Health Freedom Louisiana
3301 17th Street #7443
Metairie, LA 70010
info@healthfreedomla.org

October 14, 2021

Dr. Courtney Phillips, Secretary
Louisiana Department of Health
P.O. Box 629
Baton Rouge, LA 70821-0629
Via email: courtney.phillips@la.gov

Dear Dr. Phillips,

The current COVID-19 vaccination requirements approved by the Louisiana Department of Health (LDH) for colleges and universities are not in compliance with the law, RS 17:170.[1]

First, section A(1)(a) specifies that "each person entering any school within the state for the first time, including...colleges, universities...at the time of registration or entry shall present satisfactory **evidence of immunity** to or immunization against vaccine-preventable diseases according to a schedule approved by the office of public health, Louisiana Department of Health, or shall present evidence of an immunization program in progress."

While the statute provides that colleges and universities "may require immunizations or proof of immunity *more* extensive than required by the schedule approved by the office of public health," it does not say that they can accept anything *less*. To date, Louisiana colleges and universities have excluded "evidence of immunity" to SARS-CoV-2 despite the growing body of evidence that prior immunity is not only robust but more so than that conferred by vaccination. ***See Appendix A.***

Second, RS 17:170 is specific to diseases that are **vaccine-preventable**. Emerging data suggests that LDH's approval of COVID-19 vaccination for college and university admittance was premature as the vaccines do not prevent transmission or infection of SARS-CoV-2. ***See Appendix B.*** The clinical trials for the COVID-19 vaccines available in the U.S. were not designed to determine if they prevented transmission or infection, and it was declared in all three FDA Briefing Documents that effectiveness against transmission of SARS-CoV-2 was unknown.[2] [3] [4]

In addition, communication from LDH as late as May 13, 2021, indicated that "there are limited data to address whether the vaccine can prevent transmission of the virus from person to person," (see addendum) and yet colleges and universities were still granted approval to add COVID-19 vaccines to the required list for admissions. The Centers for Disease Control (CDC) has since confirmed that not only can vaccinated individuals transmit SARS-CoV-2, but they can be infected with

[1] https://legis.la.gov/Legis/Law.aspx?d=79952
[2] https://www.fda.gov/media/144245/download Section 8.2
[3] https://www.fda.gov/media/144434/download Section 8.2
[4] https://www.fda.gov/media/146217/download Section 8.2

SARS-CoV-2, as well.[5] In fact, the current statewide mask mandate in Louisiana was prompted by this data, which was reported to the CDC in late July. As stated by Governor John Bel Edwards in a press conference on August 2, 2021,

> "Based on recent CDC data, **vaccinated people who do get infected have just as much virus in their systems as unvaccinated people**, meaning they can likely spread the virus simply because of the power of the Delta variant." The Governor's top health advisor, Dr. Joseph Kanter, added: "[I]f you are fully vaccinated and do become infected, then you can still relatively transmit the virus" and that "you will have just as much virus in your body as the early days of the pandemic as someone who was unvaccinated."[6]

If vaccinated people can transmit and be infected by SARS-CoV-2, and if vaccinated individuals can have as much virus in their bodies as an unvaccinated individual, then COVID-19 is not a vaccine-preventable disease.

Third, according to RS 17:170(F), the only consequence of submitting an exemption to vaccine requirements for school attendance is possible exclusion from school attendance during an outbreak of a vaccine-preventable disease. As stated above, COVID-19 is not a vaccine preventable disease, therefore vaccination for COVID-19 should not be a requirement for school admittance, which would eliminate exclusion from school attendance of unvaccinated individuals in the likelihood of another outbreak.

Finally, RS 17:170(F) offers the *only* consequence for submitting an exemption for vaccine requirements for school attendance: exclusion from school attendance during an outbreak of a vaccine-preventable disease.***Additional testing or masking of unvaccinated individuals is therefore in direct violation of RS 17:170,***as well as RS 40:1159.7,[7] which states:

> "Nothing contained herein shall be construed to abridge any right of a person eighteen years of age or over to refuse to consent to medical or surgical treatment as to his own person,"

and Louisiana Constitution, Article I, § 5[8] which states in part:

> "Every person shall be **secure in his person**, property, communications, houses, papers, and effects against unreasonable searches, seizures, or **invasions of privacy."**

As a reminder, RS 29:736(D)[9] states that even while under a declared public health emergency:

> "Nothing in this Chapter [on emergency powers] shall be interpreted to diminish the rights guaranteed to all persons under the Declaration of Rights of the Louisiana Constitution or the Bill of Rights of the United States Constitution. This Chapter shall not violate Article II (Distribution of Powers), Article III (Legislative Branch), or Article V (Judicial Branch) of the Louisiana Constitution."

