

Jeffrey M. Zirger
Information Collection Review Office, Centers for Disease Control and Prevention
1600 Clifton Road NE, MS- D74
Atlanta, Georgia 30329

RE: Phased Approach to the Resumption of Cruise Ship Passenger Operations 2021-09094,
Docket No. CDC-2021-0011

June 30, 2021

Executive Summary:

The CDC has proposed a new rule to resume passenger operations on cruise ships, with restrictions and precautions aimed at preventing COVID-19 spread. This process includes multiple steps, such as a simulated voyage to test the practicality of the protocol. I agree with many of the required processes the rule proposes, but I have concerns regarding the effectiveness of the processes and clarity of the success for the operations of cruise ships during the pandemic. In addition, the proposed rule is hindered by the lack of effective precautions required and unclear standards to achieving a “successful” simulation in order to gain approval for a COVID-19 sailing certificate.

Background:

According to the World Health Organization, as of June 25 2021, there have been a total of 33,257,768 confirmed cases and 597,727 deaths in the United States alone.¹ Traveling is a major cause of the rapid spread of COVID-19 across countries and continents.² The highly contagious manner of COVID-19 spread through airborne droplets among people in close proximity, and widely available domestic and international travel has made COVID-19 one of

¹ WHO Coronavirus (COVID-19) Dashboard, <https://covid19.who.int> (last visited Jun 16, 2021).

² *Id.*

the fastest spreading diseases in history.³ Therefore, cruise ship operations are most likely not a good idea to commence while the COVID-19 pandemic worsens in other parts of the globe. Ironically, one of the first known cases of COVID-19 in the United States was on March 6, 2020, where 21 passengers on a Carnival cruise in California tested positive⁴, days before the World Health Organization declared COVID-19 a pandemic. Other cruise ships across the globe were considered super-spreaders, such as the Diamond Princess ship in China during February 2020, which had to quarantine for over a month, as more than 700 passengers tested positive and 14 passengers fell dead.⁵ By the end of March, stay-at-home orders, travel bans, and state regulations continued throughout 2020.

A No Sail Order (NSO) was first set by the CDC on March 14, 2020, and was extended throughout 2020, until the conditional sailing order was put in place.⁶ The current proposed plan includes a process for the next phase of cruise ship operations to update the Conditional Sailing Order to soon permit regular passengers with a COVID-19 Conditional Sailing Certificate. Specifically, it requires a No-Sail Order response plan, which includes building laboratory capacity needed to test crew and passengers.⁷ Next, a framework for simulated voyages must be approved, as the port must establish a reasonable number of ships permitted a single port to prevent overburdening sites in the setting of an outbreak. In addition, cruise ships must enter into medical care agreement plans for evacuation and transportation to onshore hospitals, as well as

³ Ke R, Sanche S, Romero-Severson E, Hengartner N. Fast spread of COVID-19 in Europe and the US suggests the necessity of early, strong and comprehensive interventions. Preprint. *medRxiv*. 2020;2020.04.04.20050427. Published 2020 Apr 7. doi:10.1101/2020.04.04.20050427

⁴ A Timeline of COVID-19 Developments in 2020, , *AJMC* , <https://www.ajmc.com/view/a-timeline-of-covid19-developments-in-2020> (last visited Jun 16, 2021).

⁵ Benedict Carey & James Glanz, *Aboard the Diamond Princess, a Case Study in Aerosol Transmission*, *The New York Times*, July 30, 2020, <https://www.nytimes.com/2020/07/30/health/diamond-princess-coronavirus-aerosol.html> (last visited Jun 25, 2021).

⁶ CDC COVID-19 Orders for Cruise Ships | Quarantine | CDC, (2021), <https://www.cdc.gov/quarantine/cruise/covid19-cruiseships.html> (last visited Jun 16, 2021).

⁷ Federal Register, Volume 86 Issue 82 (Friday, April 30, 2021), <https://www.govinfo.gov/content/pkg/FR-2021-04-30/html/2021-09094.htm> (last visited Jun 16, 2021).

on-ship housing arrangements with facilities for isolation.⁸ Part 2B requires a simulated voyage plan at least 30 days prior to resuming cruise ship operations, followed by documentation of deficiencies in health and safety protocol and after-action report including test results for volunteer passengers/crew.⁹ The final part, to gain an approved Conditional Sailing Certificate, requires a successfully simulated voyage where the operator was able to mitigate the risks of COVID-19 on the ship.

Analysis:

Public health guidance must protect the interests of all stakeholders, including cruise ship passengers, travelers and employees, as well as those who work and live around the ports, nearby medical centers, health organizations, and hospitals.

I am writing in support the activities and objectives around the proposed plan, as the various steps seem to be thorough and necessary to return to passenger operations. Perhaps a more appropriate question is whether it is even appropriate for cruise ship operations to begin during the pandemic which is not yet over and still remains and risk for many people worldwide. Whenever the proposed rule is in effect, the efficiency of the methodology of the simulated voyage and utility of information to be collected is also questionable. It also seems unclear what determines a successful simulated voyage to gain approval for the certificate. Do these processes achieve the goal of reducing risks and mitigating spread of COVID-19 on a cruise ship?

I. It is not yet an appropriate time to resume Cruise Ship Operations during the Pandemic.

When looking to develop the next phase of cruise ship operations, it should first be evaluated whether cruise-ship travel is appropriate in any manner during the current state of our

⁸ *Id.*

⁹ *Id.*

global pandemic. The risk of COVID-19 outbreaks is dangerously heightened considering the nature of cruise ships—in which crowds of people are enclosed in small, crowded quarters—can lead to rapid spread among the passengers and crew. Outbreaks in certain popular travel destinations could easily seed COVID-19 across the globe, and limited access to medical resources in those destinations could be a deadly combination. Cruise ships are high risk for infectious diseases; the CDC notes that the risk of catching COVID-19 on a cruise ship is extremely high because of the “close quarters”¹⁰—hundreds to thousands of people from various places across the globe, closely interacting for extended periods of time, with less filtration than the air on airplanes.

A COVID outbreak would create a disaster for those aboard the cruise ship while “pos[ing] a risk for rapid spread of disease beyond the voyage.” Such risk may extend to nearby medical facilities, those living nearby the port location, and potential to spread via anyone traveling through who was not isolated or quarantined.¹¹

II. Evaluation of the proposed data collection methods:

The proposed rule requires ships to enforce their NSO plan and a simulated voyage plan, yet it fails to explicitly describe what that plan should entail. Studies from COVID-19 cruise ships recommend plans to provide pre-boarding information that includes clear protocols for travelers, such as vaccinations or medical history, nor specific capacity limits, requirements of PPE/face masks, special attention/clearance for high-risk groups, sanitation, protective barriers,

¹⁰ CDC, *COVID-19 and Your Health*, Centers for Disease Control and Prevention (2020), <https://www.cdc.gov/coronavirus/2019-ncov/travelers/faqs.html> (last visited Jun 16, 2021).

¹¹ Leah F. Moriarty, *Public Health Responses to COVID-19 Outbreaks on Cruise Ships — Worldwide, February–March 2020*, 69 *MMWR Morb Mortal Wkly Rep* (2020), <https://www.cdc.gov/mmwr/volumes/69/wr/mm6912e3.htm> (last visited Jun 16, 2021).

ventilation systems, and additional cleaning.¹² None of these are explicitly discussed in the proposed rule, yet should be required to ensure adequate measures are being taken.

I agree with other precautions are explicitly listed in the rule, as the proposed data collection of forms and agreements required from the cruise ship operators are necessary and valid to ensure safe operations. Since cruise ships have been known to pose a serious risk of COVID-19 from the initial outbreak, we know limited medical supplies on board can lead to a dangerous situation. When needing to quickly transfer all COVID-19 patients on land, hospitals can quickly become overwhelmed, in addition to those who do not need hospitalization, but need to be isolated.¹³ The proposed rule has accounted for this by requiring ships to comply with ports limited entry capacity through a port agreement to ensure the ports do not become overwhelmed and establish areas for isolation on the ship in case of positive cases. Limited access to testing has been a major problem during the COVID-19 pandemic¹⁴, so requiring ships to be equipped with labs should also aid in preventing spread. These precautions in the proposed rule are important and should be enacted.

III. It is unclear what determines a simulated voyage to be successful.

The proposed rule states that a “cruise ship operator must have successfully conducted a simulated voyage or series of simulated voyages demonstrating the cruise ship operator’s ability to mitigate the risks of COVID–19 onboard its cruise ship.” This lacks a standard as to what would be considered a successful voyage. At what point would positive cases and spreading of COVID-19 warrant distinction as an “unsuccessful voyage”? In the current state of the

¹² Ann-Christin Kordsmeyer et al., *Systematic Review on Outbreaks of SARS-CoV-2 on Cruise, Navy and Cargo Ships*, 18 Int J Environ Res Public Health (2021), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8153346/> (last visited Jun 18, 2021).

¹³ *Id.*

¹⁴ *Id.*

pandemic, it is unlikely that no cases will occur. Is it enough to satisfy that the risk is mitigated if only a certain portion or section of the ship catches COVID-19 without spreading the infection to the entire population on board? Again, this calls into question whether cruise ships should even be operating right now, considering the dangers and risk potential, even on simulated voyages. The CDC currently categorizes cruise ships as a Level-3/4 danger for the risk of catching COVID-19, specifically for those who are not fully vaccinated.¹⁵ Even if there are just a few cases, that would invoke a major need to utilize the safety protocols, which does not likely seem to be a “successful” cruise-ship voyage.

IV. Potential Implications of newly decided case: Florida v. Beracca

The case of Florida v. Beracca was just recently decided on June 18, where a Florida federal court granted Florida a Preliminary Injunction against the CDC’s restrictions on cruise ship, under the theory that the state suffers an "imminent threat of irreparable injury" as a result of these regulations.¹⁶ This case may have future implications limiting the CDC’s power to restrict cruise ship operations, such as this proposed rule. The injunction prevents the CDC from enforcing a number of rules including vaccination requirements and port limitations. What this means is that CDC orders will be no more than “guidance” among the Florida ports. The judge found cruise industry’s precautions to be enough to combat and contain infection.¹⁷ However,

¹⁵ COVID-19 and Cruise Ship Travel for Travelers Who Are Not Fully Vaccinated - COVID-19 High - Level 3: COVID-19 High - Travel Health Notices | Travelers’ Health | CDC, <https://wwwnc.cdc.gov/travel/notices/covid-3/coronavirus-cruise-ship> (last visited Jun 18, 2021).

¹⁶ Court grants Florida a victory in legal battle over restarting cruise industry, , wtsp.com (2021), <https://www.wtsp.com/article/news/regional/florida/florida-cruise-ship-lawsuit/67-6ab81e4b-053e-4e06-a98c-9151281e8a50> (last visited Jun 25, 2021).

¹⁷ Court grants Florida a victory in legal battle over restarting cruise industry, , wtsp.com (2021), <https://www.wtsp.com/article/news/regional/florida/florida-cruise-ship-lawsuit/67-6ab81e4b-053e-4e06-a98c-9151281e8a50> (last visited Jun 25, 2021).

this decision completely disregards the necessity for limitations among the ports to prevent further outbreak and could lead to future outbreaks.¹⁸ This decision is concerning because it is a step towards permitting states to disregard restrictions imposed by the CDC, undermines the role of the CDC to take action to prevent potential illness and death in response to public health concerns. The judge gave the CDC until July 2 to propose a narrower injunction permitting cruise ships to sail safely. This decision could be the first step towards reducing the CDC's ability to imposing limited restrictions on cruise ship operators. However, this proposed rule is necessary and the burden on cruise ship operators is reasonable to ensure safe travel without the spread of COVID-19 and may be considered a narrower approach to cruise ship safety as the Florida Federal Court judge requested for the CDC to do, as this rule does not require employee nor passenger vaccination, which would likely not be approved considering the outcome of this case. Therefore, if the CDC continues to enact clear regulations that cruise ships can adopt and follow, this proposed rule should be permitted.

Recommended Actions:

- It is too early to resume regular cruise ship operations, implementing the proposed rules should wait until the pandemic has diminished on a global level, where safe travel can occur without needing to utilize emergency precautions.
- Once global travel is deemed safe, the CDC should proceed with all requirements that have been listed to mitigate and prevent spread of COVID-19 aboard passenger ships.

¹⁸ *Id.*

- Consider stricter guidelines to clarify the standards that permit the validity and expectations for a successful simulation and approval of a COVID-19 Sailing Certificate.
- Explicit requirements for on-board precautions and information for travelers.

Conclusion:

Because the COVID-19 pandemic is still on going, I must again express it does not seem appropriate to risk additional lives by permitting cruise ship travel during this time. However, once the pandemic is declared over and the majority of the global the population is vaccinated, the proposed rule should be finalized, with the addition of more clear and explicit requirements for preventative plans, traveler information, and voyage simulation success.

Sincerely,

Marina DeAngelis
J.D. Candidate
Northeastern University School of Law
Email: deangelis.m@northeastern.edu

Jeffrey M. Zirger
Information Collection Review Office, Centers for Disease Control and Prevention
1600 Clifton Road NE, MS- D74
Atlanta, Georgia 30329

RE: Phased Approach to the Resumption of Cruise Ship Passenger Operations 2021-09094,
Docket No. CDC-2021-0011

June 30, 2021

Executive Summary

This comment is in response to a Federal Register regarding the Center for Disease Control’s (CDC) proposed data collection project, “Phased Approach to Resumption of Passenger Operations” (PARPO). The proposed method of data collection will not have practical utility because the methodology and assumptions used will not provide accurate data. If the Center for Disease Control and the Office of Health and Human Services (HHS) choose to pursue this means of data collection, there are several modifications that can be made to lessen the approximated burden. These modifications include use of mobile apps in transmitting and sharing COVID-19 test results, incentivizing cruise liners to mandate vaccination, and mandating post disembarkment testing at a verified testing center. Next, the PARPO should explicitly state that oral specimen will not be used in testing, per the CDC’s own instructions. Finally, as a scholar of public health, I recommend that the PARPO be postponed until a greater percentage of the global population is vaccinated.

Background

In March of 2020, the CDC issued a No Sail Order (NSO), effectively grounding all passenger cruise ships.¹ The order came in the wake of the COVID-19 pandemic, which, as of this writing, has killed 601,506 people in the United States.² Throughout the course of the

¹ https://www.cdc.gov/quarantine/pdf/signed-manifest-order_031520.pdf

² https://covid.cdc.gov/covid-data-tracker/#cases_totalcases

pandemic, it has become apparent that confined and poorly ventilated spaces pose a large risk of transmission.³ Despite initial hesitancy on the part of the CDC to conclude that the virus was airborne, one area of primary concern was cruise ships. In February of 2020, the Diamond Princess cruise ship was forced to dock in the Port of Yokohama.⁴ There, passengers were confined to their cabins and remained in masks.⁵ Over seven-hundred passengers on the Diamond Princess tested positive for COVID-19, at the time making it the second highest number of cases outside of mainland China.⁶

On February 21, 2020, the CDC recommended that cruise ship travel in Southeast Asia be avoided.⁷ Over the course of the next few weeks, the CDC expanded its recommendation to include cruise ship travel by persons with underlying health conditions and those above sixty-five.⁸ Finally, on March 14, 2020, the CDC announced the NSO, which suspended all future embarkment for cruise ships.⁹ The NSO was renewed three times following its implementation.¹⁰ However, in October of 2020, the CDC published a Framework for Conditional Sailing Order, which was supplemented and rendered complete in May of 2021.¹¹

The Conditional Sailing Order requires cruise ship operators to obtain a Conditional Sailing Certification before they may commence passenger operations.¹² The resumption plan is separated into four phases.¹³ The first phase requires that cruise ships are equipped with

³ <https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/sars-cov-2-transmission.html>

⁴ <https://www.cnn.com/travel/article/11-days-cruising-changed-forever/index.html>

⁵ *Id.*

⁶ *Id.*

⁷ <https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6912e3-H.pdf>

⁸ *Id.*

⁹ <https://www.federalregister.gov/documents/2020/03/24/2020-06166/no-sail-order-and-suspension-of-further-embarkation>

¹⁰ <https://www.cdc.gov/quarantine/cruise/covid19-cruiseships.html>

¹¹ *Id.*

¹² <https://www.regulations.gov/document/CDC-2021-0011-0001>

¹³ *Id.*

laboratory capacity to test crew and future passengers.¹⁴ The second phase introduces simulated voyages as a means of gauging cruise liner preparedness.¹⁵ This requires proof of an agreement between the cruise ship operator and a local port authority to ensure no overburdening of a locality.¹⁶ It also requires cruise ship operators to demonstrate existence of a medical care agreement between the cruise ship operator and a local health care entity and housing agreements between the cruise ship operator and shoreside quarantine facilities.¹⁷ After successfully requesting a simulated voyage, the cruise ship operator may take volunteer passengers on their cruise ship for a voyage of 2-7 days with at least one overnight trip.¹⁸ After return, the cruise ship operator must document and submit any deficiencies identified in the simulation.¹⁹ At this point, the cruise ship operator may apply for a Conditional Sailing Certificate.²⁰

On Friday, June 18, a federal judge in Florida held that the NSO exceeded the CDC's scope of power and granted a preliminary injunction, temporarily blocking the enforcement of the CDC's cruise ship restrictions.²¹ This action indicates that the plaintiff will likely be successful in its claim that the CDC's act was an "arbitrary and capricious" exercise of unconstitutional legislative power.²² This decision brings with it major implications for the CDC's ability to restrict cruise liner activity.

Analysis

The assumptions and methodologies relied upon in the proposed collection method are flawed and, as a result, likely render inaccurate calculations of certain burdens. Specifically, the

¹⁴ *Id.*

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ <https://www.cdc.gov/quarantine/cruise/ti-simulated-voyages-cso.html>

¹⁹ <https://www.regulations.gov/document/CDC-2021-0011-0001>

²⁰ *Id.*

²¹ <https://www.law360.com/articles/1395673>

²² *Id.*; <https://www.law360.com/articles/1378097/fla-seeks-injunction-in-suit-to-overturn-cdc-s-cruise-ban>

metrics used by the PARPO to assess whether a Conditional Sailing License should be issued will not result in an accurate representation of risk of infection and transmission of COVID-19 aboard the cruise liner. With a larger risk factor than represented, the burden to reach housing facility agreements, Port of Entry agreements, and agreements with health care organizations will likely be higher than the values proposed by the CDC. For the same reason, the data collected will not be of practical use because it will not provide an accurate representation of the risks of traveling via cruise liner.

The proposed collection of information, while necessary, is ineffective to ensure proper performance. This can be best seen by examining the way in which the simulated voyage varies from ordinary cruise voyages. The PARPO technical instructions provided by the CDC state that the simulation voyage must last between two and seven days and must include at least one overnight stop.²³ The CDC recommends cruise ship operators simulate a voyage lasting three days with two overnight stops.²⁴ In contrast, in 2009 the average cruise voyage was found to be 7.2 days.²⁵ Not only will the length of the simulation of the voyage be significantly shorter than one would expect a cruise voyage to be, but the CDC only mandates certain activities be conducted on the voyage.²⁶ Any activities conducted on voyages that occur outside of U.S. waters are not required to occur during the simulated voyage.²⁷ With the majority of larger cruise liners marketing international travel, this could drastically shift the risk of transmission depending upon how international activities alter proximity and congregation of passengers.²⁸ Finally, congregation on the cruise ship during simulated voyages will significantly differ from

²³ <https://www.cdc.gov/quarantine/cruise/ti-simulated-voyages-cso.html>

²⁴ *Id.*

²⁵ https://www.f-cca.com/downloads/2010-overview-book_Cruise-Industry-Overview-and-Statistics.pdf

²⁶ <https://www.cdc.gov/quarantine/cruise/ti-simulated-voyages-cso.html>

²⁷ *Id.*

²⁸ See e.g., <https://www.royalcaribbean.com/plan-a-cruise/brochures/view>

actual voyages given that the CDC requires only 10% the amount of passengers usually aboard. In conjunction, these variations have the potential to drastically skew the data collected by the PARPO. If the risk of infection is greater than presented, it will be more challenging to secure agreements with third parties.

The testing regime proposed by the CDC also raises questions. The CDC mandates that volunteer passengers be tested three to five days prior to initial departure, at disembarkment, and three to five days post disembarkment.²⁹ One such issue with the testing regime is that the technical guidelines allow cruise ship operators to test patients with nucleic acid amplified self-testing (NAAT).³⁰ Prior to disembarkment, passengers would receive education regarding the proper means of self-testing and would later send the tests to a laboratory via mail.³¹ User error in self-administered tests and mishandling of samples during transit can lead to false negative results.³² The College of American Pathologists cautions the use of self-administered mail-in testing where possible.³³ In addition to this, the CDC requires only 75% of nonvaccinated passengers to comply with the testing regime. Only testing a portion of the passengers will increase the likelihood that the reported rate of infection will not be accurate.

Another flaw of the testing regime is that, aside from embarkment, disembarkment, and post disembarkment testing, the PARPO relies on passengers to come forward with symptoms and comply with testing and potential isolation of their own volition. One foreseeable problem with this means of tracking the number COVID-19 positive passengers is that approximately forty percent to forty-five percent of those with COVID-19 are asymptomatic.³⁴ While it is

²⁹ <https://www.cdc.gov/quarantine/cruise/ti-simulated-voyages-cso.html>

³⁰ *Id.*

³¹ *Id.*

³² <https://www.youtube.com/watch?v=Jomp2YNsiw8&t=20s>

³³ *Id.*

³⁴ <https://www.acpjournals.org/doi/10.7326/M20-3012>

thought that asymptomatic carriers are less likely to transmit the virus than their symptomatic counterparts, transmission is nonetheless possible.³⁵ Of additional concern is the thought that passengers will not willingly come forward knowing that they will be isolated in a foreign location. This could result in a severe misrepresentation of the true rate of infection.³⁶

While these variations in isolation may not significantly skew the data collected, the current data collection methods present too many loose ends. Certainly, the CDC cannot require an exact simulation of a cruise voyage to be used as a metric in determining resumption, however the data collection method must be further refined to create a more accurate portrayal. The allowances granted now will result in a skewed representation of the risk of transmission and rate of infection. As this flaw becomes more apparent, the burden on cruise line operators to obtain onshore agreements with third parties will likely increase, meaning that the burdens calculated by the CDC are inaccurate.

Actions Recommended

The CDC should not resume passenger cruise line travel because it presents a significant risk to public health. If cruise liner activity resumes, the CDC can improve data collection and passenger safety in a number of ways. For example, the CDC could further regulate passenger activities to limit transmission and incentivize cruise liners to mandate vaccination. The CDC should also mandate post disembarkment testing and require that it be performed at a verified testing center. If the CDC declines to make these substantive changes, it should at the very least clarify its testing policy. It should also implement a smartphone application to decrease the burden of checking passenger health status.

³⁵ https://wwwnc.cdc.gov/eid/article/26/7/20-1595_article

³⁶ <https://www.cdc.gov/quarantine/cruise/ti-simulated-voyages-cso.html>

Dependent upon the future of *Florida v. Becerra*, the use of passenger cruise ships should not be allowed given that it poses a risk to public health. Royal Caribbean, unlike other cruise liners, requires that all adult passengers be vaccinated.³⁷ Despite this, recently a Royal Caribbean cruise operating at 30% capacity reported that two of its passengers tested positive for COVID-19.³⁸ After isolating the passengers and performing contact tracing, the cruise was allowed to continue to St. Maarten as planned.³⁹ Although vaccinated individuals are likely to carry a lower viral load and, as a result, experience less severe symptoms, these individuals may still transmit the virus.⁴⁰ While the threat of severe illness resulting from passenger-to-passenger transmission may be low, many of the islands at which these cruise ships dock have minimal access to vaccines. At the time of this writing, only 43% of the population of St. Maarten is fully vaccinated, leaving the majority of its residents vulnerable to the virus.⁴¹ The CDC currently ranks cruise travel as a level four COVID-19 risk, the highest level of risk available.⁴² The PARPO places two vulnerable populations at risk: those aboard the cruise ship and the residents of the cruise ship's destination.

The World Health Organization recently warned that the world is beginning to see a two-track pandemic.⁴³ On one track, countries like the United States are lifting restrictions.⁴⁴ Meanwhile, on the second track, poorer countries are facing extremely dangerous situations due to inequitable vaccine distribution.⁴⁵ To allow cruise ship passengers entry to poorer countries

³⁷ <https://www.royalcaribbean.com/faq/questions/do-i-need-a-covid-vaccine-to-cruise-what-counts-as-proof>

³⁸ <https://www.wsj.com/articles/as-cruises-resume-a-positive-covid-19-case-doesnt-spell-the-end-of-a-voyage-11623441869>

³⁹ *Id.*

⁴⁰ *Id.*

⁴¹ <http://www.sintmaartengov.org/government/VSA/Health-Updates/NOVELCORONAVIRUS/Pages/Vaccine.aspx>

⁴² <https://wwwnc.cdc.gov/travel/notices/covid-4/coronavirus-cruise-ship>

⁴³ <https://news.un.org/en/story/2021/06/1093472>

⁴⁴ *Id.*

⁴⁵ *Id.*

simply because the passengers are vaccinated shows an inhumane disregard for vulnerable populations. The data collection method proposes a means of keeping the passengers and crew of a cruise ship safe. Until one can be sure that the populations of cruise ship destinations are kept equally as safe, resumption is an egregious and hypocritical misstep on the part of the CDC.

