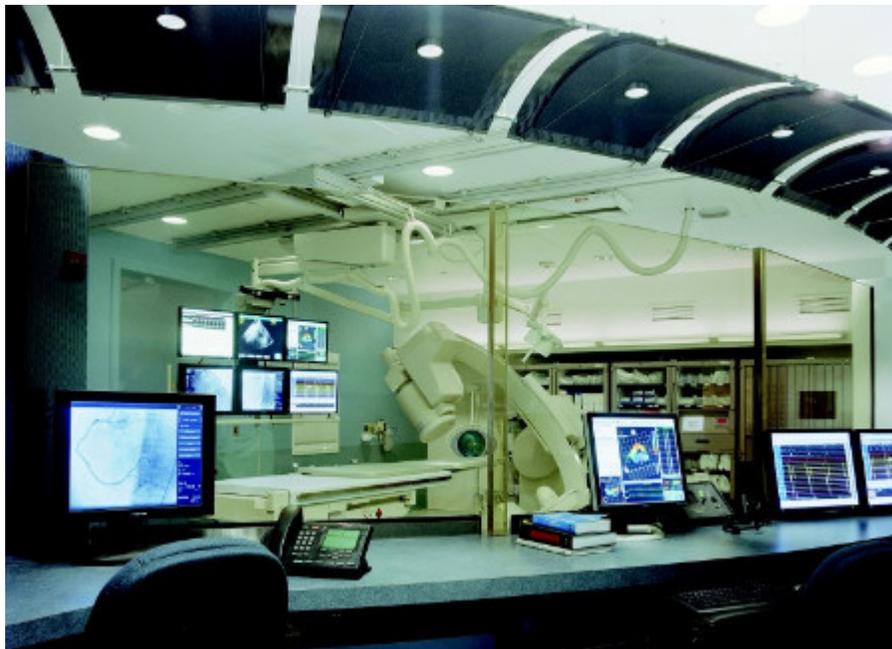
Sincerely,
Regina Au
CEO, New Product Planning/Strategic Planning
[BioMarketing Insight](#)



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For more information on our services, click on the links below:

[Product Development](#)[Market Development](#)[Marketing Strategies](#)[Scenario Planning](#) - for more information, email [me](#).



Fresh Thinking in the Next Normal

I am pleased to announce that I will be presenting at the Institute of Management Consultants event on "What Will the "Next Normal" Be for Productivity, Motivation and Retention of Employees? Four Things Employers Need to Consider." on July 20th, 2021 at 2 pm. For more information and to register click [here](#).

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Inspirations

Enjoy the song "What the World Needs Now" virtually with the students from the Berklee School of Music.



We Will Get Through It Together

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Let's End with Celine Dion & Josh Groban Singing "The Prayer"

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Lioness
FOR THE FEMALE ENTREPRENEUR

One Biotech Executive's View on the COVID-19 Vaccine

I am pleased to announce that my article on the COVID-19 Vaccine was published in Lioness Magazine. To read my article click on the link [here](#).

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美国华人生物医药科技协会

CBA BOSTON CHAPTER KICK-OFF EVENT



INNOVATION 2021:
Lessons Learned in the Pandemic and the Opportunities Afterward
FEBRUARY 20, 2021

8:45 AM - 1:00 PM (EST) ; 9:45 PM - 2:00 AM (Beijing China Time)

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- 8:45-9:00 AM - CBA-USA Boston Chapter Kick-off
- 9:00-9:30 AM - Challenge & Opportunity in US-China Collaboration during and post-pandemic
- 9:30-10:00 AM - An investor's view of the life science capital market in China
- 10:00-11:00 AM - COVID-19 testing and vaccination market insights in US
- 11:00-11:30 AM - The overlooked high-risk group screening needs
- 11:30-12:00 PM - FDA review insights and COVID-19 EUA applications for diagnostic products
- 12:00-12:45 PM - Diagnostics of sales marketing strategies and organization health
- 12:45-1:00 PM - CBA-USA Boston Chapter Operation Plan for Programs and Seminars in 2021

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LIANG YU



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ALEX LI



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February 20, 2021 - Chinese BioPharmaceutical Association:
 Innovation 2021