The race to vaccinate Louisiana college and university students created chaos for students and parents who reached out to Health Freedom Louisiana. Letters and emails to students from universities excluded vital information regarding available exemptions and included burdensome and discriminatory testing and masking policies for those who did not comply. Unethical incentives like lotteries and direct payments, as well as limitations on freedom of movement and exclusion from Greek life and athletic events, were used to coerce students into getting this invasive medical procedure. These are serious human rights violations that need to be addressed. *Coercion* has no place in medicine or public health. History has taught us this valuable lesson and yet despite universal treaties dedicated to medical ethics,[10] [11] the "greater good" argument was used to violate the God-given right of every Louisiana citizen to receive***free and informed consent*** for an invasive medical procedure.

---

[5] https://www.cdc.gov/mmwr/volumes/70/wr/mm7031e2.htm
[6] https://www.youtube.com/watch?v=UzxWZ8qe0oU
[7] https://legis.la.gov/Legis/Law.aspx?d=964703
[8] http://www.legis.la.gov/legis/Law.aspx?d=206295
[9] https://legis.la.gov/Legis/Law.aspx?d=85685
[10] https://history.nih.gov/display/history/Nuremberg+Code
[11] http://portal.unesco.org/en/ev.php-URL_ID=31058&URL_DO=DO_TOPIC&URL_SECTION=201.html

The approval granted by LDH for colleges and universities to require COVID-19 vaccination for school attendance needs to be rescinded, as COVID-19 does not fit the definition of a "vaccine-preventable disease." Discriminatory practices based upon COVID-19 vaccination status needs to end immediately. Students and parents need to be provided with accurate information on the risks associated with SARS-CoV-2 infection by age group in comparison to the risks associated with COVID-19 vaccination by age group. Vaccination, like any other medical procedure, should be an individual choice with no societal or political pressure.

Regards,
Jill Hines et al
Co-Director
Health Freedom Louisiana

Cc: Governor John Bel Edwards, adam.eitmann@la.gov, alicia.williams@la.gov
Attorney General Jeff Landry, murrille@ag.louisiana.gov
Members of the Louisiana State Legislature via email

Appendix A: Natural Immunity

Taken from: Natural Immunity and Covid-19: Twenty-Nine Scientific Studies to Share with Employers, Health Officials, and Politicians[12]

One-year sustained cellular and humoral immunities of COVID-19 convalescents, by Jie Zhang, Hao Lin, Beiwei Ye, Min Zhao, Jianbo Zhan, et al. Clinical Infectious Diseases, October 5, 2021.

> "SARS-CoV-2-specific IgG antibodies, and also NAb can persist among over 95% COVID-19 convalescents from 6 months to 12 months after disease onset. At least 19/71 (26%) of COVID-19 convalescents (double positive in ELISA and MCLIA) had detectable circulating IgM antibody against SARS-CoV-2 at 12m post-disease onset. Notably, the percentages of convalescents with positive SARS-CoV-2-specific T-cell responses (at least one of the SARS-CoV-2 antigen S1, S2, M and N protein) were 71/76 (93%) and 67/73 (92%) at 6m and 12m, respectively. Furthermore, both antibody and T-cell memory levels of the convalescents were positively associated with their disease severity."

Comparing SARS-CoV-2 natural immunity to vaccine-induced immunity: reinfections versus breakthrough infections, by Sivan Gazit, Roei Shlezinger, Galit Perez, Roni Lotan, Asaf Peretz, Amir Ben-Tov, Dani Cohen, Khitam Muhsen, Gabriel Chodick, Tal Patalon. MedRxiv, August 25, 2021.

> "Our analysis demonstrates that SARS-CoV-2-naïve vaccinees had a 13.06-fold increased risk for breakthrough infection with the Delta variant compared to those previously infected, when the first event (infection or vaccination) occurred during January and February of 2021. The increased risk was significant for a symptomatic disease as well…. **This analysis demonstrated that natural immunity affords longer lasting and stronger protection against infection, symptomatic disease and hospitalization due to the Delta variant of SARS-CoV-2, compared to the BNT162b2 two-dose vaccine-induced immunity.**"

[12] brownstone.org/articles/natural-immunity-and-covid-19-twenty-nine-scientific-studies-to-share-with-employers-health-officials-and-politicians/

Shedding of Infectious SARS-CoV-2 Despite Vaccination, by Kasen K. Riemersma, Brittany E. Grogan, Amanda Kita-Yarbro, Gunnar E. Jeppson, David H. O'Connor, Thomas C. Friedrich, Katarina M. Grande, MedRxiv, August 24, 2021.

> "The SARS-CoV-2 Delta variant might cause high viral loads, is highly transmissible, and contains mutations that confer partial immune escape. **Outbreak investigations suggest that vaccinated persons can spread Delta.** We compared RT-PCR cycle threshold (Ct) data from 699 swab specimens collected in Wisconsin 29 June through 31 July 2021 and tested with a qualitative assay by a single contract laboratory. Specimens came from residents of 36 counties, most in southern and southeastern Wisconsin, and 81% of cases were not associated with an outbreak. During this time, estimated prevalence of Delta variants in Wisconsin increased from 69% to over 95%. Vaccination status was determined via self-reporting and state immunization records."

Necessity of COVID-19 vaccination in previously infected individuals, by Nabin K. Shrestha, Patrick C. Burke, Amy S. Nowacki, Paul Terpeluk, Steven M. Gordon, MedRxiv, June 5, 2021.