However, given the recent holding in *Florida v. Becerra*, the ability of the CDC to regulate and restrict cruise ship activity is uncertain. The holding of *Becerra* indicates that the CDC will be unable to regulate the resumption of passenger activities.⁴⁶ Further, the judge's order stated that the CDC could not mandate that cruise ship passengers be vaccinated or require vaccine passports.⁴⁷ Nonetheless, the CDC may impose certain less rigid regulations on cruise liners to promote passenger safety during the course of voyage.

While the CDC currently requires social distancing aboard cruise liners, it may prohibit certain activities that are likely to impede upon the effectiveness of social distancing.⁴⁸ For example, the CDC may ban use of cruise liner night clubs and buffets. Further, it may impose capacity limits on enclosed spaces to ensure easy compliance with social distancing. The CDC may also attempt to incentivize cruise liners to mandate vaccination. Several major cruise liners already mandate that passengers be vaccinated prior to boarding the cruise.⁴⁹ The CDC may choose to provide some type of monetary compensation or tax credit to cruise liners that do opt to mandate vaccination. *Becerra* does not explicitly state that the CDC may not provide incentive for vaccine mandates.⁵⁰ Further, even if an "honor code" system must be used in some states, a mandate will at the very least incentivize some passengers to be vaccinated prior to travel.

⁴⁶ <https://www.law360.com/articles/1378097/fla-seeks-injunction-in-suit-to-overturn-cdc-s-cruise-ban>

⁴⁷ *Id.*

⁴⁸ <https://www.cdc.gov/quarantine/cruise/ti-simulated-voyages-cso.html>

⁴⁹ <https://www.royalcaribbean.com/faq/questions/do-i-need-a-covid-vaccine-to-cruise-what-counts-as-proof>

⁵⁰ [http://myfloridalegal.com/webfiles.nsf/WF/SSWN-C44RE6/\\$file/Order+on+PI.pdf](http://myfloridalegal.com/webfiles.nsf/WF/SSWN-C44RE6/$file/Order+on+PI.pdf)

Finally, the CDC should attempt to educate the public regarding the dangers of cruise ship travel during the pandemic. Although these options are decidedly less effective than a total ban on resumption, they may still serve to limit the spread of COVID-19 and protect public health.

If passenger operations resume, the CDC should also reassess its current method of testing. To begin, the CDC should require that all post disembarkment testing is done at a verified testing center. The Department of Health and Human Services provides a state-by-state list of testing options.⁵¹ The majority of the testing facilities listed are large pharmacy chains like Walgreens and CVS.⁵² Domestically, there are nearly ten thousand CVS stores, making it widely available to passengers who might wish to be tested.⁵³ Cruise liners can screen potential simulation passengers to ensure that they have access to a verified testing center at which they can be tested post disembarkment.

If the CDC opts not to make substantive changes to its data collection methods, it should provide greater guidance regarding the specimen type to be used in testing. Per the CDC's own guidelines, use of saliva in NAAT testing or antigen testing is not preferred.⁵⁴ This oversight should be remedied by specifying that nasal specimen will be used in testing. Additionally, the CDC should give further instructions regarding potential discordant testing.

The burden on data collection may be alleviated if the CDC commences usage of a smartphone application. The CDC could create an app or contract with the makers of health information sharing apps, such as the Commons Project. The burden on the patient to provide documentation of vaccine status (if applicable) and test results, along with the burden on the cruise staff to verify the documentation, would be decreased through use of a smartphone app.

⁵¹ <https://www.hhs.gov/coronavirus/community-based-testing-sites/index.html>

⁵² *Id.*

⁵³ <https://cvshealth.com/about-cvs-health/our-company-at-a-glance>

⁵⁴ <https://www.cdc.gov/coronavirus/2019-ncov/lab/naats.html>

The app would limit the required communication between off-site testing facilities and the cruise liners, further decreasing the burden.

Sincerely,

Alexandra Baskfield
J.D. Candidate
Northeastern University School of Law
Email: baskfield.a@northeastern.edu

Jeffrey M. Zirger
Information Collection Review Office, Centers for Disease Control and Prevention
1600 Clifton Road NE, MS- D74
Atlanta, Georgia 30329

RE: Phased Approach to the Resumption of Cruise Ship Passenger Operations 2021-09094,
Docket No. CDC-2021-0011¹

June 30, 2021

Executive Summary:

This Proposed Rule to resuming cruise ship operations raises notable concerns and poses potential dangers to the well-being of passengers, crew, and local communities at the scheduled destination sites. The proposal allows an experimental program to use volunteers when the full health risks are not known. This is potentially reckless and exposes human subjects to uncontrolled factors. It is likely that passengers and crew members may not know the various potential effects of COVID-19. The informed consent requirements may require further specifications. The private cruise operators may need to take additional financial and procedural steps to ensure passenger safety.

Issues of individual privacy, federalism, and unfair or discriminatory policy impact are additional barriers. There are still legal disputes over the forms of protections the federal or state governments may impose, and the potential liability cruise ships face for infection outbreaks is another litigious issue. Certain privacy concerns, such as the passenger and crew surveillance, the collection of medical data, and enforcing quarantining and social distancing restrictions within passenger rooms and crews' quarters are also worth examining. Equity poses another barrier as well. It is not clear whether the private cruise ship companies or the CDC is considering the policy's full impact on communities of color, low-income communities.

NOTE: This public comment was prepared for a Northeastern University School of Law class.

While the cruise economy has been significantly impacted by the pandemic, cruise services are not medically necessary or essential. Until more is known about the health and legal terrain of the “new normal,” it may be in the best interest of the CDC to delay the experimental voyages.

Background:

This comment is addressing the second phase of the CDC’s Framework for Conditional Sailing Order. The second phrase permits certain cruise ship operators to take part in experimental simulated voyages as long as they have fulfilled specific requirements. Currently, they must have: (1) port agreement between the cruise ship operator and any port authority they may stop at during the course of their voyage; (2) medical care agreement between the cruise operator and health care entities to address potential outbreaks; (3) housing agreements between the cruise ship operators and local facilities to ensure possible isolation and quarantine of passengers, crew members, and close contacts. This phase also requires daily testing of staff and passengers and “after-action” reporting to address deficiencies in health and safety protocol.

Confined spaces such as cruise ships or jails pose their own set of risks for infections. Even before the current pandemic, cruise ships experienced outbreaks of infection through water-borne, food contamination, or person-to-person transmission.² In February 2020, the Diamond Princess Ship experienced 454 coronavirus infection cases stemming from one passenger.³ Already, cruise ships are having difficulty maintaining the safety of their own crew.⁴

² Bert, F., Scaioli, G., Gualano, M.R. et al. Norovirus Outbreaks on Commercial Cruise Ships: A Systematic Review and New Targets for the Public Health Agenda. *Food Environ Virol* 6, 67–74 (2014). <https://doi.org/10.1007/s12560-014-9145-51>; Lawrence, D.N. Outbreaks of gastrointestinal diseases on cruise ships: Lessons from three decades of progress. *Curr Infect Dis Rep* 6, 115–123 (2004). <https://doi.org/10.1007/s11908-996-0007-7>

³ Kenji Mizumoto & Gerardo Chowell, *Transmission Potential of the Novel Coronavirus (COVID-19) Onboard the Diamond Princess Cruises Ship, 2020*, 5 *Infectious Disease Modelling* 264 (2020), available at <https://www.sciencedirect.com/science/article/pii/S2468042720300063>.

A Royal Caribbean Cruise Ship which has been approved to participate in this trial program has had to postpone its departure because eight crew members tested positive for coronavirus.⁵ During the pandemic, cruise ships presented a challenging debacle for public health officials. However, the proposed policy does not effectively address the major public health, legal, or equity issues that may arise. In fact, the policy seems to be prematurely implemented before sufficient public health and legal guidance is available.

Analysis:

Public Health Concerns:

This policy unnecessarily puts human beings in conditions which may expose them to disease or chronic harm. Notably, given the confined space available on a cruise ship, cruise trips are considered a high-risk activity and should be postponed until the rates of global vaccinations increase and more is known about the long-term effects of coronavirus infections. Recent studies have found unexpected health complications arising from COVID-19 infections, a constellation of symptoms known as “long COVID.” The study tracked nearly two million people within the United States who were positive for the coronavirus last year and found that “one month or more after their infection, almost one-quarter — 23 percent — of them sought medical treatment for new conditions.”⁶ These post-COVID health issues were present among individuals who experienced mild, moderate, or no symptoms from the virus.⁷ Given the uncertain risks, it would

⁴ Hanna Sampson, *Royal Caribbean cruise postponed after 8 crew members test positive for coronavirus*, The Washington Post (June 16, 2021), <https://www.washingtonpost.com/travel/2021/06/16/royal-caribbean-odyssey-crew-covid/>.

⁵ *Id.*

⁶ Pam Belluck, *Many Post-Covid Patients Are Experiencing New Medical Problems, Study Finds*, The New York Times (June 15, 2021), <https://www.nytimes.com/2021/06/15/health/covid-19-patients.html>.

⁷ *Id.*

be difficult for volunteer passengers and crew members to provide their full consent to participate in a cruise.

There is also some uncertainty about the potential consequences of collecting health-related passenger information. Although Cruise ships operators and staff are not “covered entities” under HIPPA, there are still health privacy concerns as cruise operators begin to request and collect vaccination history or vaccination status of passengers. There are definite questions regarding how private cruise ship operators will collect, store, and protect this information from hack and leaks. What is the extent of the surveillance and what privacy rights are implicated? Are private room and entrances being watched? How routinely is this data being stored or erased? How informed are passengers and crews that they are being monitored? Individual privacy rights still matter even when waivers are signed, and it is important that the CDC consider how monitoring for social distancing violations may infringe individual privacy rights. The CDC or private cruise ship operators must provide volunteer passengers and crew members with a full and comprehensive risks and benefits before they can be expected to participate in the program.

Legal Concerns:

There are serious legal questions that have not been fully addressed, as well as serious federalism issues regarding what kind of quarantine and vaccination disclosures private entities may impose on customers or guests. Many legal questions are still being addressed in federal court. It is unclear whether states or federal agencies have the authority to establish and enforce pandemic-related restrictions. A recent Supreme Court decision held in favor of churchgoers, holding that the certain states exceeded their authority in imposing COVID-19 related

restrictions for in-person attendance.⁸ Furthermore, in two popular cruise states, Florida and Texas, the state administrations have been hostile to mandatory vaccination requirements or disclosures of vaccination status.⁹ In Florida, Republic Governor DeSantis issued fines for cruise lines that ask for proof of vaccination status.¹⁰ This poses grave concern over what safety standards cruise lines will have to comply with and the potential consequences of violating states-specific policies. Recently, a United States District Court also enjoined the CDC's conditional sailing order in *State of Florida v. Becerra*.¹¹ This decision blocks the CDC from enforcing its pandemic-related restrictions for cruise lines operating in Florida because it was highly likely that the CDC exceeded its authority when it created these regulations.¹²

Equity Concerns:

It is important to understand that this policy has significant potential to harm individuals who did not consent to participate in this program even with reduced passenger capacity. Passengers and staff may consent to be there, but others do not consent to increased risk of exposure from cruise ship passengers. Port authority employees, local communities at destination sites, the family, friends, colleagues, and neighbors of all the participants and crew members may also be affected. In one study, researchers found that “between 56.7 and 74.3 million increased-risk US adults lived with or were themselves essential workers who could not [work at home]”.¹³ Nonconsenting individuals may be exposed to COVID-19 or may see their loved ones infected. This is particularly worrying for low-income communities and communities

⁸ *South Bay United Pentecostal Church v. Newsom*, 140 S. Ct. 1613 (May 29, 2020).

⁹ Alissa Musto, *I work on cruise ships. We can't get back to normal if we can't require vaccines*, Washington Post (June 16, 2021), <https://www.washingtonpost.com/outlook/2021/06/16/cruise-vaccines-desantis-florida/>.

¹⁰ *Id.*

¹¹ *Florida v. Becerra*, No. 8:21-cv-839-SDM-AAS, 2021 U.S. Dist. LEXIS 114297 (M.D. Fla. June 18, 2021)

¹² *Id.*

¹³ McWilliams JM, Russo A, Mehrotra A. Implications of Early Health Care Spending Reductions for Expected Spending as the COVID-19 Pandemic Evolves. *JAMA Intern Med.* 2021;181(1):118–120. doi:10.1001/jamainternmed.2020.5333

of color, which have lower rates of vaccination and higher rates of COVID-19-related deaths. For example, tourists have recently flocked to popular vacation sites such as Puerto Rico or Cancun, and this has increased COVID-19 infection rates among local populations who cannot easily access vaccines.¹⁴ Even if cruise lines were to provide vaccinations to all consenting participants and crew members, there could still be a chance that vaccinated individuals can spread the virus.¹⁵

Furthermore, the crew is at a disproportionate risk during any outbreak. One study of the Diamond Princess Ship's infection rates found that quarantine protocols reduced infection rates among passengers, but infection rates remained steady for crew members because they needed to continue providing essential services to isolated passengers.¹⁶ The CDC should give greater consideration to the class and racial demographics of those who will have to work on cruise ships and risk greater exposure, as compared to those who can voluntarily board a cruise ship as a passenger.

Private cruise ship operators will not be able to completely choose what passengers will self-select into participating as well. It is unlikely that those with more cautionary and rule-obeying tendencies will choose to participate in an that may expose them to a COVID-19 or other disease outbreak. Cruise companies can never be fully sure that passengers will always comply with all policies. Even if the cruise ship operators choose to increase their surveillance and monitoring of passengers, this poses its own concerns to the well-being of passengers and crew.

¹⁴ Carol Murphy Marcos, *Puerto Rico sees a surge in tourism—and a rise in aggressive tourist behavior*, the Guardian (Mar. 12, 2021), <https://www.theguardian.com/world/2021/mar/12/puerto-rico-tourists-aggressive-behavior-coronavirus>.

¹⁵ Sanjay Mishra, *Can people vaccinated against COVID-19 still spread the coronavirus*, PBS (May 27, 2021), <https://www.pbs.org/newshour/health/can-people-vaccinated-against-covid-19-still-spread-the-coronavirus>.

¹⁶ Kenji Mizumoto & Gerardo Chowell, *Transmission Potential of the Novel Coronavirus (COVID-19) Onboard the Diamond Princess Cruises Ship, 2020*, 5 *Infectious Disease Modelling* 264 (2020), available at <https://www.sciencedirect.com/science/article/pii/S2468042720300063>.

Recommended Actions:

First and foremost, I would recommend the delay the implementation of simulated voyages until at least some of the legal and health issues are fully adjudicated or subside. If this suggestion is refused, then I would recommend the following to address or mitigate the potential negative outcomes:

- **Informed consent should be thorough and uniformly distributed to all passengers and crew members:**
 - Before any passenger or crew member boards the cruise ship, they must consult with a healthcare worker who is able to explain the potential medical consequences of their participation. The cruise ship should be responsible for providing access to the healthcare professional and for ensuring that the healthcare professional provides all medically pertinent information in a language that the passenger is fluent in and comprehends. It is possible to do this through a tele-health system as well to decrease in-person contact.
- **Cruise ship companies who participate in this pilot program should be obligated cover the medical costs** that can be reasonably attributed to this experimental policy for the crew, human subjects, and those that are otherwise exposed through contact with passengers and crew (such as port authority staff).
- **Employee protections should be clear and uniform across participating companies:** Ensure the employees who choose not to participate in simulated voyages are not penalized for prioritizing their own safety. Employees should not be terminated, black-listed, or otherwise penalized for choosing not to participate.

- **Stringent contact tracing should be required before, during, and after the voyage.**

All passengers, crew, and other employees who choose to participate in this program should share detailed logs of all persons and locations that they have come into contact before embarking on the cruise ship and before disembarking the cruise ship at any of the port locations. While the CDC no longer requires this for vaccinated individuals in general, it would be important to keep rigorous documentation of possible spread of the virus.

Sincerely,

Mahathi Vemireddy
J.D. Candidate, Class of 2022
Northeastern University School of Law
E-mail: vemireddy.m@northeastern.edu

Jeffrey M. Zirger
Information Collection Review Office, Centers for Disease Control and Prevention
1600 Clifton Road NE, MS- D74
Atlanta, Georgia 30329

RE: Phased Approach to the Resumption of Cruise Ship Passenger Operations 2021-09094,
Docket No. CDC-2021-0011

June 30, 2021

Executive Summary

The CDC recently issued a phased plan for cruise ship operators to resume their operations. Though safety of all on board the ship must be prioritized, this phased approach is overly burdensome on requirements and reporting, which is reflected in recent court decisions. Looking at other industries, there are various mitigation efforts that can be taken to reduce the risk of aerosolized transmission of COVID-19 – which is the most concerning method of transmission on cruise ships. If cruise ships can adopt these mitigation measures and require robust COVID-19 testing and/or full vaccination status in order to board the ship, the risk of COVID-19 transmission onboard will be considerably reduced, and there will be significantly less to report to the CDC. Vaccines have proven to be effective, and if cruise ship operators take a strong stance on vaccination requirements and/or devote the necessary resources to effective testing, the immense burden that the current phased approach has on both the cruise ship operators and the CDC would be substantially reduced. Guidance on resuming cruise ship operations should instead focus on improving the cabin and common spaces on cruise ships and requiring negative tests or vaccines to mitigate the spread – not simply having resources in place. These plans should be tested through simulated voyages, with a robust reporting system when positive cases are identified. This guidance would enable the cruise industry to resume operations without jeopardizing the health and safety of their guests and crew.

COVID-19 Impact on Cruises

The COVID-19 pandemic, though appearing to be on the decline in the United States, is not over yet and risks for COVID-19 surges in the future must still be considered. As of June 23, 2021, the United States has confirmed over 33 million COVID-19 cases and has lost over 600,000 individuals to the virus.¹

Cruise ships in Asia were sites of the earliest COVID-19 outbreaks in early 2020. The *Diamond Princess* ship had a symptomatic individual on board on January 25, 2020, and 19.2% of the population on board (712 of the 3,711 individuals) eventually tested positive for COVID-19— many required critical care and some cases resulted in death.² The *Grand Princess* ship sailed twice, resulting in 159 COVID-19 cases and eight deaths.³ Since tens of thousands of passengers and crew members were on cruise ships at the start of the pandemic and had travel plans booked for the future, the CDC took action to mitigate the spread of COVID-19. It is, however, important to note that at the time of these outbreaks in 2020 on cruise ships, there were no mitigation measures in place, because of the “unknown” and early stage of the pandemic, so individuals were not wearing masks or social distancing.

The director of the CDC issued a “No Sail Order and Other Measures Related to Operations” on March 14, 2020, which ordered cruise ships to stop sailing; the decision was supported by the Cruise Lines International Association.⁴ This resulted in cruise ship operations being suspended from U.S. ports for the next 30 days. This order was renewed on April 9, 2020,

¹ *COVID Data Tracker*, CTRS. FOR DISEASE CONTROL AND PREVENTION, <https://covid.cdc.gov/covid-data-tracker/#datatracker-home> (last visited June 23, 2021).

² *Framework for Conditional Sailing and Initial Phase COVID-19 Testing Requirements for Protection of Crew*, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES & CTRS. FOR DISEASE CONTROL AND PREVENTION, https://www.cdc.gov/quarantine/pdf/CDC-Conditional-Sail-Order_10_30_2020-p.pdf (last visited May 22, 2021).

³ *Id.*

⁴ *CDC COVID-19 Orders for Cruise Ships*, CTRS. FOR DISEASE CONTROL AND PREVENTION, <https://www.cdc.gov/quarantine/cruise/covid19-cruiseships.html> (last visited May 22, 2021).

and extended and modified on July 16, 2020 and September 30, 2020.⁵ On October 30, 2020, the CDC released a Framework for Conditional Sailing which put forth requirements of cruise ship operators to mitigate COVID-19 risks and explained the framework of the phased approach that was going to be used to begin operating cruise ships again.⁶ On April 2, 2021 and May 5, 2021, additional phases of the framework for Conditional Sailing Order were released, giving cruise ship operators all requirements and recommendations to begin re-starting their operations.⁷

The CDC now requires cruise ship operators to obtain a COVID-19 Conditional Sailing Certificate, which requires operators to report the following in each phase⁸:

- Phase 1: Mass testing of crew and laboratory capacity to test the crew and future passengers
- Phase 2: A port agreement between the cruise ship operator and the port authority to determine how many ships will operate out of a port at any given point; medical care agreements with health care entities to ensure medical care; housing agreements with shoreside facilities for quarantine and isolation purposes; requests for approval to conduct simulated voyages; after-action reports of each simulated voyages including all test results
- Phase 3: successful simulations and other application forms for restricted voyages.

Analysis of CDC Phases

The very nature of a cruise ship brings different populations together, to live, eat, drink, dance, and relax in close, often enclosed, spaces with minimal ventilation. Furthermore, COVID-19 is most likely to be spread through aerosolized particles, which can result in so-called “super spreader” events.⁹ Aerosolized droplets are released when people are speaking and can infect people over 15 feet away if the duration of exposure is extensive.¹⁰ It should come as no surprise, then, that the risk of COVID-19 exposure and infection is very high on cruise ships. This

⁵ *Id.*

⁶ *Id.*

⁷ *Id.*

⁸ *Id.*

⁹ David A. Edwards et al., *Exhaled aerosol increases with COVID-19 infection, age, and obesity*, PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES OF THE UNITED STATES OF AMERICA, January 12, 2021, at 1. <https://www.pnas.org/content/pnas/118/8/e2021830118.full.pdf>

¹⁰ *Id.*

environment not only poses a risk to those on board the ship, but to those at port cities throughout the United States and abroad, as well as when passengers disembark and travel back to their hometowns after exposure on board. Despite the high risk, various mitigation measures can be implemented to safely sail cruise ships, especially at this stage of the pandemic. The mitigation measures have proven to be successful in other high-risk industries and many high-risk situations have had zero COVID-19 cases when all mitigation measures are complied with.¹¹ This, combined with the high vaccination rates across the United States, make this extensive reporting unnecessarily burdensome both on cruise ship operators reporting this information and, on the CDC, collecting and reviewing this information. Courts have also found this to be true in the most recent case addressing the phased re-opening of the cruise industry in State of Florida v. Becerra.¹² A United States District Court ruled in favor of the State of Florida, and against the CDC, stating that the CDC is “preliminarily enjoined from enforcing against a cruise ship arriving in, within, or departing from a port in Florida the conditional sailing order and the later measures.”¹³

Comparison to Other Industries

Other industries that are also at a high risk for COVID-19 are not subject to the strict conditional orders that the cruise industry is. This is seen in high-risk settings such as health facilities, schools, and the other sectors of the travel industry.

¹¹ See *COVID-19 Report Card*, NEW YORK STATE DEPARTMENT OF HEALTH, <https://schoolcovidreportcard.health.ny.gov/#/home> last visited May 22, 2021); see also Mary Beth Versaci, *ADA study finds COVID-19 rate among dentists less than 1%*, AMERICAN DENTAL ASSOCIATION, <https://www.ada.org/en/publications/ada-news/2020-archive/october/ada-study-finds-covid-19-rate-among-dentists-less-than-1-percent> (last visited May 22, 2021).

¹² Florida v. Becerra, No. 8:21-cv-839-SDM-AAS, 2021 U.S. Dist. LEXIS 114297, at *3 (M.D. Fla. June 18, 2021)

¹³ *Id.*

Dentistry is one of the most at-risk jobs for COVID-19 infection and has been experiencing significantly lower COVID-19 rates of infection than other health professions.¹⁴ Individuals going to the dentist are unable to wear a mask, given the nature of dentistry, which is a significant mitigation factor that is required on board cruise ships.¹⁵ This low infection rate is likely a direct result of the increased mitigation measures those dental offices are required to implement before opening their doors to patients. Even with only 72.8% of dentists using PPE as recommended by the CDC's guidance, 99.7% of dentists implemented all necessary infection prevention measures such as enhanced disinfection, temperature screening, symptom screening, encouraging a social distance in their office, and improving ventilation – especially when using dental handpieces on patients that produce aerosolized particles.¹⁶

In addition to the less-strict re-opening orders in the health industry, schools (made up largely of unvaccinated individuals) also do not face such burdensome restrictions. Among private schools on Long Island that have been open for in-person learning since the start of the 2020-2021 school year – infection rates have remained low when mitigation measures have been adopted.¹⁷ Many of these schools have installed air purifiers in their classrooms, which exchanges air every 30 minutes. Among schools that had their students distanced at 3 feet apart since September (despite the CDC's recommendation of 6 feet at the start of the year), the number of students who have been reported as positive has been under 4%.¹⁸ Of those students, there have been no reports of on-site COVID-19 transmission and all of the positive cases were a

¹⁴ Mary Beth Versaci, *ADA study finds COVID-19 rate among dentists less than 1%*, AMERICAN DENTAL ASSOCIATION, <https://www.ada.org/en/publications/ada-news/2020-archive/october/ada-study-finds-covid-19-rate-among-dentists-less-than-1-percent> (last visited May 22, 2021).

¹⁵ *Order: Wearing of face masks while on conveyances and at transportation hubs*, CTRS. FOR DISEASE CONTROL AND PREVENTION, <https://www.cdc.gov/quarantine/masks/mask-travel-guidance.html> (last visited May 22, 2021).

¹⁶ *Id.*

¹⁷ *See COVID-19 Report Card*, NEW YORK STATE DEPARTMENT OF HEALTH, <https://schoolcovidreportcard.health.ny.gov/#/home> (last visited May 22, 2021).