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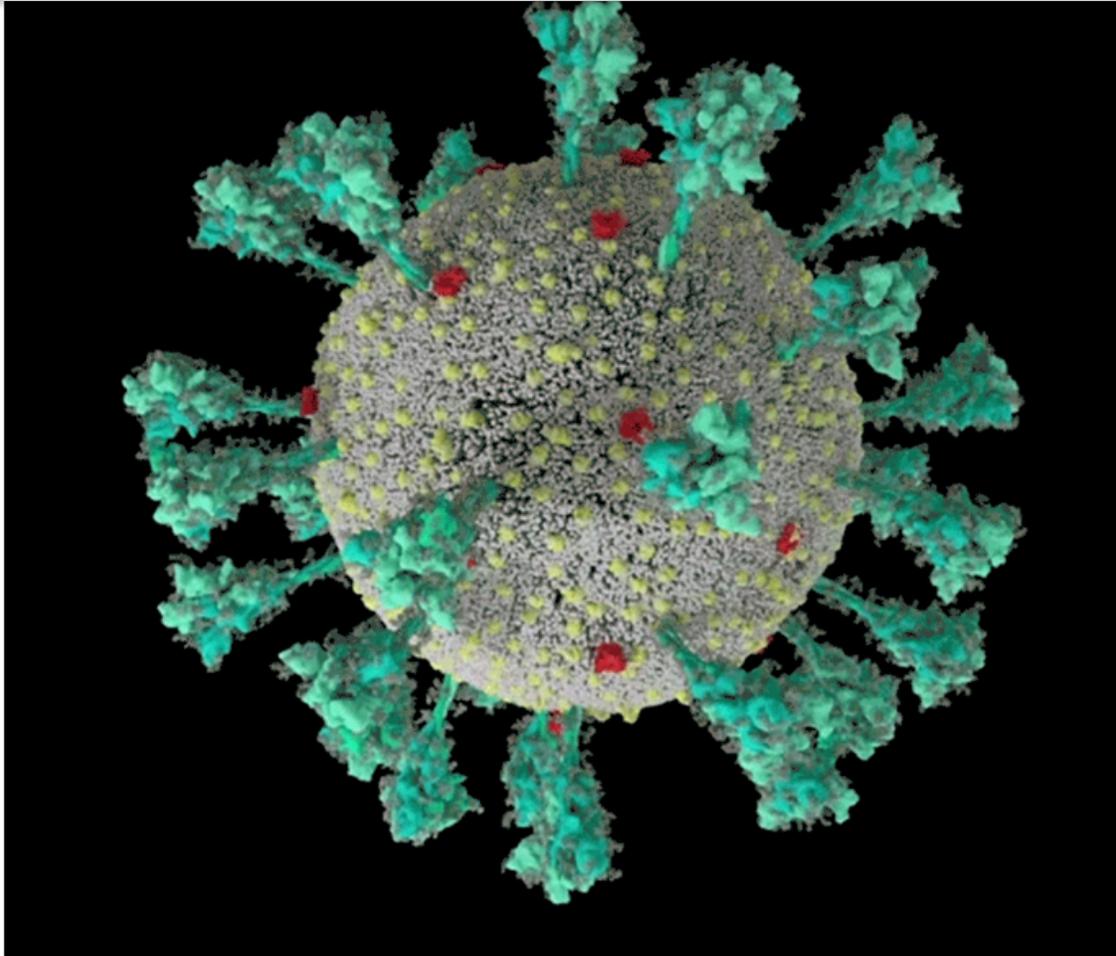
Association USA on Feb. 20, 2021. The theme of the event is "Innovation 2021: Lessons Learned in the Pandemic and the Opportunities Afterwards". My presentation will be on COVID-19 Testing and Vaccination Market Insights in US. For more information click on this [link](#).

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Another Crisis is Brewing

I am pleased to announce that my article "Another Crisis is Brewing" has been published in the European Biopharmaceutical Review's October 2020 issue. To read this article click [here](#) and go to page 16.

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Why Vaccinated People Need to Wear Masks

Source: Janet Iwasa, University of Utah

In June 2021, due to the surge of the Delta variant, the World Health Organization ([WHO](#)) "urged fully vaccinated people to continue to wear masks, social distance and practice other Covid-19 pandemic safety measures as the highly contagious delta variant spreads rapidly across the globe."