> "Individuals who have had SARS-CoV-2 infection are unlikely to benefit from COVID-19 vaccination, and vaccines can be safely prioritized to those who have not been infected before."

Large-scale study of antibody titer decay following BNT162b2 mRNA vaccine or SARS-CoV-2 infection, by Ariel Israel, Yotam Shenhar, Ilan Green, Eugene Merzon, Avivit Golan-Cohen, Alejandro A Schäffer, Eytan Ruppin, Shlomo Vinker, Eli Magen. MedRxiv, August 22, 2021.

> "This study demonstrates individuals who received the Pfizer-BioNTech mRNA vaccine have different kinetics of antibody levels compared to patients who had been infected with the SARS-CoV-2 virus, with higher initial levels but a much faster exponential decrease in the first group."

Discrete Immune Response Signature to SARS-CoV-2 mRNA Vaccination Versus Infection, by Ellie Ivanova, Joseph Devlin, et al. Cell, May 2021.

> "While both infection and vaccination induced robust innate and adaptive immune responses, our analysis revealed significant qualitative differences between the two types of immune challenges. In COVID-19 patients, immune responses were characterized by a highly augmented interferon response which was **largely absent in vaccine recipients**."

SARS-CoV-2 infection induces long-lived bone marrow plasma cells in humans, by Jackson S. Turner, Wooseob Kim, Elizaveta Kalaidina, Charles W. Goss, Adriana M. Rauseo, Aaron J. Schmitz, Lena Hansen, Alem Haile, Michael K. Klebert, Iskra Pusic, Jane A. O'Halloran, Rachel M. Presti, Ali H. Ellebedy. Nature, May 24, 2021.

> "This study sought to determine whether infection with SARS-CoV-2 induces antigen-specific long-lived BMPCs in humans. We detected SARS-CoV-2 S-specific BMPCs in bone marrow aspirates from 15 out of 19 convalescent individuals, and in none from the 11 control participants…. Overall, our results are consistent with SARS-CoV-2 infection eliciting a canonical T-cell-dependent B cell response, in which an early transient burst of extrafollicular plasmablasts generates a wave of serum antibodies that decline relatively quickly. This is followed by more stably maintained levels of serum antibodies that are supported by long-lived BMPCs."

Longitudinal analysis shows durable and broad immune memory after SARS-CoV-2 infection with persisting antibody responses and memory B and T cells, by Kristen W. Cohen, Susanne L. Linderman, Zoe Moodie, Julie Czartoski, Lilin Lai, Grace Mantus, Carson Norwood, Lindsay E. Nyhoff, Venkata Viswanadh Edara, et al. MedRxiv, April 27, 2021.

> "Ending the COVID-19 pandemic will require long-lived immunity to SARS-CoV-2. We evaluated 254 COVID-19 patients longitudinally from early infection and for eight months thereafter and found a predominant broad-based immune memory response. SARS-CoV-2 spike binding and neutralizing antibodies exhibited a bi-phasic decay with an

extended half-life of >200 days suggesting the generation of longer-lived plasma cells. In addition, there was a sustained IgG+ memory B cell response, which bodes well for a rapid antibody response upon virus re-exposure."

Incidence of Severe Acute Respiratory Syndrome Coronavirus-2 infection among previously infected or vaccinated employees, by N Kojima, A Roshani, M Brobeck, A Baca, JD Klausner. MedRxiv, July 8, 2021.

"Previous SARS-CoV-2 infection and vaccination for SARS-CoV-2 were associated with decreased risk for infection or re-infection with SARS-CoV-2 in a routinely screened workforce. The was no difference in the infection incidence between vaccinated individuals and individuals with previous infection. Further research is needed to determine whether our results are consistent with the emergence of new SARS-CoV-2 variants."

Single cell profiling of T and B cell repertoires following SARS-CoV-2 mRNA vaccine, by Suhas Sureshchandra, Sloan A. Lewis, Brianna Doratt, Allen Jankeel, Izabela Ibraim, Ilhem Messaoudi. BioRxiv, July 15, 2021.

"Interestingly, clonally expanded CD8 T cells were observed in every vaccinee, as observed following natural infection. TCR gene usage, however, was variable, reflecting the diversity of repertoires and MHC polymorphism in the human population. **Natural infection induced expansion of larger CD8 T cell clones occupied distinct clusters, likely due to the recognition of a broader set of viral epitopes presented by the virus not seen in the mRNA vaccine.** Our study highlights a coordinated adaptive immune response where early CD4 T cell responses facilitate the development of the B cell response and substantial expansion of effector CD8 T cells, together capable of contributing to future recall responses."

Immunological memory to SARS-CoV-2 assessed for up to 8 months after infection, Jennifer M. Dan, Jose Mateus, Yu Kato, Kathryn M. Hastie, et al., Science, January 6, 2021.