¹⁸ *Id.*

result of outside exposures.¹⁹ This indicates that were students to “live” at school, like they would “live” on the cruise ship, in their close quarters of nearly 20 students in a classroom for 8 hours a day – the onsite COVID-19 transmission rate likely would still be very low.

Additional Consideration: Fairness for the Cruise Industry

Other sectors of the travel industry have resumed their “new normal” operations for a significant period of time and hotels are not subject to the same reporting standards that the cruise industry is subject to. CDC guidance for hotel employers essentially requires more cleaning than normal and use of contact tracing measures.²⁰ Hotels often have restaurants and a lobby where people congregate. Guests are often “in and out” from their travels, business meetings, and events, and are at great risk of exposure. On cruise ships, individuals are often “in and out” participating in activities, such as offshore excursions, gathering in cohorts, and “residing” on the ship together as they would in a hotel. Though individuals on cruise ships may intermingle more than individuals in hotels, this only justifies enhanced safety measures as is, explained above, required in hotels – not an extensive phased re-opening with overburdening reporting standards.

Additionally, as vaccination rates increase, COVID-19 transmission rates have been steadily decreasing. More is known about the COVID-19 virus now as compared to early 2020. The CDC, along with many state health departments, has now stated that if an individual is vaccinated against COVID-19, they are not required to quarantine as a result of that exposure.²¹ Furthermore, if an individual is vaccinated, they are not required to wear a mask or social

¹⁹ *Id.*

²⁰ *COVID-19 Employer Information for Hotels, Resorts, and Lodges*, CTRS. FOR DISEASE CONTROL AND PREVENTION, <https://www.cdc.gov/coronavirus/2019-ncov/community/organizations/hotel-employers.html> (last visited May 22, 2021).

²¹ *Interim Public Health Recommendations for Fully Vaccinated People*, CTRS. FOR DISEASE CONTROL AND PREVENTION, <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated-guidance.html> (last visited May 22, 2021).

distance.²² The phased guidance regarding cruise ship operations resuming does not address vaccination status and still places a heavy burden on both the CDC and cruise ship operators. If a cruise operates with 100% of individuals fully vaccinated – they are still required to do a significant amount of reporting. This is despite the CDC stating that “if you are fully vaccinated, you can resume activities that you did prior to the pandemic.”²³ In fact, in the recent win for the state of Florida in State of Florida v. Becerra, the CDC’s failure to address vaccination status in this phased reopening plan was used as evidence that the CDC is acting arbitrarily in this policy.²⁴ Additionally, if a cruise ship operator states that their policy is to only sail with fully vaccinated individuals, as Carnival Cruises has²⁵, there should be no need to go through the extensive phases that are put forth. Contact tracing can still be done in the event that a vaccinated individual tests positive, but the likelihood of this is slim and this likelihood should be weighed against the costs and burden of this phased approach. The guidance does not line up that Madison Square Garden in New York City, an enclosed indoor venue, along with many other enclosed indoor venues, can have “fully vaccinated” sections, where masks are not required and a social distance does not have to be maintained, with no reporting requirements, but cruise ships cannot sail with the same guidance.²⁶

Even if cruise ships were not given the same relaxed guidance as other industries across the country have been given, other industries have been permitted to resume operations, provided that individuals present a negative COVID-19 test via a rapid test within 6 hours of “entering” or

²² *When You’ve Been Fully Vaccinated*, CTNS. FOR DISEASE CONTROL AND PREVENTION, <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated.html> (last visited June 24, 2021).

²³ *Id.*

²⁴ Florida v. Becerra, No. 8:21-cv-839-SDM-AAS, 2021 U.S. Dist. LEXIS 114297, at *3 (M.D. Fla. June 18, 2021)

²⁵ *Have Fun. Be Safe. COVID-19 Guest Protocols*, CARNIVAL CRUISES, <https://www.carnival.com/legal/covid-19-legal-notice/covid-19-guest-protocols> (last visited June 24, 2021).

²⁶ *What Do I Need to Know?*, MADISON SQUARE GARDEN ENTERTAINMENT, <https://www.msg.com/reopening-faq#needtoknow> (last visited May 22, 2021).

a PCR test within 72 hours of “entering.”²⁷ This applies to individuals who want to attend venues without full vaccination status and many ceremonies such as graduations and weddings (both indoors and outdoors). This was also the travel guidance before it was eliminated – presumably because the robust testing was no longer necessary.²⁸ If the CDC has eliminated testing requirements after travel in other settings, the same should apply for cruise ships and cruise ships should not be held to a higher standard. When COVID-19 tests are required in some, specific, settings, these test results are not required to be submitted to state health departments or the CDC. Though there is a risk of false negative tests, the recommendations below explain how this risk can be mitigated and that the benefits of this method, at this stage in the COVID-19 pandemic where the U.S. is experiencing a decline in test positivity rate and a rise in vaccination rates, may outweigh the harms.²⁹

Recommendations

The phased operations approach to resuming the sailing of cruise ships **should be eliminated**. Significant reporting administrative burdens will be reduced for the CDC and the cruise ship operators. The phased reopening guidance has a heavy emphasis on reporting and on having medical equipment available. Though this is one approach that could be successful, it is overly burdensome and does not address the root of the ending the COVID-19 pandemic – proactive mitigation. Guidance from the CDC for cruise ship operators should instead require the following, which focus on providing safe spaces on board; whenever a cruise ship operator submits proof of the following, their vessels should be cleared for sailing.

²⁷ *Id.*

²⁸ *Updated Interim Guidance for End of Academic Year Celebrations During the COVID-19 State of Emergency*, NEW YORK STATE DEPT. OF HEALTH, https://coronavirus.health.ny.gov/system/files/documents/2021/04/doh_covid19_updatedgraduationguidance_042721.pdf (last visited May 22, 2021).

²⁹ *Daily State by State Testing Trends*, JOHNS HOPKINS UNIVERSITY OF MEDICINE, <https://coronavirus.jhu.edu/testing/individual-states> (last visited May 22, 2021).

Require Improved Ventilation on Board

As noted in studies by the CDC and other private sector entities, improving ventilation to minimize the risk of aerosolized transmission of COVID-19 is critical to stopping the spread of the virus.³⁰ These studies also indicate that airborne transmission can be reduced if airflow and ventilation are improved.³¹ In an environment like a cruise ship, if individuals in large indoor spaces are breathing air that is filtered and turned over every 30 minutes, the risk of infection will be significantly lower. Part of the reason cruise ships had massive outbreaks in early 2020 was because individuals were not wearing masks in poorly ventilated spaces. Given that masks will be worn when a social distance cannot be maintained on the ship, the severity of any potential outbreaks will likely be significantly reduced. Requiring this will not only be helpful during the COVID-19 pandemic, but in reducing the spread of any airborne virus in the future.

Require Individuals to be Fully Vaccinated or Consent to Robust COVID-19 Testing

Vaccines are safe and effective against COVID-19. Guidance from the CDC and state and local health departments encourage all individuals to get the COVID-19 vaccine as soon as possible. Vacationing on cruise ships should not be an exception to this. As explained above, the vaccine permits individuals to stop using their mask, “resume activities that you did prior to the pandemic,”³² and stop maintaining a social distance in many settings and industries. Most of these industries have not experienced major outbreaks, as of this writing on June 24, 2021, because of the new policy. If individuals are fully vaccinated, they can upload proof of vaccination status to their cruise ship account and this will allow them to have this on record for any future sailing. Since many individuals are vaccinated against COVID-19 now, this one-step

³⁰ Lidia Morawska et al., *How can airborne transmission of COVID-19 indoors be minimised?*, ENVIRONMENTAL INTERNATIONAL, September 2020, at 1.

³¹ *Id.*

³² *When You've Been Fully Vaccinated*, CTRS. FOR DISEASE CONTROL AND PREVENTION, <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated.html> (last visited June 24, 2021).

reporting measure would replace the many reporting requirements that the phased approach currently requires.

If individuals are not fully vaccinated – and if the cruise ship operator opts to not have only vaccinated individuals travel – they should be required to consent to robust COVID-19 testing in order to board the ship. As in many other industries, this would include a test before boarding the ship, during their travels, and before leaving the ship to return home. Many universities require their students to test for COVID-19 every three days if they would like to attend classes in person.³³ This has proven to be successful and has resulted in both low transmission and low-test positivity rates.³⁴ In terms of minimizing the reporting necessary, COVID-19 tests can be pooled for more effective testing and only positive test results should be required to be reported to the CDC. This means that test samples from multiple people would be analyzed under one laboratory test to see if any of the samples have the SARS-CoV-2 virus.³⁵ If the pooled result is negative, all the people who provided samples are assumed to be negative and only if the pooled test result is positive does each sample in the pool need to be tested individually to determine which sample is positive.³⁶ This is a method that is recommended by the CDC when the number of positive test results is expected to be low, which is something that should be considered given the current low test-positivity rate in the country as a result of the high vaccination rates.³⁷

Require that Operators Have Effective Medical Treatment and Contact Tracing Resources Available

³³ *Testing Protocols and FAQs*, NORTHEASTERN UNIVERSITY, <https://news.northeastern.edu/coronavirus/reopening/testing-protocols/> (last visited May 22, 2021).

³⁴ *Testing Dashboard*, NORTHEASTERN UNIVERSITY, <https://news.northeastern.edu/coronavirus/reopening/testing-dashboard/> (last visited May 22, 2021).

³⁵ Interim Guidance for Use of Pooling Procedures in SARS-CoV-2 Diagnostic, Screening, and Surveillance Testing, CTRS. FOR DISEASE CONTROL AND PREVENTION, <https://www.cdc.gov/coronavirus/2019-ncov/lab/pooling-procedures.html> (last visited June 24, 2021).

³⁶ *Id.*

³⁷ *Id.*

If an individual becomes symptomatic or tests positive for COVID-19, the cruise ship operators should have the resources they need to quickly address the situation – whether they are at port or at sea. This includes having medical equipment on board for the positive individual and ensuring that individuals on the ship are trained in proper contact tracing to isolate the positive individual and quarantine individuals who were in close contact with that person. This is not very different than what is currently required, but the cruise ship operators should not eliminate infection control procedures when the phased approach is eliminated.

Eliminate the Simulated Voyages

There is no other industry requires their operations to undergo trial runs before beginning. It is understood that the COVID-19 pandemic had devastating impacts on cruise ships in early 2020. As explained above, it is important to note that the early outbreaks were, in part, a result of no mask or social distancing mandates. Since that time, much has been learned about COVID-19, particularly which safety measures work, and which do not. Guidance has been adapted to adjust for the guidelines that were ineffective³⁸, mitigation measures are effective, and protocols are in place for isolating COVID-19 positive individuals when the situation presents itself. Furthermore, having vaccinated individuals board a ship at 10% capacity for a simulated voyage is not an accurate representation of what a cruise would be like at 50% or 100% capacity. Simulated voyages are only further delaying the cruise industry from setting sail and safely returning to “the new normal” like many other industries are while requiring more reporting to the CDC.

³⁸ See *Operational Strategy for K-12 Schools through Phased Prevention*, CTRS. FOR DISEASE CONTROL AND PREVENTION, <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated-guidance.html> (last visited May 22, 2021). (removing barriers as a recommendation when they were determined to be ineffective).

The recommendations I have made above are similar to the existing phased approach, as they pertain to prioritizing the safety of those on board and relying on evolving guidance from public health officials. The extensive reporting that is required of cruise ship operators is excessive and overburdensome. Cruise ship operators should not have to work within the limits of each phase when nearly every other industry has been able to open beyond the scope of what these phases provide.

Sincerely,

Kyla Portnoy
J.D./M.P.H Candidate
Northeastern University School of Law & Tufts University School of Medicine
Email: portnoy.k@northeastern.edu

Jeffrey M. Zirger
Information Collection Review Office, Centers for Disease Control and Prevention
1600 Clifton Road NE, MS– D74
Atlanta, Georgia 30329

RE: Phased Approach to the Resumption of Cruise Ship Passenger Operations 2021-09094,
Docket No. CDC-2021-0011

June 30, 2021

Executive Summary:

The subject of this comment hardly needs an introduction. On June 12, 2021, a year and a few months after the World Health Organization (WHO) declared COVID-19 to be a pandemic, it was reported that in the United States, deaths due to COVID-19 exceeded 600,000 people.¹ A Reuters tally reports that this number accounts for about 15% of the world’s total coronavirus deaths.² To contextualize this devastation, President Biden stated, “Today, we mark a truly grim, heartbreaking milestone: 500,071 dead. That’s more Americans who have died in one year in this pandemic than in World War I, World War II and the Vietnam War combined.”³

After over a year of living in a society not only impacted but truly shaped by the constant threat of rising disease prevalence, we now find ourselves in a time in which rates of transmission and contraction of COVID-19 have decreased.⁴ This, occurring alongside a vast increase of vaccinated people.⁵ As constituents ache to return to the world in which we lived pre-COVID, we are starting to see a litany of proposed legislation and policies aimed at finding the best way to “re-open.” In this paper, I examine the Centers for Disease Control and Prevention’s (CDC) plan to phase back into cruise ship operations—just one of the many (but perhaps one of

¹ <https://www.usnews.com/news/top-news/articles/2021-06-14/us-covid-19-deaths-cross-painful-600-000-milestone-as-country-reopens>

² <https://graphics.reuters.com/world-coronavirus-tracker-and-maps/>

³ <https://www.npr.org/sections/health-shots/2021/02/03/962811921/the-u-s-battles-coronavirus-but-is-it-fair-to-compare-pandemic-to-a-war>

⁴ <https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html>

⁵ <https://www.bloomberg.com/graphics/covid-vaccine-tracker-global-distribution/>

the most unwieldy) industries attempting to re-open. While the CDC's plan seems to merely relax those that were previously implemented during the height of the pandemic, I argue that the proposed measures are not sufficient.

Background:

Data indicate that the setting of a cruise ship is uniquely suited to disease spread.⁶ The Diamond Princess cruise ship, which departed from the Port of Yokohama on January 20, 2020, clearly illustrates this point.⁷ On February 1st, in response to reports of active COVID-19 cases on board, the ship called into the Naha Port in Okinawa to quarantine. By February 4th, it was revealed that 10 out of 31 tested passengers were infected. In response, all Diamond Princess passengers and crew—a total of 3,700 people—were told to isolate on-board for two weeks.⁸ By February 18th, the total number of confirmed cases totaled to 542 people. It was later calculated that each confirmed case of COVID-19 on-board the Diamond Princess transmitted the virus to about 15 other people, which is four times higher than the rate of transmission in Wuhan, China--the original epicenter of the outbreak.⁹ With the devastation of the Diamond Princess in mind, on March 9th, 2020, the United States left the Grand Princess cruise ship docked at the Port of Oakland due to a COVID-19 outbreak on board.¹⁰ The cruise ship was connected to 159 confirmed COVID-19 cases, with eight reported deaths.¹¹

⁶ Ward, K. A., Paul, A., Mcanulty, J. M., Iwasenko, J. M. & Dwyer, D. E. Outbreaks of pandemic (H1N1) 2009 and seasonal influenza A (H3N2) on cruise ship. *Emerging Infectious Diseases* 16, 1731–1737 (2010).

⁷ "[Coronavirus: Dozens more catch virus on quarantined cruise ship](#)". BBC. 7 February 2020. *Archived* from the original on 11 February 2020

⁸ Chen, CM; Jyan, HW; Chien, SC; Jen, HH; Hsu, CY; Lee, PC; Lee, CF; Yang, YT; Chen, MY; Chen, LS; Chen, HH; Chan, CC (5 May 2020). "[Containing COVID-19 Among 627,386 Persons in Contact With the Diamond Princess Cruise Ship Passengers Who Disembarked in Taiwan: Big Data Analytics](#)". *Journal of Medical Internet Research*. **22** (5): e19540. doi:10.2196/19540. PMC 7202311. PMID 32353827

⁹ Journal of Travel Medicine by Rocklov et. Al:

¹⁰ <https://abc7news.com/coronavirus-oakland-grand-princess-cruise-ship-port-of-bay-area/5998499/>

¹¹ <https://www.nytimes.com/2021/06/15/us/coronavirus-california-timeline.html>

On March 13, 2020, the Cruise Line International Association stated that its members would voluntarily suspend cruise ship operations.¹² Thus, it fell upon the CDC to institute a framework for cruise ships that did not voluntarily suspend operations. The CDC issued a Travel Health Notice, warning travelers to wait to travel internationally. As cases continued to be reported on cruise ships, the CDC ultimately issued the *No Sail Order* (NSO).¹³ Data indicate that without this intervention, which was designed to prevent intercontinental and interstate disease spread in an extremely close-quartered setting, future cruise voyages would continue to exacerbate the spread of COVID-19. This is due in part to the high population density on board cruise ships, as well as the fact that crew must both live and work in close, partially enclosed quarters in close relation to cruise ship guests, making social distancing nearly impossible. Community comments revealed desire for routine testing of passengers and crew, social distancing, coordinating between the CDC and the cruise industry, limiting ports of call to private islands, and creating agreements between local public health officials and medical facilities. In October of 2020, the CDC backed these regulations by stating that, “Based on the evidence gathered and explained in the No Sail Order issued on March 14, as modified and extended on April 15, July 16, and September 30, 2020, there is ample reason to believe that absent mitigation measures of the type needed to prevent further transmission, cruise ship travel has the potential to exacerbate and amplify the spread of SARS coronavirus 2.”¹⁴

Implementing this ethos, *The Framework for Conditional Sailing Order* was published in the Federal Register on November 4, 2020.¹⁵ This framework prohibited a cruise ship operator

¹² [https://cruising.org/en/news-and-research/press-room/2020/november/clia-cruise-line-members-voluntarily-extend-suspension-of-us-operations#:~:text=3%2C%202020\)%E2%80%94Cruise%20Lines,remainder%20of%20the%20year%20to](https://cruising.org/en/news-and-research/press-room/2020/november/clia-cruise-line-members-voluntarily-extend-suspension-of-us-operations#:~:text=3%2C%202020)%E2%80%94Cruise%20Lines,remainder%20of%20the%20year%20to)

¹³ <https://www.cdc.gov/quarantine/cruise/covid19-cruiseships.html>

¹⁴ https://www.cdc.gov/quarantine/pdf/CDC-Conditional-Sail-Order_10_30_2020-p.pdf

¹⁵ <https://www.federalregister.gov/documents/2020/11/04/2020-24477/framework-for-conditional-sailing-and-initial-phase-covid-19-testing-requirements-for-protection-of>

from commencing or continuing operations without a COVID-19 Conditional Sailing Certificate issued by the U.S. Department of Health and Human Services (HHS) and the CDC. Cruise ships that were not in United States' waters during the NSO must have an NSO response plan deemed complete and accurate. Cruise ship operators must then continue to follow their individual lines' complete, accurate, and acknowledged NSO response plans. In establishing these guidelines, the *Framework for Conditional Sailing Order* attempts to implement a phased approach to the resumption of cruise ship passenger operations. These phases begin by implementing mass testing of crew; conducting simulated voyages designed to test a cruise ship's ability to mitigate COVID-19 spread; expanding on-shore laboratory capability to test both crew and passengers; and establishing an agreement to determine the number of cruise ships operating out of a single port, address evacuation and medical transport to onshore hospitals for passengers and crew, and include housing agreements for the isolation and quarantine of passengers with COVID-19 with U.S. port authorities and local health authorities. It was within this framework that the CDC addressed some of the social pushback it would likely encounter: "Public health oversight is further needed to correct a market failure stemming from information asymmetry, i.e., the public is often not fully informed in such a way to adequately determine the extent to which any given measure mitigates their personal risk, particularly in light of asymptomatic cases. CDC is therefore overcoming this market failure by ensuring that the measures taken by cruise ship operators are those that are most likely to adequately mitigate such risks."¹⁶

With this statement, I concur. The question becomes, does this framework—with the international and interstate nature of cruise ship travel, seriousness of the illness, rate of spread on cruise ships, and capacity to implement effective testing measures in mind—effectively

¹⁶ <https://www.govinfo.gov/content/pkg/FR-2020-11-04/html/2020-24477.htm>

mitigate potential disease spread as cruise ship operations return to a “new normal.” As variants continue to spread and develop around the world, once again placing people at a higher risk of contracting COVID-19, it behooves the CDC to continue along this preventative trajectory.¹⁷

Analysis

While drafting this comment, on June 18, 2020, *Florida v. Becerra* was decided. In this case, a federal judge granted a preliminary injunction against the CDC from enforcing its NSO.¹⁸ Florida brought this lawsuit to block the NSO implemented in March of 2020, alleging “imminent injury”.¹⁹ Florida Governor Ron DeSantis hailed this ruling. This opinion is in line with Governor DeSantis’ prior actions. In an executive order, DeSantis blocked any business or government entity from requiring proof of COVID-19 vaccination, and after signing Senate Bill 2006 on May 3, 2021, codified this order by banning the use of vaccine passports.²⁰ Most recently, the CDC stated that ships with at least 95% of both crew and passengers fully vaccinated, “cruise ship operators, at their discretion, may advise passengers and crew that they do not have to wear a mask or maintain physical distance in any areas.” This policy may make more sense if it can truly be concluded that 95% of all people on-board a cruise ship are truly vaccinated. These data can hardly be accurately collected in the face of Governor DeSantis’ aforementioned ban on the use of “vaccine passports” on private entities. This recommendation provides cruise ships with a great amount of leniency and thus, potential to spread disease among a cruise ships’ inherently tight quarters.

¹⁷ Apuzzo, Matt; Rich, Motoko; Yaffe-Bellany, David (8 March 2020). ["Failures on the Diamond Princess Shadow Another Cruise Ship Outbreak"](#). *The New York Times*.

¹⁸ <http://myfloridalegal.com/webfiles.nsf/WF/SSWN-C44RE6/%24file/Order+on+PI.pdf>

¹⁹ <https://www.nbcmiami.com/news/local/judge-rules-in-floridas-favor-in-lawsuit-over-cdcs-no-sail-order-for-cruises/2476238/>

²⁰ <https://www.flgov.com/2021/05/03/governor-ron-desantis-signs-landmark-legislation-to-ban-vaccine-passports-and-stem-government-overreach/>

This loosening of regulations in light of Florida’s new legislation and court ruling is particularly dangerous because, inherent to cruise ships is their interstate and international nature. While Florida may have limited the ability of individual businesses and the federal government from being able to regulate disease spread and distinguish between vaccinated and non-vaccinated passengers, other states and other countries did not choose this risky path. In a study conducted in the 90’s during an influenza outbreak on-board a cruise ship, it was concluded that a disease, which originated from passengers of a single country, spread to crew who were in contact with those passengers. In this study, the authors note that “cruise ships can present infection control issues similar to those in nursing homes. Cruise ships often serve high-risk passengers” . . . “the survey of passengers on the ship in this investigation showed that about three-fourths were elderly and about one-fourth reported having at least 1 additional risk factor for respiratory complications of influenza.”²¹ Should COVID-19, a respiratory disease as is influenza, be exposed to a similar demographic aboard cruise ships with limited oversight as to the confirmation of vaccination status, similar spread may occur.

With these issues in mind, while this framework attempts to implement mass testing of crew; conduct simulated voyages designed to test a cruise ship's ability to mitigate COVID-19 spread; expand on-shore laboratory capability; and establish an agreement to determine the number of cruise ships operating out of a single port, address evacuation and medical transport to onshore hospitals for passengers and crew, and include housing agreements for the isolation and quarantine of passengers with COVID-19 with U.S. port authorities and local health authorities, these measures seem a topical fix at best. Even if cruise ships were able to determine passenger’s vaccination status or whether they previously contracted COVID-19, it is important to note that,

²¹ <https://academic.oup.com/cid/article/31/2/433/295546>

while survivors of COVID-19 are significantly less likely to become reinfected by COVID-19, the risk of reinfection is not zero.²² In a cohort of 3.2 million people in the United States, one study found that individuals who are seropositive for COVID-19 antibodies may be at decreased future risk of SARS-CoV-2 infection.²³

Actions Recommended

With the current political climate in Florida in mind, acknowledging DeSantis' ban on "vaccination passports" and the recent ruling in *Florida v. Becerra*, I argue that the newly proposed CDC guidelines would provide Florida with a perfect situation in which COVID-19 may once again be spread. Perhaps the greatest difficulty in implementing any public health regulation is striking an acceptable balance between what is perceived to be "personal liberty" and prevention. Considering the political landscape, this could be a particularly difficult battle in Florida. Thus, the CDC needs to do more than just implement more regulatory measures. In our very individualistic culture in the United States, scholars have found that framing a health policy issue as something that is universal to the environment is more likely to garner support. Additionally, scholars have found that the public is more likely to resist policy that specifically addresses individual behaviors.²⁴ Thus it is imperative that the CDC begin this new venture by placing a greater emphasis upon the framing of these re-opening procedures, perhaps in a messaging campaign, in senior centers, at town halls, in community centers, in schools, and even in cruise ships themselves.

Additionally, when considering the above behavioral science associated with the framing of health, Thus, rather than trying to mitigate the potential harm done by Governor DeSantis by

²² <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2776810>

²³ <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2776810>

²⁴ <https://www.tandfonline.com/doi/pdf/10.1080/23311886.2016.1268748>

regulating individual behavior, the CDC ought to crack down and tighten the proposed policies that impact the systems themselves. For example, testing protocol ought to be further expanded. While the CDC currently recommends that unvaccinated people get tested 1-3 days before they travel, this ignores the possibility of false negatives.²⁵ I argue that individuals ought to be tested while on board the ship as well. As the CDC recommends that unvaccinated people get tested in a range of 1-3 day before embarkment, it would make sense to continue utilizing the same timeframe while passengers are living on the cruise ship. Similarly, cruise ship operations ought to be further honed—particularly isolation and quarantine procedures.