"People cannot feel safe just because they had the two doses. They still need to protect themselves," [Dr. Mariangela Simao](#), WHO assistant director-general for access to medicines and health products, said during a news briefing from the agency's Geneva headquarters.

"Vaccine alone won't stop community transmission," Simao added. "People need to continue to use masks consistently, be in ventilated spaces, hand hygiene ... the physical distance, avoid crowding. This still continues to be extremely important, even if you're vaccinated when you have a community transmission ongoing."

The CDC and California governors followed up with recommending that everyone wear a

[Houston Methodist Hospital System](#) in Texas was the first healthcare system to mandate vaccination of their employees. One hundred employee's sued the hospital for this mandate and a Texas Federal Judge upheld the requirement because it is legal to mandate vaccination for employment. Following the Federal decision 153 Houston Methodist employees have resigned or were fired for refusing COVID-19 vaccination.

Other healthcare systems such as Mass General Brigham, Beth Israel Lahey, Wellforce, Tufts, Harvard Pilgrim, Trinity Health and the list goes on have all followed suit by requiring vaccination for employment because it is imperative that vulnerable patients who are critically ill or immuno-compromised be protected.

Since then, seven (7) [infectious disease organization](#) have mandated mask among healthcare professionals with no exceptions. Those who may have medical reasons may delay getting vaccinated, but they still need to get vaccinated when it is safe:

- The Society for Healthcare Epidemiology of America (SHEA)
- AMDA – The Society for Post-Acute and Long-Term Care Medicine
- The Association for Professionals in Infection Control and Epidemiology
- The Infectious Diseases Society of America
- The HIV Medicine Association
- The Pediatric Infectious Disease Society
- The Society of Infectious Disease Pharmacists

The [National Nurses United](#) have called on the CDC to reinstate masks with the spike in Delta cases.

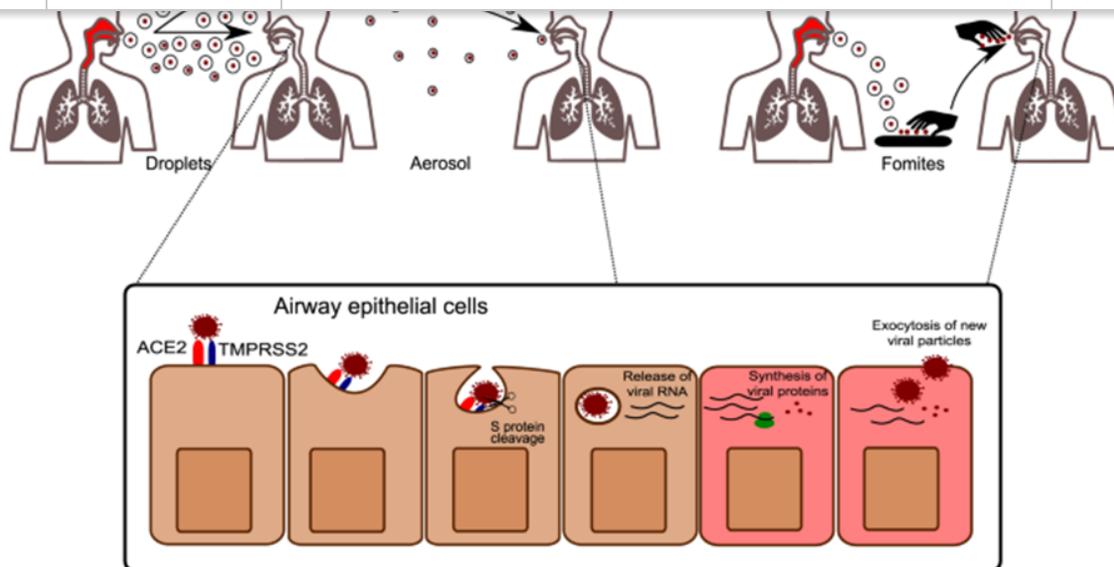
Why are health officials recommending mask to vaccinated people when the CDC fist said that vaccinated people are protected and don't need to wear mask both indoor and outdoor?

To answer this questions, for those who are not in the field, we have to look at the Delta variant in detail as scientists are still learning about the emerging variants and mutations. As new information comes to light, they may have to revise their recommendation. This is one example of such circumstances.