"Understanding immune memory to SARS-CoV-2 is critical for improving diagnostics and vaccines, and for assessing the likely future course of the COVID-19 pandemic. We analyzed multiple compartments of circulating immune memory to SARS-CoV-2 in 254 samples from 188 COVID-19 cases, including 43 samples at ≥ 6 months post-infection. IgG to the Spike protein was relatively stable over 6+ months. Spike-specific memory B cells were more abundant at 6 months than at 1 month post symptom onset. SARS-CoV-2-specific CD4+ T cells and CD8+ T cells declined with a half-life of 3-5 months. By studying antibody, memory B cell, CD4+ T cell, and CD8+ T cell memory to SARS-CoV-2 in an integrated manner, we observed that each component of SARS-CoV-2 immune memory exhibited distinct kinetics."

Persistence of neutralizing antibodies a year after SARS-CoV-2 infection, by Anu Haveri, Nina Ekström, Anna Solastie, Camilla Virta, Pamela Österlund, Elina Isosaari, Hanna Nohynek, Arto A. Palmu, Merit Melin. MedRxiv, July 16, 2021.

"We assessed the persistence of serum antibodies following wild-type SARS-CoV-2 infection six and twelve months after diagnosis in 367 individuals of whom 13% had severe disease requiring hospitalization. We determined the SARS-CoV-2 spike (S-IgG) and nucleoprotein IgG concentrations and the proportion of subjects with neutralizing antibodies (NAb)."

Quantifying the risk of SARS‐CoV‐2 reinfection over time, by Eamon O Murchu, Paula Byrne, Paul G. Carty, et al. Rev Med Virol. 2021.

"Reinfection was an uncommon event (absolute rate 0%–1.1%), with no study reporting an increase in the risk of reinfection over time. Only one study estimated the population‐level risk of reinfection based on whole genome sequencing in a subset of patients; the estimated risk was low (0.1% [95% CI: 0.08–0.11%]) with no evidence of waning immunity for up to 7 months following primary infection. These data suggest that naturally acquired SARS‐CoV‐2 immunity does not wane for at least 10 months post‐infection. However, the applicability of these studies to new variants or to vaccine‐induced immunity remains uncertain."

SARS-CoV-2 antibody-positivity protects against reinfection for at least seven months with 95% efficacy, by Laith J. Abu-Raddad, Hiam Chemaitelly, Peter Coyle, Joel A. Malek. The Lancet, July 27, 2021.

> "Reinfection is rare in the young and international population of Qatar. Natural infection appears to elicit strong protection against reinfection with an efficacy ~95% for at least seven months."

Natural immunity against COVID-19 significantly reduces the risk of reinfection: findings from a cohort of sero-survey participants, by Bijaya Kumar Mishra, Debdutta Bhattacharya, Jaya Singh Kshatri, Sanghamitra Pati. MedRxiv, July 19, 2021.

> **"These findings reinforce the strong plausibility that development of antibody following natural infection not only protects against re-infection by the virus to a great extent, but also safeguards against progression to severe COVID-19 disease."**

Protection of previous SARS-CoV-2 infection is similar to that of BNT162b2 vaccine protection: A three-month nationwide experience from Israel, by Yair Goldberg, Micha Mandel, Yonatan Woodbridge, Ronen Fluss, Ilya Novikov, Rami Yaari, Arnona Ziv, Laurence Freedman, Amit Huppert, et al.. MedRxiv, April 24, 2021.

> "Similarly, the overall estimated level of protection from prior SARS-CoV-2 infection for documented infection is 94·8% (CI:[94·4, 95·1]); hospitalization 94·1% (CI:[91·9, 95·7]); and severe illness 96·4% (CI:[92·5, 98·3]). **Our results question the need to vaccinate previously-infected individuals.**"

Immune Memory in Mild COVID-19 Patients and Unexposed Donors Reveals Persistent T Cell Responses After SARS-CoV-2 Infection, by Asgar Ansari, Rakesh Arya, Shilpa Sachan, Someshwar Nath Jha, Anurag Kalia, Anupam Lall, Alessandro Sette, et al. Front Immunol. March 11, 2021.

> "Using HLA class II predicted peptide megapools, we identified SARS-CoV-2 cross-reactive CD4+ T cells in around 66% of the unexposed individuals. Moreover, we found detectable immune memory in mild COVID-19 patients several months after recovery in the crucial arms of protective adaptive immunity; CD4+ T cells and B cells, with a minimal contribution from CD8+ T cells. Interestingly, the persistent immune memory in COVID-19 patients is predominantly targeted towards the Spike glycoprotein of the SARS-CoV-2. This study provides the evidence of both high magnitude pre-existing and persistent immune memory in Indian population."

Live virus neutralisation testing in convalescent patients and subjects vaccinated against 19A, 20B, 20I/501Y.V1 and 20H/501Y.V2 isolates of SARS-CoV-2, by Claudia Gonzalez, Carla Saade, Antonin Bal, Martine Valette, et al, MedRxiv, May 11, 2021.