Sincerely,

Julia Winett
J.D. Candidate
Northeastern University School of Law
E-mail: winett.j@northeastern.edu

²⁵ https://www.cdc.gov/quarantine/pdf/CDC-Conditional-Sail-Order_10_30_2020-p.pdf

Jeffrey M. Zirger
Information Collection Review Office, Centers for Disease Control and Prevention
1600 Clifton Road NE, MS- D74
Atlanta, Georgia 30329

RE: Phased Approach to the Resumption of Cruise Ship Passenger Operations 2021-09094,
Docket No. CDC-2021-0011

June 30, 2021

Executive Summary

As the rules governing the final phases of the Conditional Sailing Order are promulgated, it is imperative that the Centers for Disease Control and Prevention remember that the COVID-19 pandemic is a threat to global health, and that public health in the United States is not set apart from global health. The risks posed to passengers, crew, and communities in the United States are vital to consider, but the risks posed to people and communities in the countries visited by cruise ships sailing from U.S. ports must be considered to a much greater degree than is comprehended in the proposed rules. The currently proposed rules may reduce the risks associated with Covid-19 to individual cruise ships passengers, but they do not sufficiently mitigate the larger public health threat posed by resumption of cruise ship voyages while the Covid-19 pandemic endures.

Cruise ships offer an ideal environment for the virus that causes COVID-19 to spread, and early COVID-19 outbreaks on cruise ships illustrated just how easily an outbreak on a cruise ship can lead to a public health catastrophe. Given the unique threat posed by unvaccinated passengers on a cruise ship visiting multiple countries with varying rates of vaccination, outbreak severity, and health care resources, it is imperative that cruises sailing from U.S. ports require all crew and passengers aged to submit proof of vaccination if voyages are to resume in the near future. Given the widespread, severe ramifications of resuming cruise ship operations with

unvaccinated passengers, HHS and the CDC should consider challenging state laws that would conflict with a rule requiring proof of vaccination for all cruise ship passengers. Alternatively, the CDC should seek to promulgate rules that consider the larger public health ramifications of cruise ship operations during the Covid-19 pandemic and mitigate the negative effects of resumed cruise ship voyages on stakeholders both within and outside the United States.

Background

Cruise ships are, in many ways, the ideal environment for a pathogen such as the COVID-19 virus to spread. Given that the COVID-19 virus is highly transmissible, mechanistically spread through droplets and aerosols and transmissible from hosts who often show no symptoms, the close quarters of a cruise ship put passengers and crew on board at high risk of contracting the virus if fellow passengers are infected.¹ Indeed, cruise ships contributed to the initial spread of the COVID-19 virus in early 2020 and immediately posed a public health quagmire as ships such as the *Diamond Princess* and the *Grand Princess* floated off the coasts of Japan and California respectively, awaiting permission to dock and disembark as COVID-19 spread amongst those on-board and health authorities scrambled to find an appropriate solution.²

3

Over a year after the *Diamond Princess* and *Grand Princess* provided an unwelcome opportunity for scientists to study how the novel coronavirus spreads, millions of people around the world have died from COVID-19.^{4 5} A No Sailing Order prohibited cruise ships from sailing from U.S. ports; a new Conditional Sailing Order allows cruises to resume if various

¹ <https://www.pnas.org/content/118/8/e2015482118>

² <https://www.nature.com/articles/d41586-020-00885-w>

³ <https://www.latimes.com/california/story/2020-12-23/covid-19-spread-despair-grand-princess>

⁴ <https://www.nature.com/articles/d41586-020-00885-w>

⁵ <https://coronavirus.jhu.edu/data/mortality>

precautionary measures are taken and has been implemented in a phased approach.⁶ As safe and effective vaccines become increasingly available to the general population in the United States, pressure to resume normal cruise ship voyages from U.S. ports is growing.⁷ This pressure has come with a battle over whether unvaccinated passengers should be permitted on cruises sailing from U.S. ports.⁸ While the state of Florida has imposed fines for private entities that require proof of vaccination, a recent survey suggested that would-be cruise ship passengers would specifically look for a cruise line that mandated vaccination to sail.⁹ This dissonance suggests that Florida’s approach to removing Covid-19 related restrictions on economic activities may actually be self-defeating, as Florida’s prohibition on “vaccine passports” blocks what may be the only path to resuming activities such as cruise ship voyages safely, responsibly, quickly, and profitably.

As rules for the final phases of the Conditional Sailing Order are promulgated, it is imperative that the Department of Health and Human Services and the Centers for Disease Control and Prevention remember that the COVID-19 pandemic is a threat to global health; this threat can not and will not disappear if the United States treats its own public health as a separate from that of the global community.

Analysis

In the spring of 2021 – as vaccinations became widely available and daily new cases began to decline in the United States – many in the United States began to view the COVID-19 outbreak as fundamentally over. As a result, the expectation that typical activities can resume

⁶ <https://www.cdc.gov/quarantine/cruise/covid19-cruiseships.html>

⁷ <https://www.washingtonpost.com/travel/2021/05/26/royal-caribbean-test-sailing-covid/>

⁸ <https://www.miamiherald.com/opinion/editorials/article251904668.html>

⁹ <https://www.forbes.com/sites/suzannerowankelleher/2021/06/02/most-americans-would-specifically-look-for-a-cruise-line-with-a-vaccination-mandate-per-survey/?sh=2cf790c1239f>

with precautions largely discarded has grown in the United States. When considering resumption of an activity such as cruise ship voyages, however, it is necessary to keep in mind that the COVID-19 pandemic is by no means over for most of the world and still poses a serious threat to even the most vaccinated of countries if efforts to combat the global pandemic are undermined or abandoned.

Arguments for the resumption of cruise ship operations tend to categorically ignore the many non-U.S. residents and communities involved in cruise ship voyages and the risks posed to them from resumption of voyages amidst the COVID-19 pandemic. Cruises do not exclusively visit U.S. ports and locales, frequently docking at ports and visiting locales in multiple other countries, many of which have lagging vaccination rates, continued surges in infections, and finite health care resources. Across Latin America and the Caribbean, vaccination rates remain much lower than those in the United States, with only one tenth of the region's population vaccinated as of the end of May.¹⁰ Allowing cruises to resume normal operations risks the wellbeing of communities in these countries in multiple ways. Firstly, resumption of normal cruise ship operations, even with many precautions in place, puts communities in countries visited by these cruise ships at risk of further outbreaks.¹¹ Outbreaks within these communities, or outbreaks on visiting cruise ships themselves, threaten to overwhelm local health care systems.¹² The Conditional Sailing Order's requirement that cruise lines arrange for medical care and housing at each port on a voyage in case of an outbreak considers the needs of those onboard a ship in case of an outbreak, but does not sufficiently consider the impact that such arrangements may have on the availability of health care resources for local communities, nor

¹⁰ <https://www.miamiherald.com/news/nation-world/world/americas/haiti/article251071689.html>

¹¹ <https://www.miamiherald.com/news/business/tourism-cruises/article251853143.html>

¹² <https://www.miamiherald.com/news/business/tourism-cruises/article251853143.html>

does it address the ramifications of outbreaks associated with a visiting cruise ship after the ship has departed. Permitting unvaccinated travelers to take cruises to these locations exposes these communities to an unacceptable level of risk.

Permitting resumption of normal cruise ship operations places many vulnerable people within the United States at risk as well. While the United States has a relatively high overall vaccination rate, vaccination rates fluctuate from state to state, county to county, city to city.¹³ Vaccination rates vary substantially along geographic, political, and demographic lines, leaving many communities more vulnerable than overall vaccination rates would suggest.¹⁴ Furthermore, it is important to remember that children in the United States are still not able to take a vaccine, and emerging evidence suggests that immunocompromised people and organ transplant recipients do not enjoy the same high level of protection from currently available COVID-19 vaccinations as those without these medical conditions.¹⁵ ¹⁶ Given that cruise ships are an ideal environment for the spread of the COVID-19 virus, permitting resumption of cruise ship voyages with unvaccinated passengers puts many individuals and communities within the United States at increased risk from COVID-19.

While the immediate risks of resumption of normal cruise ship operations will fall most squarely on communities in countries with lagging vaccination rates visited by cruise ships, vulnerable populations within the United States, and U.S. communities with lagging vaccination rates, the long-term ramifications put everyone at greater risk of continued harm from the

¹³ <https://covid.cdc.gov/covid-data-tracker/#vaccinations-county-view>

¹⁴ <https://www.npr.org/2021/06/09/1004430257/theres-a-stark-red-blue-divide-when-it-comes-to-states-vaccination-rates>

¹⁵ <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/keythingstoknow.html>

¹⁶ Boyarsky BJ, Werbel WA, Avery RK, et al. Antibody Response to 2-Dose SARS-CoV-2 mRNA Vaccine Series in Solid Organ Transplant Recipients. *JAMA*. 2021;325(21):2204–2206. doi:10.1001/jama.2021.7489

COVID-19 pandemic. Continued evolution of the COVID-19 virus is guaranteed if the disease continues to spread. Permitting cruise ships to set sail with unvaccinated passengers threatens to provide a lifeline to the COVID-19 pandemic. “The industry poses a unique risk to global health by providing a safe haven for COVID among unvaccinated passengers, and transporting these more dangerous viruses from country to county,” according to Dr. Michael Callahan, director of the Clinical Translation, Vaccine and Immunotherapy Center at Massachusetts General Hospital.¹⁷

Actions Recommended

If cruise ship operations are to resume, it is imperative that all crew and passengers be fully vaccinated and required to submit proof of vaccination in order to sail. Until such a requirement is possible, cruise ships should not be permitted to set sail from U.S. ports. Promulgating such a rule will require the CDC to challenge Florida law prohibiting “vaccine passports.” Such a challenge should incorporate the following points:

1. In the case of *Florida v. Becerra*, in which a preliminary injunction against the CDC’s Conditional Sailing Order was granted, Florida successfully argued in part that the CDC arbitrarily failed to consider lesser alternatives to the Conditional Sailing Order – in essence arguing that the requirements of the Conditional Sailing Order were cumbersome, burdensome, and unclear.¹⁸ The need for certainty was underscored in arguing that the Conditional Sailing Order was arbitrarily burdensome to the cruise lines.¹⁹ Requiring that all passengers and crew be fully vaccinated and

¹⁷ <https://www.miamiherald.com/news/business/tourism-cruises/article251853143.html>

¹⁸ <http://myfloridalegal.com/webfiles.nsf/WF/SSWN-C44RE6/%24file/Order+on+PI.pdf>

¹⁹ <http://myfloridalegal.com/webfiles.nsf/WF/SSWN-C44RE6/%24file/Order+on+PI.pdf>

provide proof of vaccination to sail would provide cruise lines with a clear path to resuming voyages, providing cruise lines with the certainty they seek. The straightforward requirement would certainly be less cumbersome than the current requirements of the Conditional Sailing Order. Given the highly effective vaccines now widely available in the United States, such a requirement would also more successfully ensure that cruise ships can resume voyages safely and without jeopardizing the public health of communities within and outside of the United States that may be affected by resumed voyages. In short, requiring all passengers and crew provide proof of vaccination to sail is the obvious “lesser alternative” to the current Conditional Sailing Order.

2. Given the arguments made above and the economic concerns underpinning Florida’s desire to remove barriers to resuming activities such as cruise ship voyages, Florida should consider that prohibiting “vaccine passports” is not removing a barrier to resumption of activities such as cruise ship voyages. Indeed, such a law is erecting a substantial barrier to resumed cruise ship operations, as a vaccination requirement for all passengers and crew aboard cruise ships is the only way to sufficiently mitigate the risks associated with cruise ship voyages during the Covid-19 pandemic to justify resuming normal cruise ship operations while satisfying the limits on CDC restrictions of cruise ship voyages foreshadowed by the preliminary injunction granted in the *Florida v. Becerra* case.

Additionally, requirements that cruise lines sponsor and facilitate vaccination clinics in communities visited by their ships should be explored. The feasibility of such a requirement depends heavily on availability of vaccines in the countries in question, or on the willingness of

the United States to donate some of its excess vaccine supply to other countries. Encouraging cruise lines to facilitate vaccination clinics for employees at ports visited by cruise ships is certainly a step in the right direction, but the larger public health risks to communities visited by these cruise ships should be considered as well. Alternatively, cruise lines should be prohibited from visiting ports in countries with low vaccination rates or insufficient health infrastructure. Such a requirement would ensure that cruise ships only visit countries where the risk is lower for all parties while incentivizing cruise lines to sponsor vaccination efforts in communities where vaccination rates are not sufficient for inclusion on their ships' voyages.

Sincerely,

Samantha Cardwell
J.D./M.P.H. Candidate
Northeastern University School of Law / Tufts University School of Medicine
E-mail: cardwell.s@northeastern.edu



Jeffrey M. Zirger
Information Collection Review Office, Centers for Disease Control and Prevention
1600 Clifton Road NE, MS- D74
Atlanta, Georgia 30329

RE: Phased Approach to the Resumption of Cruise Ship Passenger Operations 2021-09094,
Docket No. CDC-2021-0011

June 30, 2021

Executive Summary

This brief explains why the information collection plan proposed by the United States Centers for Disease Control and Prevention (CDC) under the project titled Phased Approach to the Resumption of Passenger Operations does not exceed CDC's statutory and regulatory authority and is necessary for the proper performance of the functions of the agency. Three sources of legal authority that confer the requisite power to CDC for the regulation of international cruise ship travel – the Public Health Service Act, the Constitution of the United States, and the Administrative Procedure Act – are central to this analysis and are discussed in turn.

Background

Early in the COVID-19 pandemic, close quarters, shared meals, and communal activities on cruise ships produced an array of devastating – and deadly – super-spreading events. By March 2021, 17% of the reported COVID-19 cases in the U.S. could be linked back to cruise travelers.¹ In the wake of outbreaks aboard the Diamond Princess in Japan and the Grand Princess in the San Francisco Bay, CDC issued a no-sail order on March 14, 2020 “for all cruise ships not

¹<https://www.npr.org/2021/05/29/1001354354/the-buffet-can-stay-what-the-future-of-the-cruise-line-industry-looks-like>

voluntarily suspending operations.”² This no-sail order was extended on April 15, 2020,³ July 16, 2020,⁴ and September 30, 2020. On October 30, 2020, the day before the final extension was to expire,⁵ CDC issued a Framework for Conditional Sailing Order which contained the following four phases building to a resumption of cruise ship travel: “(1) Establishment of laboratory testing of crew onboard cruise ships in U.S. waters; (2) simulated voyages designed to test a cruise ship operators' ability to mitigate COVID-19 onboard cruise ships; (3) a certification process; and (4) a return to passenger voyages in a manner that mitigates the risk of COVID-19 introduction, transmission, or spread among passengers and crew onboard ships and ashore to communities.”⁶ On April 2, 2021, CDC released a set of technical instructions for cruise ship operators preparing for their ships to set sail under the conditional sailing order,⁷ and these new guidelines were met with criticism from the cruise industry.⁸ The industry’s trade group, the Cruise Lines International Association (CLIA), called the instructions “so burdensome and ambiguous that no clear path forward or timetable can be discerned.”⁹ Amidst concerns that the new technical instructions would ensure “that the cruise industry would not re-open” in time for summer, on April 8, 2021, Florida sued in federal court and moved for preliminary injunction,¹⁰ citing an \$82 million loss in tax revenue for the state, a \$8.1 billion loss in income for the cruise industry and related Floridian enterprises, and the elimination of 159,000 jobs.¹¹ In its suit,

²<https://www.federalregister.gov/documents/2020/03/24/2020-06166/no-sail-order-and-suspension-of-further-embarkation>

³<https://www.federalregister.gov/documents/2020/04/15/2020-07930/no-sail-order-and-suspension-of-further-embarkation-notice-of-modification-and-extension-and-other>

⁴<https://www.federalregister.gov/documents/2020/07/21/2020-15810/no-sail-order-and-suspension-of-further-embarkation-second-modification-and-extension-of-no-sail>

⁵*Id.*

⁶<https://www.federalregister.gov/documents/2020/11/04/2020-24477/framework-for-conditional-sailing-and-initial-phase-covid-19-testing-requirements-for-protection-of>

⁷<https://www.cdc.gov/quarantine/cruise/index.html>

⁸<https://www.nytimes.com/2021/04/05/business/cruise-lines-guidance.html>

⁹*Id.*

¹⁰*State of Florida v. Becerra* (M.D. Fla., 8:21-cv-00839), p. 9

¹¹<https://www.floridaphoenix.com/2021/06/25/judges-epic-124-page-cruise-ship-order-reveals-clash-between-boosting-the-economy-and-keeping-people-alive/>

Florida successfully argued that CDC’s conditional sailing order “exceeds CDC’s statutory and regulatory authority,”¹² and on June 18, 2021, the court granted a preliminary injunction blocking CDC “from enforcing against a cruise ship arriving in, within, or departing from a port in Florida the conditional sailing order.”¹³ The court stayed the preliminary injunction until July 18, 2021, “at which time the conditional sailing order and the measures promulgated under the conditional sailing order will persist as only a non-binding ‘consideration,’ ‘recommendation’ or ‘guideline,’ the same tools used by CDC when addressing the practices in other similarly situated industries, such as airlines, railroads, hotels, casinos, sports venues, buses, subways, and others.”¹⁴

Analysis

This brief explains why the information collection plan proposed by the United States Centers for Disease Control and Prevention (CDC) under the project titled Phased Approach to the Resumption of Passenger Operations does not exceed CDC’s statutory and regulatory authority and is necessary for the proper performance of the functions of the agency. Three sources of legal authority that confer the requisite power to CDC for the regulation of international cruise ship travel – the Public Health Service Act, the Constitution of the United States, and the Administrative Procedure Act– are central to this analysis and are discussed in turn.

The Public Health Service Act: The Public Health Service Act codifies the federal government’s “basic authority to make regulations to prevent the spread of disease into this country or between the States.”¹⁵ The provision of the Public Health Service Act that is most relevant to the present inquiry is 42 U.S.C. § 264(a). It reads as follows: “The Surgeon General, with the approval of the

¹² State of Florida v. Becerra (M.D. Fla., 8:21-cv-00839), p. 2

¹³ State of Florida v. Becerra (M.D. Fla., 8:21-cv-00839), p. 123

¹⁴ State of Florida v. Becerra (M.D. Fla., 8:21-cv-00839), p. 123

¹⁵H.R. Rep. No. 78-1364, at 24 (1944)

Secretary, is authorized to make and enforce such regulations as in his judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession. For purposes of carrying out and enforcing such regulations, the Surgeon General may provide for such inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings, and other measures, as in his judgment may be necessary.”

From a textualist perspective, whether the conditional sailing order exceeds the authority delegated to CDC under Section 264(a) hinges in large part on whether the second sentence of Section 264(a) should be read as a limit on the first sentence of Section 264(a) – that is, whether the Surgeon General’s authority to “take such measures to prevent such spread of the diseases as he/she deems reasonably necessary” is narrowed and clarified by the enumerated list of activities that follows. Of course, contained in that enumerated list provided by the second sentence is a seemingly broader grant of authority contained in the phrase, “and other measures, as in his judgment may be necessary.” It can be argued, however, that this phrase, as governed by the canon construction *ejusdem generis*, is “controlled and defined by reference to the enumerated categories . . . before it.” *Tiger Lily, LLC v. United States Dep’t of Hous. & Urb. Dev.*, 992 F.3d 518, 522–23 (6th Cir. 2021) (quoting *Cir. City Stores, Inc. v. Adams*, 532 U.S. 105, 106 (2001)).

In other words, it is debatable whether the “other measures” contemplated by Section 264(a) signal an unbridled grant of authority to CDC or if it is referencing only those activities that are similar in nature and scope to those noted earlier in the list. If the latter is the case, CDC’s conditional sailing order reasonably could be held to exceed its authority under the Public Health Service Act unless CDC can show that the requirements of the conditional sailing order’s four

phases building to a resumption of cruise ship travel are sufficiently similar in nature and scope to “inspection, fumigation, disinfection, sanitation, pest extermination, [and] destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings.”

The Constitution of the United States (“the Constitution”): Even if Section 264(a) of the Public Health Service Act grants the comprehensive, unencumbered authority that some argue would be necessary to authorize CDC to promulgate and enforce its conditional sailing order, it would potentially raise a constitutional issue. In the United States, state police power is derived from the Tenth Amendment to the Constitution, which reserves for the states those rights and powers “not delegated to the United States.” It is contended that, historically, “the public health power, including the power to quarantine, was traditionally understood — and still is understood — as a function of state police power.”¹⁶ Thus, if Section 264(a) of the Public Health Service Act is interpreted broadly, some argue that the rights claimed by CDC in the enforcement of its conditional sailing order may infringe on state police powers and threaten federalism. For example, CDC’s conditional sailing order does not require cruise passengers and crew to be vaccinated, but if ships maintain a 95% vaccination rate, the conditional sailing order allows ships to forgo test cruises.¹⁷ However, Florida’s Governor Ron DeSantis, whose state is “home to the largest operators and busiest cruise ports in the world,”¹⁸ has referred to this incentive as “coercive”¹⁹ and has called CDC’s conditional sailing order an “unprecedented federal overreach.”²⁰ Florida recently passed a law prohibiting businesses from requiring proof of

¹⁶State of Florida v. Becerra (M.D. Fla., 8:21-cv-00839), p. 37

¹⁷<https://www.cdc.gov/quarantine/cruise/covid19-operations-manual-cso.html>

¹⁸<https://www.washingtonpost.com/travel/2021/05/28/florida-governor-cruise-desantis-vaccine/>

¹⁹<https://www.seatrade-cruise.com/legal-regulatory/floridas-vaccine-passport-ban-cruises-likely-unconstitutional-attorney-says>

²⁰<https://www.washingtonpost.com/travel/2021/06/18/florida-cruise-lawsuit-desantis/>

vaccination from their customers,²¹ and DeSantis has claimed that cruise ships that require proof of vaccination from their passengers would be in violation of Florida state law and liable for fines of \$5,000 per passenger.²² DeSantis told reporters at a press conference in May 2021 that he refused to make an exception to Florida’s vaccine passport ban for cruise ships because “[y]ou don’t pass laws and then not enforce it against giant corporations; it doesn’t work that way. Everybody is equal before the law.”²³ In order to prevail over a constitutional challenge to its conditional sailing order, CDC must demonstrate its vaccination provisions are neither coercive nor an infringement on the police powers claimed by the states in establishing a vaccination passport ban like the one passed in Florida.

Administrative Procedure Act (“APA”): If CDC’s conditional sailing order survives both a strict, textualist statutory construction of the Public Health Service Act and challenges on constitutional grounds, it still must withstand an attack under the APA. The APA vests a reviewing court with the authority to “decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall— (1) compel agency action unlawfully withheld or unreasonably delayed; and (2) hold unlawful and set aside agency action, findings, and conclusions found to be— (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law; (B) contrary to constitutional right, power, privilege, or immunity; (C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right; (D) without observance of procedure required by law; (E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency

²¹<https://www.washingtonpost.com/travel/2021/05/28/florida-governor-cruise-desantis-vaccine/>

²²<https://www.seatrade-cruise.com/legal-regulatory/floridas-vaccine-passport-ban-cruises-likely-unconstitutional-attorney-says>

²³<https://www.washingtonpost.com/travel/2021/05/28/florida-governor-cruise-desantis-vaccine/>

hearing provided by statute; or (F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.” 5 U.S.C. § 706(2)(A).” An agency’s action is found to be “arbitrary and capricious” for the purposes of this provision of the APA “if the agency . . . entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.” *Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). CDC’s conditional sailing order has been charged with “rel[ying] on a generic, global generalization that all non-federal measures are inherently inadequate to ensure public health and safety in the cruise industry”²⁴ while “fail[ing] to offer any reasoned explanation about the inadequacy of local measures.”²⁵ Florida Attorney General Ashley Moody (R) has also accused CDC of using the conditional sailing order to “single out and lock down an entire industry indefinitely,” something she asserts that the “federal government does not, nor should it ever, have the authority [to do].”²⁶ CDC’s conditional sailing order is thus vulnerable to the charge that it is arbitrary and capricious for the purposes of the APA (and thus in danger of being set aside by a reviewing court), unless CDC can explain, to the reviewing court’s satisfaction, why the conditional sailing order’s preemption of non-federal, local measures for regulating the cruise industry and the CDC’s alleged singling out of the cruise industry represent neither a “fail[ure] to consider an important aspect of the problem,” a “decision that runs counter to the evidence before the agency,” nor an action that “is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.”

²⁴State of Florida v. Becerra (M.D. Fla., 8:21-cv-00839), p. 97

²⁵State of Florida v. Becerra (M.D. Fla., 8:21-cv-00839), p. 100

²⁶<https://www.washingtonpost.com/travel/2021/06/18/florida-cruise-lawsuit-desantis/>

Actions Recommended

Although the court which granted Florida’s request for a preliminary injunction blocking CDC from enforcing its conditional sailing order invited CDC to propose a modification which represented “a narrower injunction” intended “to further safeguard the public’s health while this action pends,”²⁷ the agency should refrain from doing so. CDC should stand its ground in this case, as it is well-posed to defend the original provisions of its conditional sailing order on appeal by relying on the following arguments.