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COVID Respiratory Transmission and Infection

Source: Nature, Gallo et al, 11.26.20

Major Mode of Transmission

To recap, the major mode of transmission for SARS-CoV-2 to spread or transmit from one person to another is aerosol or through the air. It was previously thought that when someone sneezes or coughs, the droplets or fomites carries the virus and if it gets on you and you touch your face, you can contract COVID-19. Now, since we know it is aerosol, when one talks or breaths, tiny microscopic viruses can be inhaled by other people if that person is in close proximity. The longer you are with an infected person, the more you are exposed to the virus leading to a greater risk of being infected. By wearing a mask, it helps to prevent the virus from spreading from the infected person to an unaffected person as recommended by healthcare officials.

The Delta Variant

Scientists have discovered that an infected person with the Delta variant has a viral load (amount of the virus) that can be up to [1,260 times higher](#) than an infected person with the original variant. This raises the risk of contracting the virus significantly by the sheer number of virus.

The peak viral load of someone infected is right before they have symptoms and therefore, that person is unknowingly infecting other people. The incubation time, period before symptoms is anywhere from 5-7 days for the original variant. If an infected person is asymptomatic, that person could be infecting other people unknowingly for weeks.

The [Delta virus](#) incubation time is "first detectable in people with the Delta variant four days after exposure, compared with an average of six days among people with the original strain, suggesting that Delta replicates much faster." The combination of shorter

spreading so quickly.

This also makes contact tracing more difficult due to the shorter incubation time. For large crowds with unvaccinated people not wearing mask, the exposure can lead to super-spreading events.

The Delta variant is also more virulent than the earlier variants as unvaccinated younger (17 y.o to 40 y.o) people who are infected are being hospitalized at a higher rate.

Why Vaccinated People Need to Wear Masks

For those who are vaccinated the CDC originally said, these people didn't have to wear masks indoor or outdoor and one may be thinking, why do I have to wear masks? I'm protected and even if I do get the virus, it will be a mild case.

While those who are vaccinated are protected, the vaccine is not 100% protection which is why we are seeing breakthrough infection with the vaccinated who are not wearing masks. A good analogy would be you fighting 1,000 soldiers. You can fight off a lot of the soldiers but you may not be able to fight off all of them. And while you may not be hospitalized or die from the virus, you can spread the virus to your loved one. If they are unvaccinated they have a greater risk of being hospitalized or dying.

How can vaccinated people spread the virus? If you are infected and lucky enough not to get sick, you may be carrying up to 1,000x more virus and talking or breathing can spread the virus. Everyone has ACE2 receptors in their nasal cavity or nose where the virus attaches itself to infect you. When you breath, the virus will more on to infect another person.

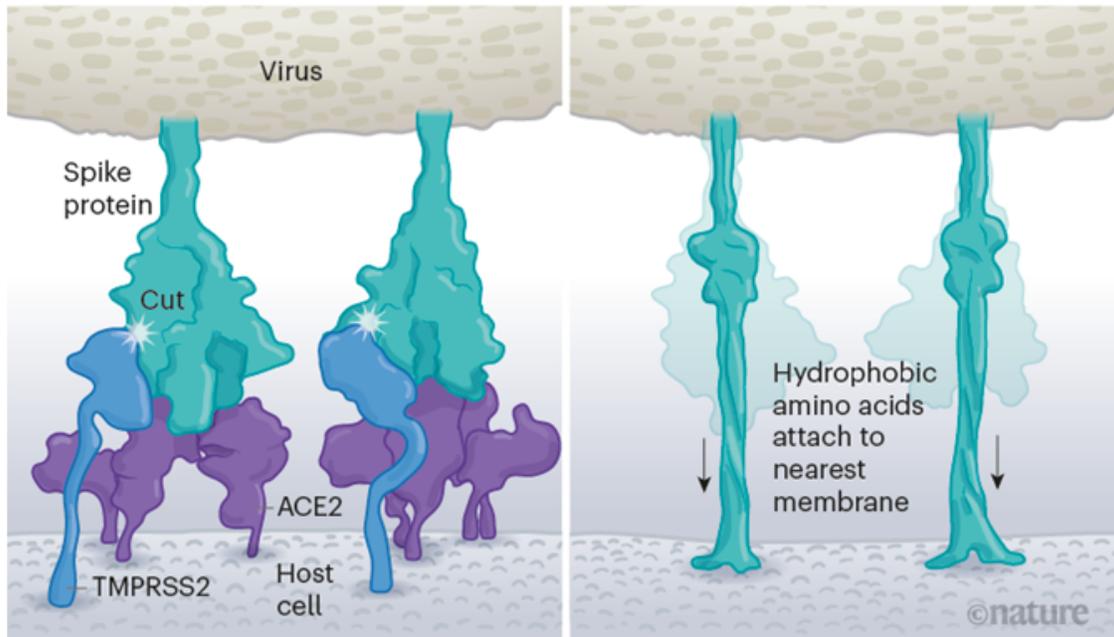
Some people may be thinking, I got the vaccine, I should have antibodies to kill the virus in my nasal cavity. Our body produces internal and external antibodies. When we get vaccinated, we produce internal antibodies, IgG and IgM which is what we get test for to see if we have immunity.