> " No significant difference was observed between the 20B and 19A isolates for HCWs with mild COVID-19 and critical patients. However, a significant decrease in neutralisation ability was found for 20I/501Y.V1 in comparison with 19A isolate for critical patients and HCWs 6-months post infection. Concerning 20H/501Y.V2, all populations had a significant reduction in neutralising antibody titres in comparison with the 19A isolate. Interestingly, a significant difference in neutralisation capacity was observed for vaccinated HCWs between the two variants whereas it was not significant for the convalescent groups."

Highly functional virus-specific cellular immune response in asymptomatic SARS-CoV-2 infection, by Nina Le Bert, Hannah E. Clapham, Anthony T. Tan, Wan Ni Chia, et al, Journal of Experimental Medicine, March 1, 2021.

> **"Thus, asymptomatic SARS-CoV-2–infected individuals are not characterized by weak antiviral immunity; on the contrary, they mount a highly functional virus-specific cellular immune response."**

SARS-CoV-2-specific T cell memory is sustained in COVID-19 convalescent patients for 10 months with successful development of stem cell-like memory T cells, Jae Hyung Jung, Min-Seok Rha, Moa Sa, Hee Kyoung Choi, Ji Hoon Jeon, et al, Nature Communications, June 30, 2021.

"In particular, we observe sustained polyfunctionality and proliferation capacity of SARS-CoV-2-specific T cells. Among SARS-CoV-2-specific CD4+ and CD8+ T cells detected by activation-induced markers, the proportion of stem cell-like memory T (TSCM) cells is increased, peaking at approximately 120 DPSO. Development of TSCM cells is confirmed by SARS-CoV-2-specific MHC-I multimer staining. Considering the self-renewal capacity and multipotency of TSCM cells, **our data suggest that SARS-CoV-2-specific T cells are long-lasting after recovery from COVID-19**, thus support the feasibility of effective vaccination programs as a measure for COVID-19 control."

Antibody Evolution after SARS-CoV-2 mRNA Vaccination, by Alice Cho, Frauke Muecksch, Dennis Schaefer-Babajew, Zijun Wang, et al, BioRxiv, et al, BioRxiv, July 29, 2021.

"**We conclude that memory antibodies selected over time by natural infection have greater potency and breadth than antibodies elicited by vaccination.** These results suggest that boosting vaccinated individuals with currently available mRNA vaccines would produce a quantitative increase in plasma neutralizing activity but not the qualitative advantage against variants obtained by vaccinating convalescent individuals." Newer version reads: "These results suggest that boosting vaccinated individuals with currently available mRNA vaccines will increase plasma neutralizing activity but may not produce antibodies with breadth equivalent to those obtained by vaccinating convalescent individuals."

Differential effects of the second SARS-CoV-2 mRNA vaccine dose on T cell immunity in naïve and COVID-19 recovered individuals, by Carmen Camara, Daniel Lozano-Ojalvo, Eduardo Lopez-Granados. Et al., BioRxiv, March 27, 2021.

"While a two-dose immunization regimen with the BNT162b2 vaccine has been demonstrated to provide a 95% efficacy in naïve individuals, the effects of the second vaccine dose in individuals who have previously recovered from natural SARS-CoV-2 infection has been questioned. Here we characterized SARS-CoV-2 spike-specific humoral and cellular immunity in naïve and previously infected individuals during full BNT162b2 vaccination. Our results demonstrate that the second dose increases both the humoral and cellular immunity in naïve individuals. On the contrary, the second BNT162b2 vaccine dose results in a reduction of cellular immunity in COVID-19 recovered individuals, which suggests that a second dose, according to the current standard regimen of vaccination, may be not necessary in individuals previously infected with SARS-CoV-2."

COVID-19 natural immunity: Scientific Brief. World Health Organization. May 10, 2021.

"Available scientific data suggests that in most people immune responses remain robust and protective against reinfection for at least 6-8 months after infection (the longest follow up with strong scientific evidence is currently approximately 8 months). Some variant SARS-CoV-2 viruses with key changes in the spike protein have a reduced susceptibility to neutralization by antibodies in the blood. While neutralizing antibodies mainly target the spike protein, cellular immunity elicited by natural infection also target other viral proteins, which tend to be more conserved across variants than the spike protein."

SARS-CoV-2 re-infection risk in Austria, by Stefan Pilz, Ali Chakeri, John Pa Ioannidis, et al. Eur J Clin Invest. April 2021.

"We recorded 40 tentative re-infections in 14 840 COVID-19 survivors of the first wave (0.27%) and 253 581 infections in 8 885 640 individuals of the remaining general population (2.85%) translating into an odds ratio (95% confidence interval) of 0.09 (0.07 to 0.13). We observed a relatively low re-infection rate of SARS-CoV-2 in Austria. **Protection against SARS-CoV-2 after natural infection is comparable with the highest available estimates on vaccine efficacies.** Further well-designed research on this issue is urgently needed for improving evidence-based decisions on public health measures and vaccination strategies."

Anti-spike antibody response to natural SARS-CoV-2 infection in the general population, by Jia Wei, Philippa C. Matthews, Nicole Stoesser, et al, MedRxiv, July 5, 2021.

"We estimated antibody levels associated with protection against reinfection likely last 1.5-2 years on average, with levels associated with protection from severe infection present for several years. These estimates could inform planning for vaccination booster strategies."