The Public Health Services Act: The provisions of CDC’s conditional sailing order will likely survive a textualist reading of the Public Health Service Act if CDC abandons the argument that Section 264(a) grants the Surgeon General absolute power to make a discretionary finding that a particular public health measure is “necessary.” Instead, CDC should concede that the second sentence of Section 264(a) does indeed narrow the first sentence and that the “other measures” provision refers only to those activities that are similar in nature and scope to those explicitly enumerated in the list, which includes the activity “inspection.” As the provisions of the conditional sailing order fall squarely under the category of “inspection,” CDC can persuasively argue that the conditional sailing order does not exceed CDC’s delegated authority under the Public Health Service Act.

The Constitution: CDC can prevail over a federalism-based constitutional challenge to its conditional sailing order on the grounds of the Commerce Clause (Article 1, Section 8, Clause 3 of the U.S. Constitution). The Commerce Clause grants the federal government the authority to regulate international commerce, and to manage who and what comes in and out of the country.. While Florida alleges in its lawsuit that CDC is not empowered to “make or enforce regulations

²⁷State of Florida v. Becerra (M.D. Fla., 8:21-cv-00839), p. 97

that suspend the operations of cruise ships,”²⁸ CDC could counter with the argument that its enactment of a conditional sailing order in contravention of provisions of state and local law is permissible because, in the words of Northeastern University School of Law’s Professor Wendy Parmet, “the idea that the federal government in general doesn’t have the authority to set the conditions for cruise ships and that Florida somehow has more authority over who comes in and out of the ports, that’s really an odd one.”²⁹

APA: CDC can defeat a claim that its conditional sailing order is “arbitrary and capricious” for the purposes of the APA by explaining why the conditional sailing order’s preemption of non-federal, local measures for regulating the cruise industry and the CDC’s alleged singling out of the cruise industry represent neither a “fail[ure] to consider an important aspect of the problem,” a “decision that runs counter to the evidence before the agency,” nor an action that “is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.” First, CDC can argue that non-federal measures are inherently inadequate to regulate international cruise ship travel because local state and city health inspectors, unlike the CDC, lack the authority to board and inspect vessels engaged in international sailings,³⁰ and thus the CDC’s enforcement of a conditional sailing order was far from “capricious.” Second, CDC can argue that it did not “arbitrarily” single out the cruise industry for stricter regulation in the fallout of COVID-19 because cruise ships are unique from other types of venues in material respects. For example, CDC’s prior orders “found markedly higher transmission rates on board cruise ships than exist in other settings; crew and passengers live onboard for prolonged periods of time

²⁸<https://www.cruiselawnews.com/2021/05/articles/disease/why-the-state-of-florida-will-lose-its-motion-for-preliminary-injunction-against-the-cdc-tomorrow>

²⁹<https://www.washingtonpost.com/travel/2021/05/28/florida-governor-cruise-desantis-vaccine/>

³⁰<https://www.cruiselawnews.com/2021/04/articles/disease/governor-desantis-lawsuit-against-the-cdc-a-craven-political-stunt-pandering-to-cruise-lines/>

in enclosed spaces in which social distancing is challenging at best.”³¹ Finally, CDC can point to ongoing cruise ship infections as an evidenced-based rationale for its conditional sailing order. For example, in June 2021, Royal Caribbean International had to postpone one of the first voyages scheduled to depart from the United States after eight crew members tested positive for COVID-19. Moreover, two passengers on a St. Maarten cruise tested positive for COVID-19 despite a requirement that all adults on board be fully vaccinated.³² These kinds of episodes speak to the incredible difficulty of keeping COVID-19 off of cruise ships and underscore the necessity of CDC’s conditional sailing order.

Sincerely,

Kayla Larkin
J.D. Candidate
Northeastern University School of Law
E-mail: larkin.k@northeastern.edu

NOTE: This document was prepared in fulfillment of a requirement for the course “Problems in Public Health Law” at Northeastern University School of Law.

³¹<https://www.cruiselawnews.com/2021/05/articles/disease/why-the-state-of-florida-will-lose-its-motion-for-preliminary-injunction-against-the-cdc-tomorrow/>

³²<https://www.washingtonpost.com/travel/2021/06/18/florida-cruise-lawsuit-desantis/>

Jeffrey M. Zirger
Information Collection Review Office, Centers for Disease Control and Prevention
1600 Clifton Road NE, MS- D74
Atlanta, Georgia 30329

RE: Phased Approach to the Resumption of Cruise Ship Passenger Operations 2021-09094,
Docket No. CDC-2021-0011

June 30, 2021

Executive Summary: *Since the World Health Organization (WHO) designated the outbreak of the novel coronavirus SARS-CoV-2 (COVID-19) a public health emergency of international concern on January 30th 2020¹, the organization has confirmed that 3,840,223 people have died and 177,108,695 people have been infected with the disease worldwide², although actual numbers are likely two to three times greater³. Cruise Ships pose a unique risk of COVID-19 transmission and risk for exacerbating the global pandemic. Further, resumption of cruise ship travel must be done in a conscientious and cautious manner. CDC's reporting requirements are a necessary step, but until there is greater global equity in access to essential medical supplies, personal protective equipment and COVID-19 vaccines, the CDC should extend the No Sail Order.*

Background

Since the World Health Organization (WHO) declared the outbreak of the novel coronavirus SARS-CoV-2 (COVID-19) a public health emergency of international concern on January 30, 2020⁴, the organization has confirmed that as of June 18th, 3,840,223 people have died and 177,108,695 people have been infected with the disease worldwide⁵, although actual

¹Tedros Adhanom Ghebreyesus, *WHO Director General Statement On IHR Emergency Committee on Novel Coronavirus (2019-NCoV)*, World Health Organization, January 30th, 2020. [https://www.who.int/director-general/speeches/detail/who-director-general-s-statement-on-ih-er-emergency-committee-on-novel-coronavirus-\(2019-ncov\)](https://www.who.int/director-general/speeches/detail/who-director-general-s-statement-on-ih-er-emergency-committee-on-novel-coronavirus-(2019-ncov)).

² *WHO Coronavirus (COVID-19) Dashboard*, World Health Organization, June 18^h 2021. <https://covid19.who.int/>

³ Emma Farge and John Revill, *Real COVID-19 death toll could be 'two to three' times above official stats: WHO*, Reuters, May 21st, 2021. <https://www.reuters.com/world/covid-19-death-tolls-are-likely-significant-undercount-who-says-2021-05-21/>

⁴Tedros Adhanom Ghebreyesus, *WHO Director General Statement On IHR Emergency Committee on Novel Coronavirus (2019-NCoV)*, World Health Organization, January 30th, 2020. [https://www.who.int/director-general/speeches/detail/who-director-general-s-statement-on-ih-er-emergency-committee-on-novel-coronavirus-\(2019-ncov\)](https://www.who.int/director-general/speeches/detail/who-director-general-s-statement-on-ih-er-emergency-committee-on-novel-coronavirus-(2019-ncov)).

⁵ *WHO Coronavirus (COVID-19) Dashboard*, World Health Organization, June 18^h 2021. <https://covid19.who.int/>

numbers are likely two to three times greater⁶. The day after the WHO declaration, Secretary of Health and Human Services (HHS) Alex Azar declared a public health emergency in the United States.

Prevailing wisdom in infectious disease outbreak and control prior to the COVID-19 epidemic held that travel restrictions served limited utility in preventing disease spread, but often hampered outbreak response measures by limiting the movement of experts, medical professionals and supplies to the outbreak zone. Yet, despite the fact that the original WHO statement specifically discouraged any “measures that unnecessarily interfere with international travel and trade⁷”, the United States and other countries took swift action to limit international travel across their borders. As part of this effort, and through authority granted to him through the Public Health Service Act, Centers for Disease Control and Prevention (CDC) Director Robert Redfield issued the first No Sail Order (NSO) on May 14, 2020. This specific action was taken to prevent the infection and “contamination with a quarantinable communicable disease”, to avoid further exacerbating the spread of COVID-19, and to avoid further burdening strained health systems⁸. The order notes that given the scope and nature of cruise ship travel - its role in interstate and international travel and high risk for transmission - industry, state and local attempts at regulation would be insufficient to address the dangers posed⁹. The order makes specific reference to the outbreaks that took place aboard the Diamond Princess and Grand Princess cruise ships, to highlight the increased risk of infection aboard cruise ships, the

⁶ Emma Farge and John Revill, *Real COVID-19 death toll could be 'two to three' times above official stats: WHO*, Reuters, May 21st, 2021. <https://www.reuters.com/world/covid-19-death-tolls-are-likely-significant-undercount-who-says-2021-05-21/>

⁷ Tedros Adhanom Ghebreyesus, *WHO Director General Statement On IHR Emergency Committee on Novel Coronavirus (2019-NCoV)*, World Health Organization, January 30th 2020. [https://www.who.int/director-general/speeches/detail/who-director-general-s-statement-on-ihf-emergency-committee-on-novel-coronavirus-\(2019-ncov\)](https://www.who.int/director-general/speeches/detail/who-director-general-s-statement-on-ihf-emergency-committee-on-novel-coronavirus-(2019-ncov)).

⁸ *No sail order and other measures related to operations*. US Dept. HHS, CDC, May 14th 2020.

⁹ Id.

increased risk of spread in home communities and docking sites for cruises, and the difficulty of adequately implementing infection control through quarantine, isolation and contact tracing in such scenarios¹⁰.

The initial NSO was valid for 30 days but subject to renewal and modification as needed¹¹. As part of successive renewal processes and additional modifications, the CDC released technical assistance guidelines requesting that cruise lines seeking to renew operations in the future submit no sail order management plans to the agency¹². In the April 15th renewal, CDC also instituted new surveillance requirements, including weekly submission of the “Enhanced Data Collection During COVID-19 Pandemic Form”. This new form allowed for specific monitoring of potential COVID-19 cases among crew and guests of cruise ships¹³. The NSO was renewed and kept in place until October 30, 2020, when the CDC issued a Framework for Conditional Sailing Order and a phased resumption of cruise ship operations¹⁴.¹⁵

Several ships now have approved NSO management plans and have been granted conditional permission to resume operations¹⁶ – though ships must either guarantee that more than 95% of passengers are fully vaccinated – or participate in simulated voyages with limited passengers to ensure that infection mitigation and control efforts are carried out in a manner that will ensure safety of passengers, crew, and home communities¹⁷. With several ships set to

¹⁰ Id.

¹¹ Id.

¹² *Framework for Conditional Sailing and Initial Phase COVID-19 Testing Requirements for Protection of Crew*, Federal Register, November 4th, 2020. <https://www.federalregister.gov/d/2020-24477>

¹³ Id.

¹⁴ See Appendix 1 for info graphic from <https://www.cdc.gov/coronavirus/2019-ncov/travelers/pdf/CSO-Phased-Approach-Infographic-p.pdf>

¹⁵ Id.

¹⁶ See Appendix 2: <https://www.cdc.gov/coronavirus/2019-ncov/travelers/crew-disembarkations-commercial-travel.html>

¹⁷ *Cruise Ship Color Status*, Centers for Disease Control and Prevention, 2021.

<https://www.cdc.gov/coronavirus/2019-ncov/travelers/crew-disembarkations-commercial-travel.html>

resume operations from U.S. ports in the coming weeks, CDC is seeking updated information collection policies for cruise ship operators. These new reporting requirements are intended to ensure compliance with essential aspects of the phased resumption framework and to ensure adequate safeguards are in place to test, identify, isolate, and care for passengers and crew during their time on board, and if needed to evacuate them to an appropriate medical facility off ship, as well as provide timely surveillance statistics to the CDC.

Analysis and Recommendations

The documentation and reporting requested by the CDC in order to approve a conditional sail order is burdensome but necessary to provide safeguards for the public health in the midst of an ongoing pandemic. It is certainly less burdensome to cruise ship operators than continuation of a full NSO. At every step of the process, the CDC has engaged relevant stakeholders in the cruise ship industry and worked with them to put forward a conscientious plan based in science. The CSO offers feasible steps to resumption of operations, with the recognition that it would be impossible to completely eliminate the risk of COVID-19 transmission¹⁸. The CDC, HHS and FDA worked together with industry leaders to convene a panel of experts to propose methods of safe resumption of operations¹⁹. The Healthy Sail Panel published the results of its work, recommending a phased approach responsive to the changing conditions of the pandemic is needed while proposing 74 steps and pre-requisites to safe resumption of cruise ship recommendations²⁰.

¹⁸ Helene Gayle et. al, *Recommendations from the Healthy Sail Panel: advice to cruise operators to advance their public health response to COVID-19, improve safety and achieve readiness for the safe resumption of operations*, September 21st, 2020.

¹⁹ Id.

²⁰ Id.

Industry experts agree that a careful, phased approach to resumption of operations with concern for public health is essential to the sustainability of the industry²¹. Further, a survey of public opinion shows widespread support for adoption of public health measures and restrictions to reduce the spread of COVID-19 aboard cruise ships²². The resumption of cruise ship travel places a burden on government resources at the international, federal, state and local levels and places additional stress on the local health care systems and international pandemic response. The burdens imposed on the cruise ship industry ensure that the industry share in the burdens and costs of safe resumption of travel, and do their part to prevent further expenditures of government resources as the result of future outbreaks seeded by leisure travel.

The requirements for creating a comprehensive COVID-19 mitigation plan include entering into contracts to provide for the testing, treatment, and care of crew and passengers and contracting with port, local health authorities, and private entities to plan for the disembarkation, quarantine and treatment of potentially infected persons. This burden is reflected in the Framework created by the CDC and the documentation requirements they have implemented are a measured response to the potential burden to international public health posed by cruise ship travel²³.

Specifically, the additional paperwork and personnel time required to submit the Enhanced Data Collection During COVID-19 Pandemic Form on a daily as opposed to weekly basis for surveillance efforts is warranted and justifiable. When originally approved, the form

²¹ Id.

²² *Order under Sec. 361 & 365 of the Public Health Service Act and 42 Code of Federal Regulations Part 7 and Part 71: Framework for Conditional Sailing and Initial Phase Covid-19 Testing Requirements for Protection of Crew.* Department of Health and Human Services, Centers for Disease Control and Prevention, October 30th, 2020. https://www.cdc.gov/quarantine/pdf/CDC-Conditional-Sail-Order_10_30_2020-p.pdf

²³ Id.

was estimated to take a staff person 13 minutes to complete²⁴. This small amount of staff time provides the CDC with up to date information about any new cases of COVID-19 occurring on board or among persons who have been on cruise ships within the past 14 days. This information is crucial for monitoring potential outbreaks and for effective contact tracing to contain spread of disease. Given that current testing protocols imposed by the CDC do not mandate daily testing of crew and passengers²⁵ and only pose a 14 day quarantine on embarking crew, but not passengers, regular testing and reporting will be key to identify potential infections²⁶. Viral load peaks and a great deal of transmission occurs in the pre-symptomatic phase²⁷, so regular testing is needed to capture cases early before the infection is spread to others. The 13 minutes required to record the necessary data and transmit the information to the CDC is well worth the potential impact in infection control.

Even with these measures in place, it may not be wise at this point in time to resume cruise ship travel. While the advent of vaccines offers hope for an end to the COVID-19 pandemic, the lack of vaccine access and equity across the globe and spread of more transmissible and potentially more severe variants of the virus should weigh on any decision to resume recreational travel that poses a risk to global health. As the original NSO²⁸ and Framework for Conditional Sail acknowledge, cruise ship travel may exacerbate the global

²⁴ Form **0920-0134** Enhanced Data Collection During COVID-19 Pandemic OMB Report. January 13th, 2021. <https://omb.report/icr/202009-0920-024/doc/105038201>

²⁵ Id.

²⁶ Technical Instructions for Mitigation of COVID-19 Among Cruise Ship Crew. <https://www.cdc.gov/quarantine/cruise/management/technical-instructions-for-cruise-ships.html>

²⁷ Cevik M, Kuppalli K, Kindrachuk J, Peiris M. Virology, transmission, and pathogenesis of SARS-CoV-2 *BMJ* 2020; 371 :m3862 doi:10.1136/bmj.m3862

²⁸ *No sail order and other measures related to operations*. US Dept. HHS, CDC, May 14th 2020.

spread of COVID-19;²⁹. Although the number of deaths, hospitalizations and infections attributed to COVID-19 in the United States have been on a steady decline with the advent of highly effective vaccines, as of June 30th, 2021 only 46.7% ³⁰of the population has been fully vaccinated, and many communities still remain vulnerable. In fact, on June 30th it was reported that cases were beginning to rise again, with the U.S. seeing more than a 17% increase in cases over the past week³¹.

Vaccines approved for use in the United States are only available to those 12 and older³², yet according to a 2017 cruise travel report, the average cruise travel party contains two children and 42% of guests have children under the age of 18³³. These unvaccinated guests are at risk of COVID-19 infection and of transmitting the virus to others. While cruise travel is popular among older adults who are at greater risk for COVID-19, many older Americans are now vaccinated, but families with young children who may also be eager to travel still face risks when engaging in the high density environment of a cruise ship. While vaccines have proven to be incredibly effective, with the continuing proliferation of ever more infectious variants, there are still risks. Recent data out of Israel indicates that in a new outbreak of the Delta variant almost half of positive cases were amongst fully vaccinated individuals³⁴.

²⁹ *Framework for Conditional Sailing and Initial Phase COVID-19 Testing Requirements for Protection of Crew*, Federal Register, November 4th, 2020. <https://www.federalregister.gov/d/2020-24477>

³⁰ <https://covid.cdc.gov/covid-data-tracker/#vaccinations>

³¹ https://www.washingtonpost.com/graphics/2020/national/coronavirus-us-cases-deaths/?itid=sn_coronavirus_1/

³² <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/adolescents.html>

³³ *Cruise Travel Report January 2017*, Cruise Lines International Association. <https://cruising.org/-/media/research-updates/research/consumer-research/2017-cruise-travel-report.pdf> at pg. 23.

³⁴ Dov Lieber, *Delta Outbreak in Israel Infects Some Vaccinated Adults*, The Wall Street Journal, June 25th, 2021. <https://www.wsj.com/articles/vaccinated-people-account-for-half-of-new-covid-19-delta-cases-in-israeli-outbreak-11624624326>

While COVID-19 vaccines are readily available in the United States, the same cannot be said of the rest of the world³⁵. Cruise travel originating from U.S. ports this summer will visit popular locations in Mexico, the Bahamas, and the Caribbean³⁶, where there is limited vaccine access, low percentages of residents have received even one dose of the vaccine, and they are currently experiencing high levels of COVID-19 infections and deaths³⁷³⁸.

Guidelines from the CDC indicate that cruise ships should actively encourage and facilitate vaccination of cruise crew members, and many cruise lines have mandated that all staff be vaccinated, but CDC guidelines do not provide any recommendations beyond education and suggestion for other workers either those who temporarily enter the ship or those who interact with guests and crew at ports of call³⁹. The technical guidance and guiding principles published by the CDC and the Healthy Sail Plan both profess that cruise ship mitigation efforts should not impose a hardship on the health infrastructure of ports of call, but they also require cruise operators to contract for provision of services that may not be available to many of the staff of port facilities and citizens of those localities⁴⁰. The recommendations also mandate creation of adequate laboratory testing and personal protective equipment on board for ship medical personnel and staff use when even in the United States there is an ongoing of personal protective

³⁵ Jennifer Kates, Josh Michaud, Anna Rouw and Adam Wexler, *Global COVID-19 Vaccine Access: A Snapshot of Inequality*, Kaiser Health News, March 17th, 2021. <https://www.kff.org/policy-watch/global-covid-19-vaccine-access-snapshot-of-inequality/>

³⁶ Morgan Hines, *They're Coming Back: Here are the ships that have received CDC approval to sail soon*, USA Today, June 12th, 2021. <https://www.usatoday.com/story/travel/cruises/2021/06/12/cruise-ship-return-us-ships-cdc-approved-sailings-test-cruises/7636627002/>

³⁷ *Which Cruise Lines Require a COVID Vaccination?* <https://www.cruisecritic.com/articles.cfm?ID=5872>

³⁸ COVID-19 Vaccination Tracker, Reuters, <https://graphics.reuters.com/world-coronavirus-tracker-and-maps/vaccination-rollout-and-access/>

³⁹ <https://www.cdc.gov/quarantine/cruise/management/technical-instructions-for-cruise-ships.html>

⁴⁰ Helene Gayle et. al, *Recommendations from the Healthy Sail Panel: advice to cruise operators to advance their public health response to COVID-19, improve safety and achieve readiness for the safe resumption of operations*, September 21st, 2020.

equipment and testing supplies⁴¹. The resumption of leisure cruise ship travel poses a danger to the health of passengers, crew and communities, and it will further exacerbate the stress on public health infrastructure and supply chains attempting to cope with the ongoing immediate health needs of those infected with COVID-19. A policy that looked to the international nature of the pandemic and the danger posed to the health of US citizens and health infrastructure as long as the virus continues to proliferate internationally would limit non-essential and risky activities and limit use of essential medical supplies until the global response to COVID-19 was better equipped to manage current needs.

Critics may claim that with the remarkable efficacy of COVID-19 vaccines, the requirements imposed by the CDC on leisure travel are overly cautious. However, cruise ships have proven to be unique in their capacity to spread infection among passengers, and across the globe⁴². The R_0 calculated for the COVID-19 outbreak on the Diamond Princess proved to be four times greater than that calculated for the outbreak in Wuhan, China, the epicenter of the pandemic; over 20% of passengers aboard the ship became infected⁴³. The outbreak on the Grand Princess cruise ship impacted passengers from over 50 countries, illustrating the wide-ranging impact an outbreak aboard a single cruise ship can have on international public health.⁴⁴ In March 2020, cruise ship passengers accounted for 17% of confirmed US cases⁴⁵.

⁴¹ *Medical Device Shortages During the COVID-19 Public Health Emergency*, US Food and Drug Administration (Current as of 6/10/2021). <https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/medical-device-shortages-during-covid-19-public-health-emergency#shortage>

⁴² Are'zou Minoee and Leland S. Rickman, *Infectious Diseases on Cruise Ships*, Clinical Disease Society of America, 1999. <https://academic.oup.com/cid/article/29/4/737/451491>

⁴³ Epidemiology of COVID-19 Outbreak on Cruise Ship Quarantined at Yokohama, Japan, February 2020. *Emerging Infectious Diseases*. 2020;26(11):2591-2597. doi:10.3201/eid2611.201165.

⁴⁴ *No sail order and other measures related to operations*. US Dept. HHS, CDC, May 14th 2020.

⁴⁵ <https://www.npr.org/2021/05/29/1001354354/the-buffet-can-stay-what-the-future-of-the-cruise-line-industry-looks-like>

Cruise ships have already begun sailing abroad, but with mixed success. Despite several rounds of testing before boarding, the first cruise ship to resume operations experienced positive COVID-19 cases among seven passengers and two crew members within five days of departure⁴⁶. Cruise lines in Singapore, which has had a strict COVID-19 response and high success rate of containment, experienced COVID-19 cases even on a “cruise to nowhere.”⁴⁷ In June a cruise departing from Italy detected four positive cases, isolating and disembarking passengers who had already undergone two rounds of testing before boarding the ship⁴⁸. Likewise in June eight partially vaccinated and asymptomatic cruise ship crew members and two fully vaccinated cruise ship guests tested positive in routing testing in the first ships to depart North American ports, causing the cruise company to delay and cancel future planned trips⁴⁹. These cases show that the strict and comprehensive testing and reporting protocol is effective and necessary. However, the fact that breakthrough cases are occurring even amongst partially and fully vaccinated passengers⁵⁰ raise serious concerns about the safety of resuming regular cruise ship travel.

Recent developments further complicate the ability for cruise ships to resume operations safely. Florida Governor DeSantis has signed into law a ban on businesses requiring vaccine passports – against significant objections by cruise ship industry leaders who view vaccination

⁴⁶ Silva, Ana Lucia Rodrigues da. “An overview of the impact of COVID-19 on the cruise industry with considerations for Florida.” *Transportation research interdisciplinary perspectives* vol. 10 (2021): 100391. doi:10.1016/j.trip.2021.100391

⁴⁷ Bill Chappel, *Cruise to Nowhere Returns to Singapore Early After Positive Covid-19 Test*, National Public Radio, December 2020. <https://www.npr.org/sections/coronavirus-live-updates/2020/12/09/944585484/cruise-to-nowhere-returns-to-singapore-early-after-positive-covid-19-test>

⁴⁸ <https://www.cnn.com/travel/article/italy-cruise-covid-test-scli-intl/index.html>

⁴⁹ <https://www.forbes.com/sites/alisondurkee/2021/06/16/royal-caribbean-postpones-cruise-after-crew-members-test-positive-for-covid-19/?sh=5a45a5664447>

⁵⁰ <https://www.travelpulse.com/news/cruise/two-passengers-on-fully-vaccinated-cruise-test-positive-for-covid-19.html>

requirements as key to a smooth resumption of operations⁵¹. This vaccination passport ban is in direct conflict with the CDC's framework for resumption of operations. Ongoing litigation challenging the validity of CDC's no sail order dealt a significant blow to the CDC with a District Court Judge's decision to allow a preliminary injunction against enforcement of cruise ship conditional sail requirements on ships in Florida⁵², and ordering the CDC to narrow the scope of protocols or risk reduction of cruise ship orders to mere recommendations⁵³. If the CDC is unable to challenge the decision, it is possible that unvaccinated passengers and crew will board cruise ships from US ports and potentially risk the health and safety of fellow passengers, crew, and citizens of the localities of ports of call. Based on the Judge's decision questioning whether the CDC no sail order is within the scope of its delegated powers under 42 USC Section 264, or if it constitutes an unconstitutional delegation of legislative power, it is clear that the issue will not be resolved soon. The CDC should challenge the decision, and in keeping with the judge's order, issue more limited regulations and requirements by July 2nd. However, along with these narrower requirements the CDC should submit ample evidence of ongoing risks of transmission amongst vaccinated individuals, including evidence from prior cruise ship cases. The CDC should also include data regarding the dangers posed by the Delta variant to US citizens, but also to spreading infection to other countries where ships may dock in ports of call.