However, our body produces external, IgA antibodies in our nasal cavity. Scientist don't know if external, IgA antibodies will kill the virus because the viral load was low with the original variant and why Dr. Fauci stated that the spread of the virus with a vaccinated person is low. In a internal unpublished [CDC study](#) from a third party outbreak investigation, it revealed that vaccinated individuals infected with the delta variant may be able to transmit the virus as easily as those who are unvaccinated because vaccinated people infected with delta have measurable [viral loads](#) similar to those who are unvaccinated and infected with the variant.

This data caused the CDC to change their mask requirements recommending that

VIRAL ENTRY UP CLOSE

Virus and host-cell membranes fuse after the TMPRSS2 enzyme cuts a SARS-CoV-2 spike protein. This exposes hydrophobic amino acids in the spike that rapidly embed themselves into the nearest membrane — that of the host cell.



Viral Entry Up Close

Source: Janet Iwasa, Univ. Utah

Breakthrough Infections

Getting the vaccine and building up antibodies helps to protect people from contracting COVID-19. However, the vaccine is not a 100% protective and depending on how healthy a person's immune system is, will determine whether a person is protected and a very small percentage can get infected with the original or alpha variant. If a person does get infected, they will usually have a mild case and the vaccine helps to prevent hospitalization and death compared to no vaccine.

Here are what experts are saying about the Delta variant. The Delta variant being 60% more transmittable, "...does not have some of the mutations seen in other variants that can help the virus evade antibodies. But the delta floods the zone. It grows so quickly in the nose that it may be overwhelming the body's vaccine-enhanced defenses before the immune system can marshal a robust response," said [William Hanage](#), an epidemiologist at the Harvard T.H. Chan School of Public Health.

"The immune response, once activated, takes a while to kick in even among people who have been vaccinated," Hanage said. "As a result if the virus can copy itself really quickly it might be able to get a few rounds of replication in, even in vaccinated folks, before the

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The [Singapore Ministry of Health](#) recently found that three-fourths of coronavirus cases in the past four weeks were in people who were fully or partially vaccinated, most with no or mild symptoms. And in India, vaccinated health-care workers showed high viral loads when infected with the delta, according to a study from University of Cambridge researchers that is not yet peer-reviewed.

The variant's fitness advantage could feasibly allow it to build up a high viral load before vaccinated immune systems crank out enough antibodies to quash it, says [Hana Akselrod](#), an infectious disease physician at George Washington University.

Anatomically speaking, it's possible that while antibodies induced by current vaccines form high, protective levels in the lungs—where infection is associated with severe COVID-19 symptoms—they might be less able to access mucosal tissues in the nose and upper respiratory tract, allowing viral replication to occur there, virologist [Paul Bieniasz](#) of Rockefeller University speculates.

[Richard Kennedy](#), an immunologist at the Mayo Clinic in Rochester, Minnesota speculates that the variant replicates faster inside cells or binds more tightly to human cells' ACE2 receptor, which the virus's spike protein uses to enter cells

[P681R](#), a mutation on the Delta variant which lies at the junction between two subunits of SARS-CoV-2's spike protein, allows the human cellular enzyme furin to cleave the spike into two parts. This [cleavage](#), essential for S-protein-mediated cell-cell fusion and entry into human lung cells could prime the spike proteins in a way that allows them to fuse more readily with a host cell's membrane.