SARS-CoV-2 infection rates of antibody-positive compared with antibody-negative health-care workers in England: a large, multicentre, prospective cohort study (SIREN), by Victoria Jane Hall, FFPH, Sarah Foulkes, MSc, Andre Charlett, PhD, Ana Atti, MSc, et al. The Lancet, April 29, 2021.

"A previous history of SARS-CoV-2 infection was associated with an 84% lower risk of infection, with median protective effect observed 7 months following primary infection. This time period is the minimum probable effect because seroconversions were not included. **This study shows that previous infection with SARS-CoV-2 induces effective immunity to future infections in most individuals.**"

SARS-CoV-2 Natural Antibody Response Persists for at Least 12 Months in a Nationwide Study From the Faroe Islands, by Maria Skaalum Petersen, Cecilie Bo Hansen, Marnar Fríheim Kristiansen, et al, Open Forum Infectious Diseases, Volume 8, Issue 8, August 2021.

"Although the protective role of antibodies is currently unknown, o**ur results show that SARS-CoV-2 antibodies persisted at least 12 months after symptom onset and maybe even longer, indicating that COVID-19-convalescent individuals may be protected from reinfection.** Our results represent SARS-CoV-2 antibody immunity in nationwide cohorts in a setting with few undetected cases, and we believe that our results add to the understanding of natural immunity and the expected durability of SARS-CoV-2 vaccine immune responses. Moreover, they can help with public health policy and ongoing strategies for vaccine delivery.

Associations of Vaccination and of Prior Infection With Positive PCR Test Results for SARS-CoV-2 in Airline Passengers Arriving in Qatar, by Roberto Bertollini, MD, MPH1; Hiam Chemaitelly, MSc2; Hadi M. Yassine. JAMA Research Letter, June 9, 2021.

"Of 9180 individuals with no record of vaccination but with a record of prior infection at least 90 days before the PCR test (group 3), 7694 could be matched to individuals with no record of vaccination or prior infection (group 2), among whom PCR positivity was 1.01% (95% CI, 0.80%-1.26%) and 3.81% (95% CI, 3.39%-4.26%), respectively. The relative risk for PCR positivity was 0.22 (95% CI, 0.17-0.28) for vaccinated individuals and 0.26 (95% CI, 0.21-0.34) for individuals with prior infection compared with no record of vaccination or prior infection."

Appendix B: Primary and Secondary Vaccine Failure

Outbreak of SARS-CoV-2 Infections, Including COVID-19 Vaccine Breakthrough Infections, Associated with Large Public Gatherings — Barnstable County, Massachusetts, July 2021

"Approximately three quarters (346; 74%) of cases occurred in fully vaccinated persons (those who had completed a 2-dose course of mRNA vaccine [Pfizer-BioNTech or Moderna] or had received a single dose of Janssen [Johnson & Johnson] vaccine ≥14 days before exposure)."
cdc.gov/mmwr/volumes/70/wr/mm7031e2.htm

Effectiveness of mRNA BNT162b2 COVID-19 vaccine up to 6 months in a large integrated health system in the USA: a retrospective cohort study

"Effectiveness against infections declined from 88% (95% CI 86–89) during the first month after full vaccination to 47% (43–51) after 5 months."
thelancet.com/journals/lancet/article/PIIS0140-6736(21)02183-8/fulltext

Waning Immune Humoral Response to BNT162b2 Covid-19 Vaccine over 6 Months

"We found that a significant and rapid decrease in humoral response to the BNT162b2 vaccine was observed within months after vaccination."
nejm.org/doi/full/10.1056/NEJMoa2114583

Waning of BNT162b2 Vaccine Protection against SARS-CoV-2 Infection in Qatar

"Estimated BNT162b2 effectiveness against any SARS-CoV-2 infection was negligible in the first 2 weeks after the first dose. It increased to 36.8% (95% confidence interval [CI], 33.2 to 40.2) in the third week after the first dose and reached its peak at 77.5% (95% CI, 76.4 to 78.6) in the first month after the second dose. Effectiveness declined gradually thereafter, with the decline accelerating after the fourth month to reach approximately 20% in months 5 through 7 after the second dose. Effectiveness against symptomatic infection was higher than effectiveness against asymptomatic infection but waned similarly. Variant-specific effectiveness waned in the same pattern."
nejm.org/doi/full/10.1056/NEJMoa2114114

Transmission of SARS-CoV-2 Delta Variant Among Vaccinated Healthcare Workers, Vietnam

"Between 11th–25th June 2021 (week 7–8 after dose 2), 69 healthcare workers were tested positive for SARS-CoV-2. 62 participated in the clinical study. 49 were (pre)symptomatic with one requiring oxygen supplementation. All recovered uneventfully. 23 complete-genome sequences were obtained. They all belonged to the Delta variant, and were phylogenetically distinct from the contemporary Delta variant sequences obtained from community transmission cases, suggestive of ongoing transmission between the workers. Viral loads of breakthrough Delta variant infection cases were 251 times higher than those of cases infected with old strains detected between March-April 2020. Time from diagnosis to PCR negative was 8–33 days (median: 21)."
https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3897733