The CDC should continue to mandate appropriate measures for infection control – including regular testing, and requirements of vaccinations for cruise ship travel. If they desire to reduce the administrative burden on cruise ship companies for testing and reporting, they could

⁵¹ Suzanne Rowan Kelleher, *Florida Governor Ron DeSantis Is Crafting A Cruise Line Exemption for His Vaccine Passport Ban*, Forbes. <https://www.forbes.com/sites/suzannerowankelleher/2021/05/30/florida-governor-ron-desantis-cruise-line-exemption-vaccine-passport-ban/?sh=7b4d80ef5ed5>

⁵² *Fla. v. Becerra*, 8:21-CV-839-SDM-AAS, 2021 WL 1990289 (M.D. Fla. May 18, 2021)

⁵³ <https://www.nytimes.com/2021/06/18/us/cdc-covid-cruises.html>

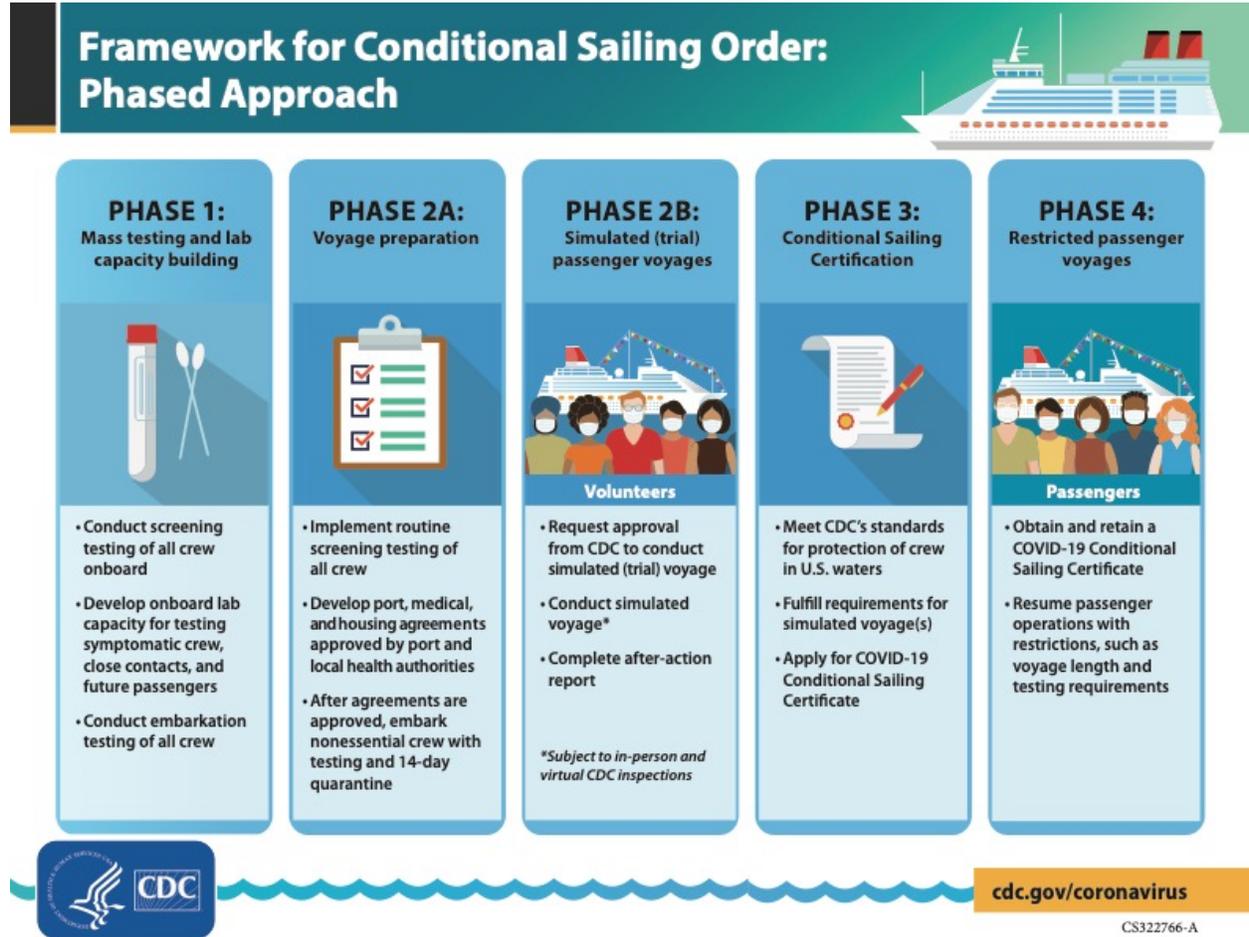
propose alternate models utilizing pooled testing, and reporting any positive results or any sick passengers to the CDC within 24hrs of presentation, as opposed to reporting data to the CDC daily as is now required for acquiring permission for conditional sailing. Additionally, until there is greater vaccine equity and cases worldwide begin to come under control, the CDC should work with cruise companies to limit their ability to dock outside of US waters, or alternately ensure that all out of country personnel that interact with cruise ship passengers are provided vaccinations by US based cruise lines.

Until there is greater consensus on the precautions necessary for cruise ship travel and greater equity in the availability of emergency medical equipment, testing supplies and COVID-19 vaccines, the CDC and HHS should ideally re-impose the blanket No Sail Order to safeguard public health. In the interim congress should pass legislation specifically delegating to the CDC broad powers to regulate as necessary for protection of the public health and mitigation of the COVID-19 pandemic.

Sincerely,

Alessandra Stevens
J.D. Candidate
Northeastern University School of Law
E-mail: stevens.ale@northeastern.edu

APPENDIX: 1



APPENDIX 2:

The following table lists cruise ships operating or planning to operate in U.S. waters during the initial phases of the CSO and have met surveillance reporting requirements. Determination for color-coding status and ability to operate in U.S. waters can only be made for ships if the following are true:

1. CDC has finished the review of the cruise line's plan.
2. Cruise line has returned an acknowledgement attesting that their No Sail Order response plan is complete and accurate.
3. Ship has submitted at least 4 weeks of surveillance data to CDC in accordance with the Technical Instructions.

Parent Company	Cruise Line	No Sail Order Response Plan Status	Ship Name	Ship Status
Bahamas Paradise Cruise Line	Bahamas Paradise Cruise Line	Complete and accurate with signed acknowledgement	Grand Classica	Orange
Carnival Corporation	Carnival Cruise Lines, Inc.	Complete and accurate with signed acknowledgement	Carnival Breeze	Orange
			Carnival Conquest	Orange
			Carnival Ecstasy	Green
			Carnival Elation	Green
			Carnival Freedom	Orange
			Carnival Horizon	Orange
			Carnival Liberty	Green
			Carnival Mardi Gras	Orange
			Carnival Miracle	Orange
			Carnival Panorama	Orange
			Carnival Pride	Green
			Carnival Sensation	Green
			Carnival Sunrise	Green
			Carnival Sunshine	Green
			Carnival Vista	Orange
	Holland America Line	Complete and accurate with signed acknowledgement	Koningsdam	Green
			Nieuw Amsterdam	Orange
			Nieuw Statendam	Green
			Noordam	Green
			Westerdam	Orange
	Princess Cruises	Complete and accurate with signed acknowledgement	Zuiderdam	Orange
			Caribbean Princess	Orange
			Coral Princess	Green
Emerald Princess			Orange	
Grand Princess			Red	
Majestic Princess			Orange	
Royal Princess			Green	
Walt Disney Company	Disney Cruise Line	Complete and accurate with signed acknowledgement	Ruby Princess	Green
			Disney Dream	Green
			Disney Fantasy	Orange
MSC Cruise Management (UK) Limited	MSC Cruises	Complete and accurate with signed acknowledgement	Disney Wonder	Red
			MSC Armonia	Orange
Norwegian Cruise Line Holdings	Norwegian Cruise Line	Complete and accurate with signed acknowledgement	MSC Meraviglia	Orange
			Norwegian Jewel	Orange
			Norwegian Sun	Green
	Oceania	Complete and accurate with signed acknowledgement	Pride of America	Green
Royal Caribbean Group	Celebrity Cruises		Regatta	Green
			Celebrity Edge	Orange

		Complete and accurate with signed acknowledgement	Celebrity Equinox	Orange
		Complete and accurate with signed acknowledgement	Celebrity Reflection	Green
		Complete and accurate with signed acknowledgement	Celebrity Silhouette	Orange
		Complete and accurate with signed acknowledgement	Celebrity Summit	Red
	Royal Caribbean International	Complete and accurate with signed acknowledgement	Allure of the Seas	Orange
	Royal Caribbean International	Complete and accurate with signed acknowledgement	Brilliance of the Seas	Green
	Royal Caribbean International	Complete and accurate with signed acknowledgement	Enchantment of the Seas	Green
	Royal Caribbean International	Complete and accurate with signed acknowledgement	Explorer of the Seas	Orange
	Royal Caribbean International	Complete and accurate with signed acknowledgement	Freedom of the Seas	Orange
	Royal Caribbean International	Complete and accurate with signed acknowledgement	Independence of the Seas	Green
	Royal Caribbean International	Complete and accurate with signed acknowledgement	Liberty of the Seas	Green
	Royal Caribbean International	Complete and accurate with signed acknowledgement	Mariner of the Seas	Orange
	Royal Caribbean International	Complete and accurate with signed acknowledgement	Navigator of the Seas	Green
	Royal Caribbean International	Complete and accurate with signed acknowledgement	Oasis of the Seas	Green
	Royal Caribbean International	Complete and accurate with signed acknowledgement	Odyssey of the Seas	Red
	Royal Caribbean International	Complete and accurate with signed acknowledgement	Rhapsody of the Seas	Green
	Royal Caribbean International	Complete and accurate with signed acknowledgement	Serenade of the Seas	Orange
	Royal Caribbean International	Complete and accurate with signed acknowledgement	Symphony of the Seas	Green
	Royal Caribbean International	Complete and accurate with signed acknowledgement	Vision of the Seas	Green

Jeffrey M. Zirger
Information Collection Review Office, Centers for Disease Control and Prevention
1600 Clifton Road NE, MS- D74
Atlanta, Georgia 30329

RE: Phased Approach to the Resumption of Cruise Ship Passenger Operations 2021-09094,
Docket No. CDC-2021-0011

June 30, 2021

Executive Summary:

The cruise industry is responsible for many of the early infections and deaths attributed to COVID-19; the communal and enclosed nature of a cruise ship could be to blame for that. This public comment will consider the CDC's Conditional Sailing Order and its role in allowing cruise ships to open at full capacity. My analysis focuses on the importance of data collections in preventing COVID transmission. Further, my analysis discusses the harms of opening too soon and the communities that will be negatively harmed. Therefore, I will recommend that we stay the course of the CDC's timeline and reopen the cruise line industry at full capacity in November 2021. Additionally, I will recommend that although tedious, cruise ships should collect data through non-digital outlets. In my recommendations, I will note communities and areas the CDC should consider when devising its re-opening strategy. To conclude, I recommend that local governments and cruise lines require vaccinations for all crew members and passengers to mitigate community transmission.

I. Background

At the beginning of the COVID-19 pandemic, the CDC had to consider preventative measures for cruise lines.¹ This was alarming for the cruise line industry because of its inherent

¹ https://www.cdc.gov/quarantine/pdf/signed-manifest-order_031520.pdf

relation to international travel. Cruise ships advertise and make a profit by offering an experience to vacation in communal close quarters. On January 30, 2020, the WHO declared COVID-19 to be a public health emergency.² In the United States, the outbreaks occurred in major cities like New York City and Seattle, eventually spreading across the country and resulting in over 600,000 recorded deaths.³ Cruise ships were a concern because of the communal aspects they embody. For example, in early 2020, a cruise ship, Diamond Princess was associated with at least six COVID deaths due to a lack of quarantine and testing capacity.⁴ "Cruises vary in size, with larger cruises involving a population of more than 4,000 passengers and crew."⁵

Cruise ships provide their guests with communal activities, endless drink selections, and community-style food. This setting is a perfect storm for an infectious disease outbreak; as Georgetown Law professor Lawrence Gostin notes, "cruise ships are super spreaders."⁶ Cruises travel all over the world and invite people from different countries to partake in the cruise experience. According to the CDC, the very nature of cruise ships makes quarantine difficult to implement.⁷ It is difficult to separate infected and exposed people since cruise ships are communal in nature. In May of 2021, the CDC released Conditional Sailing Order.⁸ The first phase of the order included no passengers at all, just volunteers. During this time, cruise lines must display a commitment to protecting their employees and passengers via access to rapid testing, quarantine, and isolation measures.⁹

² Id.

³ Id.

⁴ Id.

⁵ Id.

⁶ <https://twitter.com/LawrenceGostin/status/1406031220669095939?s=20>

⁷ Id.

⁸ <https://www.cdc.gov/quarantine/cruise/index.html>

⁹ https://scholar.harvard.edu/files/sinha/files/cdc-2021-0011-0001_content.pdf

Cruise ships were not able to set sail unless they received a Conditional Sailing Certificate from the Department of Health and Human Services (HHS) or the CDC.¹⁰ Cruise ships that did not voluntarily stop sailing must submit a No Sail Order Response Plan to determine the accuracy and completeness of their COVID protocol.¹¹ The first requirement needed to get Conditional Sailing Order is displaying the ship's ability to mass test crew members and passengers for COVID.¹² In the second phase, cruise ships must show the following elements: "A port agreement between the port authority and the cruise ship operator to prevent overuse of a single port (2) medical care agreement between onshore medical entities and the cruise ship operator to address a potential outbreak and need for ship evacuations for medical assistance (3) and housing agreements between cruise ship operators and onshore isolation facilities."¹³ Phase 2B of the Order focuses on the simulation voyages with volunteers.¹⁴ The ship must document any deficiencies that arise from the simulation voyage. Alongside these requirements, a cruise ship must provide all estimates for the cost of onboard testing, equipment, and maintenance of the ship.¹⁵

The CDC established the "COVID-19 Color Coding System" to provide transparency to COVID cases aboard.¹⁶ "Green" ship status means there are no COVID cases for 28 consecutive days among crew members onboard.¹⁷ "Yellow" ship status means that there is a reported one or more COVID cases onboard.¹⁸ "19 A "Red" ship status means that there is at least one confirmed

¹⁰ Id.

¹¹ Id.

¹² Id.

¹³ Id.

¹⁴ Id.

¹⁵ Id.

¹⁶ https://www.cdc.gov/quarantine/pdf/CDC-Conditional-Sail-Order_10_30_2020-p.pdf

¹⁷ Id.

¹⁸ Id.

¹⁹ Id.

case onboard, there were known ship-to-ship transfers, the crew was not immediately quarantined for 14 days, or that a ship failed to submit their weekly EDC forms.²⁰ "Ships with a "Red" status must follow all preventive measures, including requiring crew members to remain in cabins as much as possible during non-working hours, until the ship's status changes to "Green."²¹²²

This order allows cruises to begin sailing again so long as they follow these requirements. The CDC remained firm that cruise lines will be able to open at full capacity in November of 2021.²³ The cruise lines and cruise line associations disagree with this order and believe they should be able to open by the Summer of 2021.²⁴

II. Analysis

The proposal asks us to consider five important questions: “whether the proposed collection is necessary for the “proper performance of the functions of the agency”, the accuracy of the agency’s estimate of the burden of collecting information, enhance the quality, utility, and clarity of the information to be collected, minimize the burden of collecting data, and assess information collection costs.”²⁵ It is important to emphasize that we should prioritize safety over economic gains. The cruise line executives are interested in opening as fast as possible for economic reasons. During the pandemic, major cruise lines' stock dropped dramatically.²⁶ Major cruise lines saw a major loss of revenue.²⁷ However, to open safely and permanently, the

²⁰ Id.

²¹ Id.

²² Id.

²³ <https://www.travelpulse.com/news/cruise/cdc-sticks-to-november-timeline-for-conditional-sailing-order.html>

²⁴ <https://cruiseradio.net/timeline-2020-cruise-ship-industry-shutdown/>

²⁵ https://scholar.harvard.edu/files/sinha/files/cdc-2021-0011-0001_content.pdf

²⁶ Id.

²⁷ Id.

collection of data is essential. Measuring the influx of cases and a ship's ability to handle communal transmission is key to keeping our communities safe.

Florida is one of the states that have had a ruling in favor of the economy over public health. In *Florida v. Becerra*, a federal judge granted a preliminary injunction against the CDC enforcing the no-sail order.²⁸ The court believes that the order was beyond the scope of the CDC's regulatory power.²⁹ Now, the CDC cannot regulate cruise ships that go in and out of a port in Florida. More states will likely ignore CDC guidelines and begin opening their ports for cruise ships. Because of this ruling, the CDC guidelines are now considered recommendations and no longer mandatory in nature.³⁰

This ruling will have a lasting impact on the cruise ship industry and the greater community. Cruise ships are one of the highest super spreader environments for COVID-19. The court notes that Florida has a substantial economic injury they need to consider.³¹ Because of the halt on cruise line travel, the court felt that the CDC guidelines could sink the cruise ship industry permanently.³² While the court is valid in considering the economic harms to Florida, the court should also consider the CDC's responsibility is to protect public health. States are more likely to have economic interests for their citizens because of political pressure.

Florida is home to many ports used in the cruise industry. According to a cruise industry executive, Florida lost more than \$3.2 billion in revenue within the first six months of the pandemic.³³ Over 100,000 Floridians receive gainful employment because of the cruise

²⁸ <http://myfloridalegal.com/webfiles.nsf/WF/SSWN-C44RE6/%24file/Order+on+PI.pdf>

²⁹ <https://www.nbcmiami.com/news/local/judge-rules-in-floridas-favor-in-lawsuit-over-cdcs-no-sail-order-for-cruises/2476238/>

³⁰ *Id.*

³¹ <http://myfloridalegal.com/webfiles.nsf/WF/SSWN-C44RE6/%24file/Order+on+PI.pdf>

³² *Id.*

³³ <https://miami.cbslocal.com/2021/04/23/alaska-joins-floridas-legal-fight-cdc-no-sail-orde/>

industry.³⁴ State and local governments' interests are in direct conflict with the CDC. The state and local governments have an interest in economic success for many reasons: they are *elected* officials, the economic wellbeing of a state, and other negative outcomes of a failing economy. To emphasize, their job relies on people believing these elected officials have helped them financially. Florida has dealt with multiple protests at their ports from employees that benefit from the cruise economy, demanding that cruise lines reopen.³⁵ Many are without work until the cruises reopen.

The CDC has no direct incentive to ensure the economic wellbeing of a state. Indirectly, a failing economy does lead to harmful health outcomes. However, the CDC's job is to protect the public's health. This conflict between local officials and the CDC has made this issue of reopening cruise ships very difficult to find a solution for. The collection of data on COVID transmission could help us find a solution.

Many would argue that if the CDC is requiring cruise lines to collect data, they should have the option of collecting data digitally. While this may help with efficiency, there are dangers to digital data we should take note of.³⁶ "There may be problems such as false reporting and privacy concerns to consider."³⁷ Collecting data is also great for record-keeping and progress tracking.³⁸ While I wish that there is not another pandemic in our lifetime, data collection can help future public health leaders benchmark new policies. In the present, data collection can help us remain in the loop on which policies are working and which are not. "The pandemic has

³⁴ Id.

³⁵ <https://www.cruiseindustrynews.com/cruise-news/23727-wednesday-protests-scheduled-at-major-u-s-cruise-ports.html>

³⁶ <https://research.unc.edu/2020/10/01/the-importance-of-covid-19-data-collection-and-transmission/>

³⁷ Id.

³⁸ Id.

exposed, more than anything else, the importance of data,” says Ashok Krishnamurthy, deputy director of RENCI.³⁹

III. Recommendation

Within my recommendation, I am considering components of the passenger experience and key stakeholders that should be protected. Key components of the passenger's experience include communal eating, communal activities, and interacting with destination countries. Key stakeholders that should be protected are passengers, crew members, and destination countries.

Therefore, my recommendation is that we follow the CDC’s timeline and reopen cruise lines back to full capacity starting in November 2021. From an optics perspective, opening earlier than November 2021 would be a sign to the public that the pandemic is "over." Additionally, it would no longer incentivize people to get vaccinated. Additionally, I believe reopening now would be harmful to crew members. In efforts to protect employees, if cruise ships were to open earlier than November, I recommend requiring vaccinations for all crew and passengers.

We see in other industries, like airlines, that people have become violent with crew members that have asked them to wear a mask.⁴⁰ Fortunately for flight attendants, they are entitled to remove someone from the aircraft if they choose not to comply.⁴¹ The CDC lifted the mask mandate to all who are vaccinated. However, many unvaccinated are taking advantage of

³⁹ Id.

⁴⁰ <https://www.cbs8.com/article/news/crime/fight-southwest-plane-san-diego-flight-attendant-punch-lost-teeth-arrest-mask-dispute/509-21050218-6f19-4428-b1c0-e70ea42fe515>

⁴¹ Id.

this and not wearing their mask. Therefore, if we were to lift the order, I would recommend requiring vaccines for all passengers on the ship to protect the crew.

Further, to protect the crew, I recommend that buffet-style foods be prohibited until further notice. Buffets and communal eating are essential in community spreading. I recommend that if a cruise is allowed to be operating at full capacity, there should not be any type of communal food. Food should be pre-packaged for the passengers. Additionally, the dining hall should have reduced capacity. Pre-packaged food will reduce close-quarter interactions with other passengers. Within the dining halls, the movement could also be controlled.

Another component of the cruise ships is the activities. If the order is removed before November 2021, I recommend that cruise activities be prohibited. Community activities such as these lead to outbreaks. Another population we must consider is the staff at the destinations. Many countries rely on tourism for a thriving economy. While the economic crisis of the pandemic is tragic, we must place public health as a priority. Persons with residual income may want to enjoy a cruise. However, we also do not want the disease to transmit to less privileged countries. I would recommend that passengers must wear a mask if they are interacting with destination countries. When getting off the ship for any reason, all passengers should be provided and encouraged to wear face coverings.

Finally, I recommend investing in establishing a common data space.⁴² Stephanie Chin and Caitlin Chin at Brookings notes that the pandemic called attention to the fact that leaders do not have a shared data space to track public health statistics.⁴³ They note that the sharing of data

⁴² <https://www.brookings.edu/blog/techtank/2020/11/02/to-mitigate-the-costs-of-future-pandemics-establish-a-common-data-space/>

⁴³ Id.

during the 2015 Ebola outbreak was pivotal in defeating that epidemic.⁴⁴ Common data spaces could help governments and public health officials track outbreaks. Further, a common data space could all of us function under the same set of facts.⁴⁵ In contemporary media, facts are misconstrued for political gain. A common data space allows for transparency and a common understanding of the crisis we are dealing with.

Disclaimer: This public comment was prepared for a public health law school class.

⁴⁴ Id.

⁴⁵ Id.

Jeffrey M. Zirger
Information Collection Review Office, Centers for Disease Control and Prevention
1600 Clifton Road NE, MS- D74
Atlanta, Georgia 30329

RE: Phased Approach to the Resumption of Cruise Ship Passenger Operations 2021-09094,
Docket No. CDC-2021-0011

June 30, 2021

Executive Summary:

The recent decision to grant an injunction against the CDC's Conditional Sailing Order in order to preserve the economic interests of the Florida cruise industry has created an intensely risky public health scenario, and should be appealed. Aspects of the CSO are overly burdensome, but rejecting the CDC's authority to govern vectors of interstate disease spread and setting aside public health concerns was an error on the court's part. COVID-19 finds its perfect storm aboard most cruises where the passengers are mostly elderly, the ship is usually miles away from land and has no access to advanced medical facilities, key features such as buffets and pools are crowded, and isolation and testing of passengers is extremely difficult onboard. The CDC must both appeal the injunction and sue to overturn Florida's vaccine passport ban in order to implement the less onerous aspects of the CSO, such as requiring high vaccination rates among passengers and crew and that cruises to operate at lower passenger capacity to avoid any "superspreader" events.

Background:

I am writing to express my concerns over the recent decision to grant an injunction for Florida against the CDC's recent Conditional Sailing Order (CSO) that was in place since

October 2020.¹ Amid growing concerns over the COVID-19 pandemic in the U.S., the CDC originally halted all cruise voyages in March 2020. It extended the order multiple times until the implementation of the CSO, which had the goal of easing cruise lines back into functioning under strict regulations to avoid further COVID-19 spread. While extending the order, the CDC posted a “Request for Information” in the Federal Register to ask for public comments and considered the large volume of comments, but did not respond to them and instead invoked the CSO under the “good cause” exception to the APA’s requirement for “notice and comment.” The CSO involved four phases that cruise ships must go through before being allowed to embark: 1) A testing laboratory onboard for crew members, 2) A simulated cruise with volunteers for each ship, with approval from the CDC and various agreements in place with authorities at each port if cases arise, 3) A conditional sailing certificate at least 60 days prior to the voyage, on which modifications can be proposed to the CDC but the CDC can also revoke at any time, and 4) Voyages shorter than 7 days, and with requirements on the percentage of crew and passengers that must be vaccinated. The CDC also retained a right to update these orders as needed.