The P681R mutation [seems to allow](#) that cleavage to occur more efficiently than in the original SARS-CoV-2 strain and could help the variant to infect more cells in a given amount of time and replicate more copies of itself. "Having a more efficient furin cleavage site could lead to increased amounts of virus in the respiratory tract," said [Bieniasz](#).

Studies have found that the Delta variant reduces the ability of antibodies to neutralize the virus by around 2.5-fold compared to a previously described isolate—slightly more so than the Alpha variant but not as much as the Beta variant (B.1.351) first discovered in South Africa or the Gamma variant (P.1) first spotted in Brazil says [Hana Akselrod](#), an infectious disease physician at George Washington University.

Will Lambda, the Next Variant be Worse?

Viruses will naturally mutate and as each variant is developed, the virus tends to be more transmittable and possibly a cause a more severe infection. The "lambda" variant is gaining the attention of health officials as it spreads around the world.

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and named it lambda. VOI means the variant is increasingly showing up in communities and has mutations that are predicted to have some effect on viral characteristics, such as increased transmissibility.

Lambda has been detected in 29 countries, with high levels of spread in South American countries. Most recently, lambda variant has been detected in 81% of COVID-19 cases in Peru that underwent genetic sequencing, and in Chile, the variant was detected in about one-third of cases, according to the [WHO](#).

Officials are monitoring Lambda because it has seven mutations in the virus's "spike protein" compared with the original strain of SARS-CoV-2 detected in Wuhan, China, having the potential to cause the variant to be more transmissible or reduce the ability of certain antibodies to neutralize, or inactivate the virus according to the WHO.

One of the mutations was identified as [F490S](#) located in the spike protein's receptor-binding domain (RBD), where the virus first docks onto human cells, as a possible "vaccine escape mutation" that could make the virus more infectious and disrupt the ability of vaccine-generated antibodies to recognize the variant.

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Closing Thoughts

We are in the midst of a Delta surge where the number of new infections and hospitalization are approaching levels to where we were before the peak of the pandemic. Health experts have stated, that the only way to curb the pandemic is to get vaccinated

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I can't believe nor understand after everything we've (the world) been through, why people still won't get vaccinated or wear a mask. This is a health crisis, it's not political nor against anyone's constitution. These vaccine resistant people or hold-outs are not rational and no matter how many statistics one presents or pleas with these people, they won't get the vaccine. The more we pushed, the more they resist.

Since people can't be trusted to do the right thing, I applaud President Biden for mandating that all federal workers be vaccinated or be tested on a regularly basis and wear a mask at all times. This mandate also extends to all military personal.

I also applaud the healthcare systems for mandating all employees be vaccinated for the safety of their patients. And employers who are mandating vaccination to keep their employees safe.

In Massachusetts, some City and Town officials are currently mandating that everyone wear a mask indoors as the cases of the Delta variant rises exponentially as it did in Provincetown. And **still** there are people who refuse to get vaccinated and business owners complaining that they think it is unfair to have a mask mandate because they feel they will lose customers or don't want to enforce the mask mandate. These business owners are obviously not thinking about the safety of their patrons.

Massachusetts has one of the highest vaccination rates nationwide, yet we are only have 64% of the population fully vaccinated. We have a significant number of vaccine hesitant and vaccine holdouts blocking the goal of herd immunity (80-85%) according to epidemiologists.

While vaccine holdouts are refusing to take the vaccine, we have countries especially developing countries that want the vaccine but can't get the vaccine. My philosophy is instead of trying to convince these holdouts to take the vaccine and having vaccines expire or wasted, it would be better served to give the vaccine to the other countries who want it. Healthcare professional are still working on the vaccine-hesitant people.

These holdouts will suffer the consequences of contracting COVID-19 or having their loved ones contract COVID and risk the chance of hospitalization or even death. Unfortunately, sometimes it takes a tragedy for them to wake up and realize that they need to take the vaccine. We are now seeing this scenario play out for unvaccinated people who have been hospitalized saying they should have gotten the vaccine and are now advocating for others to get the vaccine. One pediatrician commented that her young hospitalized patients were begging for the vaccine and all she could say was "it's too late".

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