Predominance of antibody-resistant SARS-CoV-2 variants in vaccine breakthrough cases from the San Francisco Bay Area, California

"Taken together, our results suggest that vaccine breakthrough infecions are overrepresnted by circulating antibody-resistant SARS-CoV-2 variants, and that symptomatic breakthrough infections may potentially transmit COVID-19 as efficiently as unvaccinated infections, regardless of the infecting lineage."
https://www.medrxiv.org/content/10.1101/2021.08.19.21262139v2

An outbreak caused by the SARS-CoV-2 Delta variant (B.1.617.2) in a secondary care hospital in Finland, May 2021

"In conclusion, this outbreak demonstrated that, despite full vaccination and universal masking of HCW, breakthrough infections by the Delta variant via symptomatic and asymptomatic HCW occurred, causing nosocomical infections."
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8323455/

Nosocomial outbreak caused by the SARS-CoV-2 Delta variant in a highly vaccinated population, Israel, July 2021

"This nosocomial outbreak exemplifies the high transmissibility of the SARS-CoV-2 Delta variant among twice vaccinated and masked individuals."
https://www.eurosurveillance.org/content/10.2807/1560-7917.ES.2021.26.39.2100822

COVID-19 Vaccine Breakthrough Case Investigation and Reporting

"CDC monitors reported hospitalized or fatal vaccine breakthrough cases for clustering by patient demographics, geographic location, time since vaccination, vaccine type, and SARS-CoV-2 lineage. Reported data include hospitalized or fatal vaccine breakthrough cases due to any cause, including causes not related to COVID-19."
https://www.cdc.gov/vaccines/covid-19/health-departments/breakthrough-cases.html

Increases in COVID-19 are unrelated to levels of vaccination across 68 countries and 2947 counties in the United States

"At the country-level, there appears to be no discernable relationship between percentage of population fully vaccinated and new COVID-19 cases in the last 7 days (Fig. 1). In fact, the trend line suggests a marginally positive association such that countries with higher percentage of population fully vaccinated have higher COVID-19 cases per 1 million people."

"The sole reliance on vaccination as a primary strategy to mitigate COVID-19 and its adverse consequences needs to be re-examined, especially considering the Delta (B.1.617.2) variant and the likelihood of future variants." https://link.springer.com/content/pdf/10.1007/s10654-021-00808-7.pdf

Addendum: See blue box, pg 3

John Bel Edwards
GOVERNOR

Dr. Courtney N. Phillips
SECRETARY

State of Louisiana

Department of Health
Office of Public Health

DATE: May 13, 2021

TO: Louisiana COVID-19 Vaccination Providers

FROM: Dr. Joseph Kanter & Dr. Frank Welch

SUBJECT: Coronavirus (COVID-19) Update: FDA and CDC Authorize Pfizer-BioNTech COVID-19 Vaccine for Emergency Use in Adolescents aged 12 -15.

Coronavirus (COVID-19) Update: Louisiana Department of Health Adopts FDA and CDC Guidance to Immediately Expand Eligibility for Pfizer-BioNTech COVID-19 Vaccine in Adolescents Ages 12 -15.

The Louisiana Department of Health today announces it will begin administering the Pfizer COVID-19 vaccine to children ages 12-15. This is following the decision by the Advisory Committee on Immunization Practices (ACIP) to recommend to the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) that the Pfizer vaccine be made available to administer to children ages 12-15 years. The vaccine is safe and effective in preventing COVID-19. The FDA amended the EUA originally issued on Dec.11, 2020 for administration in individuals 16 years of age and older.

This guidance goes into effect now. Vaccine providers should begin scheduling and administering the Pfizer COVID-19 vaccine to this newly eligible age group immediately.

For a person younger than age 18 in Louisiana, verbal or signed parental consent is needed to be vaccinated. If parents or guardians cannot be present in-person they may send a signed consent form with their child. The Louisiana Department of Health has developed a sample consent form that can be found on its website at: https://ldh.la.gov/covidvaccine/.

"The FDA's expansion of the emergency use authorization for the Pfizer-BioNTech COVID-19 Vaccine to include adolescents 12 through 15 years of age is a significant step in the fight against the COVID-19 pandemic," said Acting FDA Commissioner Janet Woodcock, M.D. "Today's action allows for a younger population to be protected from COVID-19, bringing us closer to returning to a sense of normalcy and to ending the pandemic. Parents and guardians can rest assured that the agency undertook a rigorous and thorough review of all available data, as we have with all of our COVID-19 vaccine emergency use authorizations."

Immunization Program • 1450 Poydras St • Suite 1938 • New Orleans, Louisiana 70112
Phone: (504) 568-2600 • Fax: (504) 568-2659 • ldh.la.gov/index.cfm/subhome/61
An Equal Opportunity Employer

From March 1, 2020 through April 30, 2021, approximately 1.5 million COVID-19 cases in individuals 11 to 17 years of age have been reported to the Centers for Disease Control and Prevention (CDC). Children and adolescents generally have a milder COVID-19 disease course as compared to adults. The Pfizer-BioNTech COVID-19 Vaccine is administered as a series of two doses, three weeks apart, the same dosage and dosing regimen for adolescents 16 years of age and older.