Since the CSO issuance, cruise companies and public figures have expressed concern that these guidelines are unduly burdensome on cruise ships and meant that only a few ships were able to get through all 4 phases. Florida sued in April 2021 for a preliminary injunction since it seemed the industry could not resume functioning before the profitable summer season under the CDC’s orders. The court ended up granting this injunction in June 2021 after agreeing with arguments that Florida’s economy (heavily based on cruises) would suffer, that

¹ *UNITED STATES DISTRICT COURT MIDDLE DISTRICT of FLORIDA TAMPA DIVISION.*
<http://myfloridalegal.com/webfiles.nsf/WF/SSWN-C44RE6/%24file/Order+on+PI.pdf>

the restrictions were an overreach on the CDC's part, that the orders were too vague and prone to change, and that the restrictions were not necessary for public health and did not comport with the CDC's guidelines to other industries.

Analysis:

I disagree with the recent federal judge's decision to grant a preliminary injunction against the CDC's Framework for Conditional Sailing Order (CSO). In trying to avoid the "all-or-nothing" approach of the CDC, this decision swings the pendulum too far in the other direction. The CSO was an effort to prioritize the public health concerns of the U.S. while balancing the interests of Floridians involved in the cruise industry, but the reasoning behind the injunction overly favors the economic concerns over public health concerns.² Just as the CSO failed in its goal of allowing paths for cruise ships to resume service, this injunction against it does not meaningfully take public health concerns into account. The ideal would be an approach which recognizes and balances the CDC's authority to control the interstate threat of infectious diseases, the genuine threat of "superspreader" situations on cruise ships, and the burden on Florida that overly strict restrictions would cause.

The financial harm caused by the CSO to Floridians is undeniable, given how important the cruise industry is to Florida's economy. As NBC summarized, "Florida is the nation's cruise capital with three of the world's busiest ports: Miami, Port Canaveral near Kennedy Space Center, and Port Everglades near Fort Lauderdale. The cruise industry

² *UNITED STATES DISTRICT COURT MIDDLE DISTRICT of FLORIDA TAMPA DIVISION.*
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generates billions for the economy and employs tens of thousands of Floridians.”³ The court notes that the financial injury to Florida would not normally qualify for a preliminary injunction, but because monetary damages cannot be recovered from the federal government, they do count here.⁴ The CSO would absolutely do significant irreparable harm to the cruise industry, and by extension, to Florida. The requirements the CDC is putting forth are burdensome, evidenced by the fact that only a handful of ships have made it to the fourth and final phase to date.⁵ More reasonable rules would surely have allowed more cruise ships, who have obvious motives to want to comply, to get to this final phase of requirements since April. If done better than in the injunction, more reasonable rules would still allow for public health concerns to be addressed through evidence-based restrictions.

My concern is that the court’s decision to grant an injunction against the CSO does not take into account the public health danger that precipitated the restrictions, and as a result dismisses all of the CDC’s policies too quickly. The court cites concerns over the CDC reserving authority to issue additional instructions, stating “Imposing on the cruise industry exhaustive, indeterminate, inconsistent, and unclear requirements (each of which threatens substantial penalty), the conditional sailing order likely is by definition capricious.”⁶ The cases the courts rely upon have to do with television stations and the Fish and Wildlife service- both topics which are fundamentally unlike COVID-19. Pandemics are hard to predict and rapidly

³ NBC 6 Digital Team. Judge Rules in Florida’s Favor in Lawsuit Over CDC’s No-Sail Order for Cruises. NBC 6 South Florida. Published June 18, 2021. Accessed June 19, 2021. <https://www.nbcmiami.com/news/local/judge-rules-in-floridas-favor-in-lawsuit-over-cdcs-no-sail-order-for-cruises/2476238/>

⁴ *UNITED STATES DISTRICT COURT MIDDLE DISTRICT of FLORIDA TAMPA DIVISION*. <http://myfloridalegal.com/webfiles.nsf/WF/SSWN-C44RE6/%24file/Order+on+PI.pdf>

⁵ *UNITED STATES DISTRICT COURT MIDDLE DISTRICT of FLORIDA TAMPA DIVISION*. <http://myfloridalegal.com/webfiles.nsf/WF/SSWN-C44RE6/%24file/Order+on+PI.pdf>

⁶ *UNITED STATES DISTRICT COURT MIDDLE DISTRICT of FLORIDA TAMPA DIVISION*. <http://myfloridalegal.com/webfiles.nsf/WF/SSWN-C44RE6/%24file/Order+on+PI.pdf>

shifting situations, and new policies have to be created in response to the new COVID-19 scenarios that emerge every week. In attacking this aspect of the CSO, it is clear the courts are relying on standards set by precedential cases when there are in fact hardly any precedents for the public health threat currently facing the U.S.

Similarly, the court found that because COVID-19 was “no-longer-new” in October 2020, the CDC did not have “good cause” to avoid notice and comment in creating these orders.⁷ It is true that many of the technical instructions in the CSO are impractical and more input from cruise experts should have been considered. The court does point out that allowing for the proper APA proceedings would still allow for relying on scientific evidence, which I do agree with. However, the court takes this as a sign that the CDC was not acting in good faith, stating that “the agency failed to account to the cruise industry, to the states, and to the public.”⁸ The court’s dismissal of the CDC’s invocation of “the public interest” is concerning, as it feels like the court would still not be satisfied if the CDC had allowed for public comment and still made the choice to impose restrictions. In a public health emergency, even if protective measures would have a negative impact on an industry, it does not necessarily mean public comment from those industries should be weighted equally against scientific evidence.

This is particularly true when cruises, by their very essence, are at a heightened risk of being a “superspreader” venue according to public health experts.⁹ The enclosed spaces, being forced into close proximity for days on end, narrow hallways and exits/entrances, not having

⁷ *UNITED STATES DISTRICT COURT MIDDLE DISTRICT of FLORIDA TAMPA DIVISION*.
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⁸ *UNITED STATES DISTRICT COURT MIDDLE DISTRICT of FLORIDA TAMPA DIVISION*.
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⁹ Mallapaty S. What the cruise-ship outbreaks reveal about COVID-19. *Nature*. 2020;580(7801):18-18.
doi:10.1038/d41586-020-00885-w

access to advanced medical facilities, and a total inability to make people showing signs of illness leave the space due to being hundreds of miles out on the ocean are hallmarks of every cruise.¹⁰ On most cruises, older people also make up a disproportionate amount of cruise passengers, increasing the risk for quick transmission (due to less immune resistance to a building infections) and deaths.¹¹ The court and Florida try to frame the CDC's especially strict orders for the cruise industries as hypocrisy, given that other industries "that cater to large groups of people" are not being regulated in this manner.¹² This line of reasoning completely ignores the unique aspects of cruises that public health experts have been trying to bring attention to, and clearly shows the perils of the legal system becoming overly involved in public health matters.

The interests of cruise lines are of course to keep running and to make a profit, but this must be balanced fairly against the potential loss of health and life- something I am not sure the court is weighting correctly. In matters of emergency international and interstate public health issues, the CDC's opinions should still trump other concerns- although perhaps with small allowances for financial concerns.

Actions Recommended:

To balance the interests of stakeholders such as Floridians and the U.S. at large, I would recommend that HHS appeal this injunction in hopes of implementing a toned-down version of the CSO that would still impose restrictions on cruise ships while enabling a more

¹⁰ Mallapaty S. What the cruise-ship outbreaks reveal about COVID-19. *Nature*. 2020;580(7801):18-18. doi:10.1038/d41586-020-00885-w

¹¹ Mallapaty S. What the cruise-ship outbreaks reveal about COVID-19. *Nature*. 2020;580(7801):18-18. doi:10.1038/d41586-020-00885-w

¹² *UNITED STATES DISTRICT COURT MIDDLE DISTRICT of FLORIDA TAMPA DIVISION*. <http://myfloridalegal.com/webfiles.nsf/WF/SSWN-C44RE6/%24file/Order+on+PI.pdf>

realistic phased approach that would allow more than the current handful of cruise ships to be able to comply with the CDC. The court already hints at this in their conclusion, but based on their reasons for granting the injunction I feel they may not have similar suggestions in mind. The court erred in finding the CDC could not have authority over the cruises, as well as putting too much weight on the financial harm to cruises that the CSO would cause. Allowing the CDC to regulate cruise ships in specific ways that would minimize financial harm and still follow the most prevalent public health guidelines is the best way forward.

I would firstly advocate for more direct input from the cruise industry, rather than in the form of long public comment periods that frankly may not have as much scientific reasoning as one might hope for. The Healthy Sail Panel (HSP), created by the cruise industry and consisting of public health experts, is something I would recommend reviving in partnership with the CDC as a sort of task force to find a middle ground for cruise restrictions. The HSP is co-chaired by Gov. Leavitt, former HHS secretary, and Dr. Gottlieb, former commissioner of the FDA, and has proven a commitment to recommending evidence-based policies that do not prioritize cruise lines' interests over that of public safety.¹³ The HSP has also already backed several other of my recommended actions listed below, albeit some time ago.

Continuing to require a high vaccination rate and recent testing among crew and passengers is likely the most cost effective and simply effective step that the CDC should continue to require of cruise ships. The risk of COVID-19 spreading becomes steadily smaller as vaccination rates in large groups rise, and cruise lines do not bear the cost of the

¹³ Norwegian Cruise Line Holdings Ltd. Norwegian Cruise Line Holdings Ltd. Published April 15, 2021. Accessed July 1, 2021. <https://www.nclhltd.com/health-and-safety>

vaccinations. I would still recommend a full simulation cruise with further capacity restrictions if this cannot be met on specific trips, as in the final phase of the CSO. The main issue here is in Governor DeSantis' ban on "vaccine passports," meaning that Florida businesses cannot ask for proof of vaccination.¹⁴ Recent polls have shown that less than a quarter of Floridians support this ban with regards to cruise lines; far larger percentages support mandatory vaccinations on cruises or for cruise lines to set their own guidelines.¹⁵ The ban may even be losing money for the cruise industry, as polls also show that the vast majority of cruise-goers have expressed a desire for crew and passengers to be vaccinated on future cruises: "Nearly two thirds of those surveyed (63%) said they would be more likely to go on a cruise if the cruise line mandated that all crew and passengers be vaccinated against Covid. And nearly as many respondents (59%) went even further, saying that, if they were going to take a cruise, they would specifically look for a cruise line that mandated all crew and passengers be vaccinated against Covid."¹⁶

The best way forward would be for the CDC to sue to challenge DeSantis' ban on vaccine passports so they can make high vaccination and testing rates mandatory— at least specifically for cruises— would align with both public health experts' opinions and the desires

¹⁴ Suzanne Rowan Kelleher. Three Quarters Of Floridians Disagree With Gov. DeSantis' Cruise "Vaccine Passport" Ban. *Forbes*. <https://www.forbes.com/sites/suzannerowankelleher/2021/06/17/survey-floridians-disagree-desantis-cruise-vaccine-passport-ban/?sh=131bb1cf2266>. Published June 17, 2021. Accessed June 20, 2021.

¹⁵ Suzanne Rowan Kelleher. Three Quarters Of Floridians Disagree With Gov. DeSantis' Cruise "Vaccine Passport" Ban. *Forbes*. <https://www.forbes.com/sites/suzannerowankelleher/2021/06/17/survey-floridians-disagree-desantis-cruise-vaccine-passport-ban/?sh=131bb1cf2266>. Published June 17, 2021. Accessed June 20, 2021.

¹⁶ Suzanne Rowan Kelleher. Three Quarters Of Floridians Disagree With Gov. DeSantis' Cruise "Vaccine Passport" Ban. *Forbes*. <https://www.forbes.com/sites/suzannerowankelleher/2021/06/17/survey-floridians-disagree-desantis-cruise-vaccine-passport-ban/?sh=131bb1cf2266>. Published June 17, 2021. Accessed June 20, 2021.

of most cruise lovers. This is quite achievable, given that there is very little good public health rationale behind banning vaccine passports and the CDC should have authority over a policy that has such far-reaching interstate disease transmission implications.

Although more costly for the cruise lines, requirements about not operating at full capacity and restrictions around amenities such as buffet lines would combine best with requiring vaccines and recent tests. Polls revealed most cruise guests would also prefer non-crowded cruises during COVID-19, which would also mean more of the social distancing public health experts have been advocating for during the pandemic.¹⁷ Based on these polls, it is highly likely that cruisers would be willing to pay a premium for low-capacity cruises to ensure their own safety, which simultaneously relieves some of the financial strain on the cruise lines.

Conclusion:

The court's decision to grant this injunction ignores the CDC's legitimate right to institute restrictions on the cruise industry during the COVID-19 pandemic. As Professor Gostin, director of the World Health Organization's center on global health law, has stated about this case, "although the agency's powers are not limitless, they are "at their zenith" when it comes to interstate and international commerce."¹⁸ Although aspects of the CSO were overly financially burdensome to Florida, the CDC must both appeal the injunction and sue to

¹⁷ Suzanne Rowan Kelleher. Three Quarters Of Floridians Disagree With Gov. DeSantis' Cruise "Vaccine Passport" Ban. *Forbes*. <https://www.forbes.com/sites/suzannerowankelleher/2021/06/17/survey-floridians-disagree-desantis-cruise-vaccine-passport-ban/?sh=131bb1cf2266>

¹⁸ Dolven T. Federal judge sides with DeSantis in dispute with CDC over cruise industry. *Tampa Bay Times*. Published June 18, 2021. Accessed July 1, 2021. <https://www.tampabay.com/news/florida-politics/2021/06/18/federal-judge-sides-with-desantis-in-dispute-with-cdc-over-cruise-industry/>

overturn Florida's vaccine passport ban in order to keep certain essential restrictions. Measures such as requiring high vaccination rates and lowered passenger capacity for cruise ships are both highly effective at controlling the spread of COVID-19 and in line with what most cruise passengers desire. The court granting this injunction wholesale has created a massive risk to public health, and continuing to push for these less burdensome requirements is the only way the CDC can balance these economic issues with the public health issues they are tasked with controlling.

Sincerely,

Nayab Ajaz
J.D./M.P.H. Candidate
Northeastern University School of Law
E-mail: ajaz.n@northeastern.edu

Jeffrey M. Zirger
Information Collection Review Office, Centers for Disease Control and Prevention
1600 Clifton Road NE, MS- D74
Atlanta, Georgia 30329

RE: Phased Approach to the Resumption of Cruise Ship Passenger Operations 2021-09094,
Docket No. CDC-2021-0011

June 30, 2021

Executive Summary

CDC guidelines for CSOs are burdensome for the cruise ship industry, yet medically and scientifically sound on most accounts. While there are certain things that could be done to diminish this burden, the recent development of effective vaccines has turned these more onerous requirements into a positive incentive to get vaccinated, as ships with close to 100% vaccinated staff and guests can avoid such steps as simulated voyages and planning with ports and local health care workers. However, perhaps the CDC should not relieve vaccine-compliant cruise lines from too many of the CSO mandates. While they may not be as needed for COVID-19 due to effective vaccines, they would still be highly useful practice for the next unknown infectious disease. In addition, the CDC must be mindful of evolving law, especially in Florida where an injunction was placed on the CSO mandate for Florida-based cruise lines. In addition, a new state law prohibits Florida businesses or government entities from requiring proof of vaccination. The CDC should be willing to appeal the injunction, while engaging in media campaigns to strongly suggest their protocols even in the event they cannot be mandated. As for the proof of vaccination law, while the CDC is quite limited in what they can do, cruise lines and passengers generally do not seem in favor of it, so the political tide may change against the law regardless.

Background

Cruise lines are highly successful, representing a \$150 billion industry globally (Zhang) with an economic impact of \$55.5 billion in the U.S. in 2019 (da Silva). In the last ten years, the annual growth rate for cruise-based tourism was higher than land-based tourism (5.4% vs 4.9%, respectively) (da Silva). To maximize profits, cruise lines have built larger ships with increased capacity; new ships can house over 6,000 customers and over 4,000 crew members. The industry as a whole is a significant global force, carrying almost 30 million passengers each year on about 270 ships, as well as employing about 1.1 million people (Guagliardo).

Cruise ships are also breeding grounds for communicable disease, including but not limited to norovirus, influenza, and measles (Codreanu). They are “highly susceptible” to “rapid spread of infectious diseases because of high population density, encouragement of social interaction, and common food and water sources” (id). Although international travel in general was largely responsible for the extent to which COVID-19 affected virtually every country, cruise travel significantly contributed to the spread. COVID-19 presented unique challenges for the cruise industry. Customers and staff came from around the world, crew members were often transferred between ships, and passengers from across the world visited new port cities and countries during voyages (da Silva).

One of the earliest cruise ship outbreaks of COVID-19 was aboard the Diamond Princess, where about one in five passengers and crew were infected and thirteen people died (Codreanu). The people on board had to quarantine in the Yokohama port of Japan for almost a month (Zhang). Since then, over 50 ships have experienced COVID outbreaks (da Silva), representing about one fifth of all cruise ships globally (id).

The Centers for Disease Control and Prevention (CDC) has played a critical role in curtailing and regulating the cruise ship industry over the last year and a half. Near the start of

the pandemic, they strongly advised Americans not to go on cruise ships (da Silva). On March 14, 2020, the CDC issued a No Sail Order (Brewster). This order was lifted on October 30, 2020 and replaced with a Framework for Conditional Sale Order (CSO) (Dolven).

The CSO is divided into four stages. First, a cruise ship must construct a laboratory to test patients. Second, the ship must conduct a simulated voyage. Before the simulated voyage, the cruise ship must establish a “medical care agreement” and a “housing agreement” with each port on their route, in order to ensure adequate infrastructure in case of a COVID-19 outbreak. Third, a ship must obtain a “conditional sailing certificate” from the CDC, attesting to the ship’s compliance with CDC procedures. After the certificate is issued, the ship can engage in “restricted passenger voyages,” with restrictions encompassing elements such as duration (no longer than seven days) (Florida v Becerra at 5-6).

However, a federal district judge ruled on June 18, 2021 in a Florida lawsuit that the CDC was preliminarily enjoined from enforcing their CSO against any “cruise ship arriving in, within or departing from a port in Florida” (NBC 6 Digital Team). As far as Florida commerce is concerned, the CSO would not be binding, instead functioning merely as “recommendations” or “guidelines” (id).

While it would appear from the scope of the injunction that the CDC can still enforce the CSO for cruise lines in the rest of the U.S., this ruling serves as a significant blow to its order, nonetheless. Florida is the primary hub of the cruise ship industry in the U.S. and has “the top-three cruise ports in the world representing 59 percent of total embarks in the United States” (da Silva). Because of its prominence, Florida has a unique interest in avoiding and mitigating unduly burdensome processes that hinder restarting of the cruise line industry. The industry is responsible for almost 150,000 jobs and \$7.69 billion in wages in the state (id). Besides ports,

other businesses like “airlines, hotels, food and beverage, shopping, transportation, and tourist hotspots” are also adversely affected (id). “The estimated economic losses suffered by Florida’s ports (including cargo and cruise ports) in 2020 was \$22.2 billion” (id).

Other states with a major cruise line industry such as Texas, California, and Alaska are significantly impacted by the CSO, but do not yet have CSO injunctions in place.

Analysis

In assessing the efficacy of the CSO, the economic and other considerations of the businesses and states hardest hit and the loss of work for tens of thousands of employees should not be neglected. However, the safety of the guests and staff must always be of first priority. The prevalence of highly effective vaccines has the potential to reduce the need for excess bureaucratic processes without compromising safety. Incorporating guidance and protocols, regarding COVID-19 vaccinations, into the CSO can alleviate burdens and increase the freedom, as well as peace of mind, of passengers and crew. As of May 26, 2021, the CDC has added specific recommendations regarding vaccination and cruise ship agreements with ports and local health authorities (Technical Instructions), as well as simulated and restricted voyages (COVID-19 Operations Manual). The CDC is not mandating simulated voyages for ships with close to 100% vaccinated crew and passengers. Unfortunately, the Florida legislature passed, and the governor signed into law, a statute “blocking any business or government entity from requiring proof of COVID-19 vaccination” (News Releases, by Staff). Despite this, any changes in final regulations for cruise lines with required vaccinations of guest and crew should be included.

Without any requirement for vaccinations the CSO is perceived by much of the cruise ship industry as too burdensome, with numerous and complex requirements. For example, a

complaint from the Cruise Lines International Association stated the CSO is “unduly burdensome, largely unworkable, and seem to reflect a zero-risk objective rather than the mitigation approach” (Florida v Becerra at 8). Also, six months after the CSO, no cruise line had begun simulated voyages, a testament to the excessive difficulty of the CSO process. (id). Royal Caribbean, one of the preeminent cruise lines in the world (da Silva), was not able to engage in a simulated voyage until late June (Burke).

However, a few Royal Caribbean scheduled voyages have been delayed after crew tested positive for COVID (Wong). This arguably justifies the CDC’s insistence on such rigorous procedures. With the readily available option of individuals becoming vaccinated in the U.S., rather than reducing the burden of the CSO, cruise ships should have the option to require vaccination of guests and staff. However, the recent Florida law banning such mandates complicates this commonsense alternative. In the absence of vaccination, the CSO requirements may be burdensome but are overall reasonable.

Many of the CSO requirements are scientifically and medically appropriate. For instance, limiting voyages to seven days is quite important. One study showed that “7-day voyages had about 70% fewer cases than 14-day voyages” (Guagliardo). The study also identified four key factors, which seem to have mostly been incorporated by the CDC, which reduced transmission by 80% when implemented together (id). These four factors were (1) daily screening for symptoms and isolation if someone exhibited symptoms; (2) testing everyone including asymptomatic people twice during the seven days; (3) reducing the number of passengers and crew; and (4) limiting visiting of ports to one per voyage (id).

However, the cruise lines’ complaints about a zero-risk approach are not unfounded, and have been validated in scholarly papers. For example, one paper suggested a “holistic

perspective on how to mitigate pandemic outbreaks that includes the behavioral (e.g., social distancing), procedural (e.g., different boarding time), and technical (e.g., testing procedures) actions against infectious agents. This involves identifying bottlenecks, transmission hotspots, changing boarding and transportation procedures, and calculating which countermeasures are the most cost-efficient, that is, those with the lowest price per protection” (Niemelä). An important takeaway of approaches like this is that it is almost impossible to have a truly zero-risk approach, unless commerce is completely stymied.

Public health must come first, but it cannot be forgotten that the ability to earn a livelihood also affects health. Pragmatic approaches which are context-specific (and flexible to change in light of new developments like new scientific data) can strike an appropriate balance between the need for minimizing viral exposure and the need for people to earn a living wage.

Another consideration was whether to have different standards for smaller versus larger ships. “[F]or smaller ships, the near zero-risk is achieved by decreasing the maximal numbers of passengers, implementing health questionnaire before boarding combined with symptom and temperature measurement at check-in” (id). However, another study examining a significant outbreak on the Greg Mortimer, a ship with “relatively few passengers” and a “single shared dining space,” hypothesized that “[t]it is possible that the small size of the ship increased the likelihood of contact between travelers because of difficulty maintaining physical distancing” (Guagliardo). Even though bigger ships house more passengers and staff than smaller ships, they are not intrinsically more dangerous. Reducing the number of people on larger ships seems the optimal solution, as the size will allow sufficient social distancing while maintaining enough customers to still be economically viable. Smaller ships would have a harder time with social distancing even with reduced passengers, but also they might have a harder time taking the

economic blow of less patronage. Some of this is already balanced out in less overhead costs than larger ships, but perhaps smaller ships would have to charge more for ancillary services. This must be a carefully weighed approach, as charging too much would discourage patronage. Though close to 100% vaccination of passengers and crew would solve the majority of these issues without costing cruise lines excess funds.

There are other practices both large and smaller cruise ships were already implementing which can facilitate greater compliance with the CSO. For instance, the more people are able to be outside, the less social distancing and mask-wearing is necessary because of open-air ventilation and other factors (Shukman). Before the COVID pandemic, an increasing trend in cruise ships was that “most ships have been following the sun; in [] other words, they are expanding to cover every place with an inviting climate” (da Silva). This means maximizing the time spent outdoors, with warmer weather and increased daylight. Some ships pre-COVID were even investing in robotic bartenders (id), and other innovations to decrease unnecessary person-to-person contact and risk of transmission.

Actions Recommended

The CSO outlines necessary steps to safely resume cruise ship travel despite a perceived complexity and difficulty. For example, rigorous protocols to coordinate with ports and health care workers/facilities in case of emergency may seem challenging and overly burdensome, but they are necessary and well worth the investment of time, money, and effort. For instance, an April 2013 report from FEMA regarding the Boston Marathon bombing describes how “[h]ospitals in Boston relied on response plans, training, and coordination between facilities to save over 140 lives after the bombings” (FEMA). Had hospitals not engaged in simulations and

other exercises, “a high number of casualties [] could have overwhelmed area hospitals and exceeded their capacity to treat victims” (id).