The FDA has determined that Pfizer-BioNTech COVID-19 Vaccine has met the statutory criteria to amend the EUA, and that the known and potential benefits of this vaccine in individuals 12 years of age and older outweigh the known and potential risks, supporting the vaccine's use in this population.

"Having a vaccine authorized for a younger population is a critical step in continuing to lessen the immense public health burden caused by the COVID-19 pandemic," said Peter Marks, M.D., Ph.D., director of the FDA's Center for Biologics Evaluation and Research. "With science guiding our evaluation and decision-making process, the FDA can assure the public and medical community that the available data meet our rigorous standards to support the emergency use of this vaccine in the adolescent population 12 years of age and older."

The FDA has updated the Fact Sheets for Healthcare Providers Administering the Vaccine (Vaccination Providers) and for Recipients and Caregivers with information to reflect the use of the vaccine in the adolescent population, including the benefits and risks of the Pfizer-BioNTech COVID-19 Vaccine.

The EUA amendment for the Pfizer-BioNTech COVID-19 Vaccine was issued to Pfizer Inc. The issuance of an EUA is not an FDA approval (licensure) of a vaccine. The EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biologics for prevention and treatment of COVID-19 is terminated, and may be revised or revoked if it is determined the EUA no longer meets the statutory criteria for issuance or to protect public health or safety.

FDA Evaluation of Available Safety Data

The available safety data to support the EUA in adolescents down to 12 years of age, include 2,260 participants ages 12 through 15 years old enrolled in an ongoing randomized, placebo-controlled clinical trial in the United States. Of these, 1,131 adolescent participants received the vaccine and 1,129 received a saline placebo. More than half of the participants were followed for safety for at least two months following the second dose.

The most commonly reported side effects in the adolescent clinical trial participants, which typically lasted 1-3 days, were pain at the injection site, tiredness, headache, chills, muscle pain, fever and joint pain. With the exception of pain at the injection site, more

adolescents reported these side effects after the second dose than after the first dose, so it is important for vaccination providers and recipients to expect that there may be some side effects after either dose, but even more so after the second dose. The side effects in adolescents were consistent with those reported in clinical trial participants 16 years of age and older. It is important to note that as a general matter, while some individuals experience side effects following any vaccination, not every individual's experience will be the same and some people may not experience side effects.

The Pfizer-BioNTech COVID-19 Vaccine should not be given to anyone with a known history of a severe allergic reaction, including anaphylaxis—to any component of the vaccine. Since its authorization for emergency use, rare severe allergic reactions, including anaphylaxis, have been reported following administration of the Pfizer-BioNTech COVID-19 Vaccine in some recipients.

FDA Evaluation of Available Effectiveness Data

The effectiveness data to support the EUA in adolescents down to 12 years of age is based on immunogenicity and an analysis of COVID-19 cases. The immune response to the vaccine in 190 participants, 12 through 15 years of age, was compared to the immune response of 170 participants, 16 through 25 years of age. In this analysis, the immune response of adolescents was non-inferior to (at least as good as) the immune response of the older participants. An analysis of cases of COVID-19 occurring among participants, 12 through 15 years of age, seven days after the second dose was also conducted. In this analysis, among participants without evidence of prior infection with SARS-CoV-2, no cases of COVID-19 occurred among 1,005 vaccine recipients and 16 cases of COVID-19 occurred among 978 placebo recipients; the vaccine was 100% effective in preventing COVID-19. At this time, there are limited data to address whether the vaccine can prevent transmission of the virus from person to person. In addition, at this time, data are not available to determine how long the vaccine will provide protection.

Ongoing Safety Monitoring

As part of the original EUA request, Pfizer Inc. submitted a plan to continue monitoring the safety of the vaccine as it is used under EUA. This plan has been updated to include the newly authorized adolescent population, and includes longer-term safety follow-up for participants enrolled in ongoing clinical trials, as well as other activities aimed at monitoring the safety of the Pfizer-BioNTech COVID-19 vaccine and ensuring that any safety concerns are identified and evaluated in a timely manner.

It is mandatory for Pfizer Inc. and vaccination providers to report the following to the Vaccine Adverse Event Reporting System for Pfizer-BioNTech COVID-19 Vaccine: all vaccine administration errors, serious adverse events, cases of Multisystem Inflammatory Syndrome and cases of COVID-19 that result in hospitalization or death.

Related Information

- Pfizer-BioNTech COVID-19 Vaccine EUA Letter of Authorization
- Pfizer-BioNTech COVID-19 Vaccine EUA Fact Sheet for Healthcare Providers Administering the Vaccine (Vaccination Providers)
- Pfizer-BioNTech COVID-19 Vaccine EUA Fact Sheet for Recipients and Caregivers

Additionally, on Thursday May 13 the CDC will update all webpages which will include a pediatrician toolkit: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/index.html.