Although it makes sense that the CDC is not mandating simulated voyages for ships with vaccinated crew and passengers, ships could actually be missing out on important practice by avoiding those simulations. There will be other infectious diseases in the future. Ships that have high vaccination rates among people aboard may be grateful in the short term not to have to adhere to onerous conditions, which they perhaps would view as arbitrary regarding COVID because passengers and crew are immune. But even ships with high vaccination rates should make efforts to put infrastructure in place for simulated voyages and protocols with ports and local health care workers/facilities. If they do not, they will suffer in the long term when a new infectious disease impacts the industry.

One option for those ships would be to have at least one simulated voyage, and create worst-case-scenario relationships with ports’ healthcare resources in light of a hypothetical unknown infectious disease with an estimated danger commiserate with COVID-19, over the course of the next year or two years. In the meanwhile, the cruise line would be allowed to have passenger voyages, but if they had not conducted the simulations by the time limit, ideally the CDC could suspend operations until they complied. The recent decision in a Florida district court enjoining the CDC from making the CSO mandatory substantially complicates this approach. Despite this, and in addition to taking action to appeal the ruling, it would still be worthwhile for the CDC to take this position. Although the CDC may not be able to compel the cruise ship to comply, a public and forceful recommendation to do so can have an impact. The CDC can market this policy adherence (including through newspaper op-eds, cable news interviews, and social media) as being the smart, healthy, and forward-thinking thing to do, as

well as acknowledge compliant cruise lines on its website. Ships would want, if for no reason other than good public relations, to be perceived as taking public health and the health of their passengers seriously. Though lacking the force of legal compulsion, cruise lines would feel public pressure to comply.

The CDC must be vigilant of the precarious and dynamic state of the law, and strategize how to respond to protect public health. The CDC should focus on the rest of the U.S. in mandating its CSO while considering other unique strategies to encourage safe cruise travel for Florida, such as media campaigns. Those strategies will be useful should other states follow Florida's lead and pursue injunctions against the CSO. In tandem with reconciling how to push prudent health policies in Florida, the CDC should also appeal the decision of the federal district court. Even if the CDC is not successful in having the decision overturned, the process would send a message to other states looking to bring similar lawsuits. Although it could take a long time for a ruling on appeal, perhaps even past the time when COVID is considered as dire a health concern, it would still be important. It would set precedent for the CDC's authority which would be crucial for the next pandemic that could hit the U.S.

As previously discussed, not only did the federal district judge enjoin the CDC from mandating its CSO, but Florida also passed a law blocking local businesses from demanding proof of COVID vaccination (News Releases, by Staff). The CDC was not mandating that cruise lines compel customers to reveal vaccination status, so there is no conflict of law. Normally, because of this law, Florida-based cruise lines would not be able to reap the benefits the CDC set out for lines with close to 100% vaccination for passengers and crew, since they cannot obtain this information. But the injunction against the CSO makes possible benefits the CDC offers for high vaccination rates moot.

Still, the ultimate concern lies with the Florida-based lines themselves. Royal Caribbean, for instance, is demanding full vaccination for all guests over the age of sixteen, which will drop to age twelve after August 1st (Burk). Cruise industries were not doing this simply to get potential benefits of eased restrictions from the CSO. They were requiring vaccination to minimize risk, and increase not only safety but freedom and enjoyment for passengers and crew. In addition, a recent study showed that 80% of cruise ship passengers support vaccination (sun sentinel article). If cruise lines really prefer these policies, perhaps they should continue to implement them despite the Florida law. This will force the Florida state government to either not enforce their own law (which will be good for cruise lines, the CDC, and the country as a whole), or sue. The only party taking a significant risk in the latter case would be the Florida government. If Florida wins, the cruise lines are in much the same position they were already, but if Florida loses, this would be a major victory for sound public health policy which could have positive spill-over effects for the rest of the country. The CDC should strongly support the cruise lines if they take the legal route.

Finally, in the wake of the COVID pandemic, there are other things the cruise line industry should be doing to look towards the future, not because of the CSO but to maintain the safety and economic health of their industry. They should focus on the future risk of spreading infectious diseases on cruise ships and “design out” the problem, through a process known as prevention through design (PtD), which is encouraged by the US National Institute for Occupational Safety and Health (Brewster). Design changes can include “fewer and larger cabins, more dining areas with fewer seats, and redesigning other shared spaces to accommodate fewer people and increase personal space” (id). Besides robotic bars, other crew tasks can be automated to reduce number of crew on board (id). Those are more long-term plans, but more

expeditiously they can retrofit existing ships for “[o]ptimized ventilation” which “may reduce transmission risk on a cruise ship by limiting recirculating air, allowing more dilution with outdoor air, and applying filtration” (id). They could develop a phased plan to retrofit a portion of their fleet while continuing operations in the rest of their ships. The CDC should provide some guidance and a timeline for those larger, structural changes. COVID-19 had a large impact on the cruise ship industry, and the cruise ships served as vectors in the spread of the pandemic. We should use the lived experience of the past 18 months to prevent future health crises.

Sincerely,

Jonathan Barlam
J.D. Candidate
Northeastern University School of Law
E-mail: barlam.j@northeastern.edu

Endnotes

1. Xiaohan Zhang, "Prevention and Control of COVID-19 Pandemic on International Cruise Ships: The Legal Controversies"
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8002198/> (March 4, 2021)
2. Ana Lucia Rodrigues da Silva, "An overview of the impact of COVID-19 on the cruise industry with considerations for Florida"
<https://www.sciencedirect.com/science/article/pii/S2590198221000981> (May 6, 2021)
3. Sarah Anne J. Guagliardo, "Cruise ship travel in the era of COVID-19: A summary of outbreaks and a model of public health interventions"
<https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciab433/6274545> (May 12, 2021)
4. Tudor A. Codreanu, "Successful Control of an Onboard COVID-19 Outbreak Using the Cruise Ship as a Quarantine Facility, Western Australia, Australia"
https://wwwnc.cdc.gov/eid/article/27/5/20-4142_article (May, 2021)
5. Rebecca K Brewster, "Lessons learned for COVID-19 in the cruise ship industry"
<https://journals.sagepub.com/doi/full/10.1177/0748233720964631> (September 8, 2020)
6. Taylor Dolven, "Cruises will remain banned, CDC says, as industry pressure to restart heats up"
<https://www.detroitnews.com/story/travel/2021/03/29/cruises-remain-banned-cdc-says-industry-pressure-restart-heats-up/7044853002/> (March 29, 2021)
7. State of Florida v Xavier Becerra, et al.
<http://myfloridalegal.com/webfiles.nsf/WF/SSWN-C44RE6/%24file/Order+on+PI.pdf>
8. NBC 6 Digital Team, "Judge Rules in Florida's Favor in Lawsuit Over CDC's No-Sail Order for Cruises", <https://www.nbcmiami.com/news/local/judge-rules-in-floridas-favor-in-lawsuit-over-cdcs-no-sail-order-for-cruises/2476238/> (June 18, 2021)
9. "Technical Instructions for a Cruise Ship Operator's Agreement with Port and Local Health Authorities under CDC's Framework for Conditional Sailing Order"
<https://www.cdc.gov/quarantine/cruise/instructions-local-agreements.html>
10. "COVID-19 Operations Manual for Simulated and Restricted Voyages under the Framework for Conditional Sailing Order"
<https://www.cdc.gov/quarantine/cruise/covid19-operations-manual-cso.html#>
11. News Releases, by Staff, "Governor Ron DeSantis Signs Landmark Legislation to Ban Vaccine Passports and Stem Government Overreach",
<https://www.flgov.com/2021/05/03/governor-ron-desantis-signs-landmark-legislation-to-ban-vaccine-passports-and-stem-government-overreach/> (May 3, 2021)
12. Minyvonne Burke, "Royal Caribbean to begin test cruises with volunteer passengers in June", <https://www.nbcnews.com/news/us-news/royal-caribbean-begin-test-cruises-volunteer-passengers-june-n1268617> (May 26, 2021)
13. Wilson Wong, "Royal Caribbean delays cruise ship after 8 crew members test positive for Covid"
<https://www.nbcnews.com/news/us-news/royal-caribbean-delays-cruise-ship-after-8-crew-members-test-n1270979> (June 16, 2021)
14. Erik Niemelä, "Managing passenger flows for seaborne transportation during COVID-19 pandemics"
<https://academic.oup.com/jtm/advance-article/doi/10.1093/jtm/taab068/6265042> (May 5, 2021)

15. David Shukman, “Covid: Can you catch the virus outside?”, <https://www.bbc.com/news/explainers-55680305> (April 22, 2021)
16. FEMA, “Lessons Learned-Boston Marathon Bombings: Hospital Readiness and Response”, <https://www.hsdl.org/?view&did=744165> (April 17, 2013)
17. Ron Hurtibise, “80% of cruise enthusiasts would prefer to sail with vaccine requirement,” <https://www.sun-sentinel.com/business/fl-bz-cruise-poll-vaccine-requirement-20210601-agn07majjvhohbameyabhj2pim-story.html> (June 1, 2021)

Jeffrey M. Zirger
Information Collection Review Office, Centers for Disease Control and Prevention
1600 Clifton Road NE, MS- D74
Atlanta, Georgia 30329

RE: Phased Approach to the Resumption of Cruise Ship Passenger Operations 2021-09094,
Docket No. CDC-2021-0011

June 30, 2021

Executive Summary

This brief addresses the question posed by the proposal about what additional information cruise lines should collect before opening to general public. To begin, passenger cruise ships should not be opened yet during the pandemic until the numbers of cases reduce, and the likelihood of forced quarantine has gone down. This brief discusses the mental health effects that quarantining has on its employees and the risk of exposure to essential workers. Then, it will discuss the negative impact that having unvaccinated passengers may have on foreign countries. This brief focuses on addressing concerns about cruise lines opening to the public in general and additional precautions that should be taken.

In this analysis, discussion will center around why cruise ships should not be allowed to open despite the proposed protocol. Then the brief will discuss the actions recommended if this congressional regulation begins, despite the pandemic continuing. More explicitly, this brief will go over actions recommended for the federal government and state governments take to lower the risk of coronavirus spread from cruise lines and cruise line travel.

Background

In the Spring of 2020, multiple cruise ships had to quarantine at sea due to outbreaks of COVID-19 onboard.¹ These forced quarantines led to ships docking at foreign ports, continuously sailing until allowed to re-enter the country, and strained both the passengers and employees of these ships.²

With regards to travel generally, the Center for Disease Control and Prevention (CDC) recommends not currently travelling on cruise ships, even if vaccinated.³ They also recommend that traveler's get tested everyone to three days while travelling.^{4,5} The risk of outbreak on cruise ships is high, due to the close quarters and large population size.⁶

After the outbreak of COVID-19 on several cruise, the CDC Director issues a No Sail Order on March 14, 2020, through the Public Health Service Act.⁷ This order banned travel of passenger cruise lines.⁸ One issue cited in the transmission of COVID-19 on such cruise lines is the uncontrollable condition of the transmission at ports of calls.⁹ Another reason the CDC gave for this order is that quarantine and isolation is relatively difficult on cruise ships, depending on the capacity.¹⁰ The initial No Sail Order restricted cruise ship travel to only disembarking current

¹ Christina Zdanowicz, *Multiple Cruise Ships are Left Stranded as Coronavirus Cases Increase*, (March 17th, 2020), <https://www.cnn.com/travel/article/cruise-ships-stranded-coronavirus-trnd/index.html>.

²Bill Chappell; Vanessa Romo, *Coronavirus: Grand Princess Cruise Ship Docks Off California Coast*, (March 9, 2020), <https://www.npr.org/sections/health-shots/2020/03/09/813616982/coronavirus-u-s-has-564-cases-stricken-cruise-ship-to-dock-in-california>.

³ *COVID-19 and Cruise Ship Travel for Travelers Who Are Not Fully Vaccinated* (June 16, 2021), <https://wwwnc.cdc.gov/travel/notices/covid-3/coronavirus-cruise-ship>.

⁴*Id.*

⁵ Justin Moore, *Two Fully-Vaccinate Cruise Passengers Test Positive for COVID-19* (June 13th, 2021), <https://mynbc15.com/news/local/two-fully-vaccinated-cruise-passengers-test-positive-for-covid-19>.

⁶ Center for Disease Control and Prevention, *No Sail Order and Suspension of Further Embarkation*, (March 24, 2020), <https://www.federalregister.gov/documents/2020/03/24/2020-06166/no-sail-order-and-suspension-of-further-embarkation>.

⁷*Id.*

⁸*Id.*

⁹ *Id.*

¹⁰ *Id.*

passengers, disallowed new passengers to embark, and restricted any new operations to begin.¹¹ This order was extended and modified in April, July and September of 2020.¹² These modifications did not change the core principle of banning passenger cruise line travel.

Beginning in October 2020 the Framework for the Conditional Sailing Order was issued and released in April 2021.¹³ This Conditional Sailing order is part of what is set forth in the Congressional Proposal that this brief is commenting on today.¹⁴ The risk of continual spread of COVID-19 can be mitigated by the Cruise Industry. If the CDC moves forward with the protocol despite the risk of COVID-19, changes that should be made to the protocol to further reduce the spread.

Analysis

Beginning passenger cruise line travel will have a threefold effect: it will lead to outbreaks on COVID-19 on cruise-ships, forced quarantine will negatively impact the mental health of employees and passengers, and it will further the risk of the spread of COVID-19 to less-vaccinated foreign countries. If cruise lines were to open up, without government regulation of vaccine, not only is there an increased chance of the spread of COVID-19 internationally, but the mental health of employees of cruise lines is at risk.¹⁵ Monetary gains of one industry, when it has the resources to mandate vaccines, should not outweigh the health and safety of its employees. The CDC's proposal would mitigate the risk of quarantine at sea; however, it does

¹¹ *Id.*

¹² Center for Disease Control and Prevention, *COVID-19 Orders for Cruise Ships*, May 5, 2021), <https://www.cdc.gov/quarantine/cruise/covid19-cruiseships.html>.

¹³ *Id.*

¹⁴ Center for Disease Control and Prevention, *Framework for Conditional Sailing and Initial Phase COVID-19 Testing Requirements for Protection of Crew* (Oct. 30, 2020), https://www.cdc.gov/quarantine/pdf/CDC-Conditional-Sail-Order_10_30_2020-p.pdf

¹⁵ Sho Takahashi, MD, PhD, Kazunori Manaka, MD, PhD, Takafumi Hori, MD, PhD, Tetsuaki Arai, MD, PhD, and Hirokazu Tachikawa, MD, PhD, *An Experience of the Ibaraki Disaster Psychiatric Assistance Team on the Diamond Princess Cruise Ship: Mental Health Issues Induced by COVID-19* (August 12, 2020), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7477399/>.

not take into account the risk of carriers of the disease.¹⁶ The current proposed protocol seemingly does not take into account the risk of transmission between unvaccinated and vaccinated passengers. Already this year, two vaccinated passengers of a cruise ship were diagnosed with COVID-19. Even if travel is limited to only United States based destinations, the risk of infection on the cruise line is too high to allow for travel. Vaccinated persons can still get COVID-19.¹⁷ This means that travelers from the United States have the potential to be asymptomatic carriers, spreading the disease to people in other port cities and countries.¹⁸

I. The Health and Safety of Cruise lines Employees Should Be a Priority

It is well known that the risk of getting COVID-19 on a cruise ship is high.¹⁹ In fact, the CDC recommends that unvaccinated people do not travel in general, let alone board an enclosed ship for several days. While containing the spread of this virus is the primary purpose of these regulations, another factor that should be considered is the toll on mental health that mandated quarantining has on the employees of cruise lines. The use of passenger cruise lines is not necessary and would force those in the service industry to come back to work in unsafe conditions to serve wealthier, more privileged populations of people who have been vaccinated and are hoping to return to normal life. Quarantine will have a negative effect on anyone that experiences it; however, cruise employees specifically have shown to have severe mental health

¹⁶ Eugenia Tognotti, *Lesson from the History of Quarantine, from Plague to Influenza A* (February 19th, 2013), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3559034/>

¹⁷ U.S. Department of Health and Human Services, *Development and Licensure of Vaccines to Prevent COVID-19*, (June 2020), <https://www.fda.gov/media/139638/download>.

¹⁸ *Id.*

¹⁹ Center for Disease Control and Prevention, *Cruise Ship Travel* (May 5, 2021), <https://www.cdc.gov/coronavirus/2019-ncov/travelers/returning-cruise-voyages.html#:~:text=CDC%20recommends%20that%20all%20people.close%20quarters%20aboard%20ships>.

issues based on the unknown time frame quarantines on cruise ships have.²⁰ In fact, in Spring of 2020 multiple cruise employees committed suicide from forced quarantine.²¹

It is the responsibility of the cruise companies to address the mental health needs of their employees. Mark Czeisler refers to this as the “pandemic within a pandemic,” that the sense of loneliness that required the quarantine has created. Over the course of the COVID-19 pandemic, general quarantine has increased anxiety and depressive disorders by around 40% from the year before.²² This does not account for the forced quarantine of the many cruise line employees who were forced to stay aboard these ships for an indefinite amount of time. In many cases, these increases in mental health issues and COVID-19 cases fell disproportionately on essential workers.²³

An employee’s life should not be put at risk simply due to the fact that corporate cruise lines would like to make a large revenue by beginning cruise passages before the risk of COVID-19 has subsided. If the cruise line corporations would like to restart, the best path to avoiding a forced quarantine of employees is to mandate vaccines for employees. Employers can mandate that their employees get COVID-19 vaccines; however, under the Americans with Disabilities Act (ADA), they must require accommodations and exceptions.²⁴ A step further could be to require all passengers to be vaccinated; however, with the results of *Florida v. Becerra*, this would be specifically for cruise lines outside of Florida.²⁵ Additionally, in order to get around

²⁰ Austin Carr, *The Cruise Ship Suicides* (December 30, 2020), <https://www.bloomberg.com/features/2020-cruise-ship-suicides/>.

²¹ *Id.*

²² Center for Disease Control and Prevention, *Mental Health, Substance Use, and Suicidal Ideation During the COVID-19 Pandemic*, (August 14, 2020), <https://www.cdc.gov/mmwr/volumes/69/wr/mm6932a1.htm>.

²³ Miles Bryan, *Essential Workers are 55 % More Likely to get COVID-19, study of Philly Area Residents Finds* (March 3, 2021), <https://why.org/articles/essential-workers-are-55-more-likely-to-get-covid-19-study-of-philly-area-residents-finds/>

²⁴ Americans with Disabilities Act of 1990, Pub. L. No. 101-336, § 2, 104 Stat 328 (1991)

²⁵ *Florida v. Becerra*, NO. 8:21-cv-839-SDM-AAS, F. Supp. 3d, 1i -149, (M.D. Fla. 2021)

the Florida Executive Order, Executive Order No. 21-81, cruise companies can begin to operate more services out of their ports in different states.²⁶ Cruise line revenue should not come at the expense of employee mental and physical health.

With regards to the mental health of passengers being forced to quarantine, the relationship that the cruise lines would be required to create would ensure that these passengers would not be at sea during their quarantine.²⁷ Further, part of the health protocol could be therapist both on board the cruise ship and during the health monitoring during the proposed quarantine.

II. Travel on International Waters Should Require a Vaccine, Not Based on Port of Departure

Due to the international nature of many voyages, cruise lines travelling into foreign countries should be mandated to follow the strictest guideline of all of the countries it is visiting. Any country on the itinerary should be allowed to deny entry to those passengers who do not abide by that country's vaccination standards. While in theory, these countries can require proof of vaccination once travelers from the United States arrive, there is a chance of unvaccinated passengers getting into the country.²⁸

Common destinations of cruise ships like the Caribbean islands, could be greatly affected by the decision to allow passengers from cruise ships to travel without vaccines. The current case rate of COVID-19 has been rising as more persons from the United States begin to travel outside the country.²⁹ Honduras, a popular cruise destination, saw a COVID-19 case increase of around

²⁶ Executive Order No. 21-81

²⁷ Center for Disease Control and Prevention, *Framework for Conditional Sailing and Initial Phase COVID-19 Testing Requirements for Protection of Crew* (Oct. 30, 2020), https://www.cdc.gov/quarantine/pdf/CDC-Conditional-Sail-Order_10_30_2020-p.pdf

²⁸ World Health Organization, *Interim Position Paper: Consideration Regarding Proof of COVID-19 Vaccination for International Travellers*, (February 5, 2021), <https://www.who.int/news-room/articles-detail/interim-position-paper-considerations-regarding-proof-of-covid-19-vaccination-for-international-travellers>.

²⁹ *COVID-19 Tracker, Latin America and the Caribbean*, (June 30, 2021), <https://graphics.reuters.com/world-coronavirus-tracker-and-maps/regions/latin-america-and-the-caribbean/>.

18% within the past few weeks.^{30,31} Other Caribbean countries, like the Bahamas, Turks and Caicos, and Jamaica, are still trending much lower than their peak.³² The introduction of tourists from the United States, even if the majority of them are vaccinated, could lead to a sudden rise in cases in these countries.

Even if at port foreign countries do not allow passengers without a vaccine to enter into their country, due to the close quarters of cruise ships, vaccinated passengers may be carrying the virus. While vaccinated travelers are at a low risk, there is still a chance of infection. In fact, a recent study showed that priorly infected persons with vaccine has positive test results.³³ On a fully vaccinated cruise line that left from St. Maarten, two passengers tested positive for COVID and were isolated on the ship.³⁴

Vaccine Passports are currently being used in several countries across the globe.³⁵ Cruise ships that are going to foreign countries should be mandated to follow the stricter version of COVID-19 regulations of the two countries. Other countries should not have to handle increased exposure from United States citizens intent on vacationing during an ongoing pandemic.

³⁰ Royal Caribbean International, Caribbean Cruises, (Last Visited, June 30, 2021), https://www.royalcaribbean.com/cruise-to/roatan-honduras?ecid=sm_int_pnrst_pnt_8887.

³¹ COVID-19 Tracker, Latin America and the Caribbean, (June 30, 2021), <https://graphics.reuters.com/world-coronavirus-tracker-and-maps/regions/latin-america-and-the-caribbean/>.

³² *Id.*

³³ Roberto Bertolini, MD, MPH; Hiam Chemaitelly, MSc; Hadi M. Yassine, PhD; et al, *Associations of Vaccination and of Prior Infection with Positive PCR Test Results for SARS-CoV-2 in Airline Passengers Arriving in Qatar*, (June 9, 2021), <https://jamanetwork.com/journals/jama/fullarticle/2781112>.

³⁴ Morgan Hines, *Two Passengers Test Positive for COVID on Celebrity Millennium 'fully vaccinated' cruise*, (June 10, 2021), <https://www.usatoday.com/story/travel/cruises/2021/06/10/passengers-positive-covid-after-sailing-100-vaccinated-cruise/7645511002/>.

³⁵ Victoria M. Walker, *Want to Travel Abroad? These are the Countries Using Vaccine Passports for Travel*, (June 10, 2021), <https://thepointsguy.com/news/digital-health-passports-worldwide/>.

Actions Recommended

I. The Federal Government Should Use Its Police Power to Overturn Florida Case

Due to *Florida v. Becerra*, my first recommendation is for the U.S. Department of Health and Human Services to push for the circuit court to overrule the District Courts decision.³⁶ The next step is for Congress to pass a bill mandating the COVID-19 vaccine for United Citizens for foreign travel. This at the very least could consist of mandating COVID-19 vaccination for foreign travel to countries that require them. There is an unequal distribution and availability of vaccinations over the world.³⁷ About seventy-five percent of the number of vaccines have gone to ten countries globally.³⁸ The United States is the global leader in vaccination rates.³⁹ U.S. Citizens should not place other countries at risk simply because they are wealthy or come from a country that has a larger quantity of vaccines. This regulation would be more aligned with international law, as it allows for full transparency across borders. The CDC does not recommend travelling internationally until fully vaccinated.⁴⁰

According to the Commerce Clause, Congress can have the constitutional authority to overrule if voting to make a law that would preempt the Executive Order No. 21-81.⁴¹; ⁴² Further, through the Necessary and Proper clause congress can overrule state authority when it is so necessary to protect the health, safety and welfare of the united states population.⁴³ While Congress has to balance the weight of private interests, such as the pursuit of trades and

³⁶ *Florida v. Becerra*, NO. 8:21-cv-839-SDM-AAS, F. Supp. 3d, 1i -149, (M.D. Fla. 2021)

³⁷ Jason Beaubien, *What Does Vaccine Inequality Look Like?*, (April 22, 2021), <https://www.npr.org/sections/goatsandsoda/2021/04/22/988814093/what-does-vaccine-inequality-look-like-see-chart>.

³⁸ *Id.*

³⁹ *Id.*

⁴⁰ Center for Disease Control and Prevention, *International Travel During COVID-19*, (June 10, 2021), <https://www.cdc.gov/coronavirus/2019-ncov/travelers/international-travel-during-covid19.html>

⁴¹ U.S. Const. Art. I, § 8, cl. 3.

⁴² Executive Order No. 21-81

⁴³ U.S. Const. Art. I, § 8, cl. 18.

occupations, the threat of COVID-19, especially outside of the United States, outweighs the privacy interests. More so, If the *Florida v. Becerra* case rises to the level of the Supreme Court, they have the power to overrule the District's Court opinions.⁴⁴

II. Daily Testing Should be Mandated and Reports Should Be Sent to All Destination Points.

Daily Testing should be mandated for all employees and passengers, not just weekly testing. This would ensure that cases are not missed. Additionally, this could ensure that no COVID-19 positive passengers disembark into foreign countries. One way to keep the cost of this daily testing down is through pooled testing.⁴⁵ This technique would reduce the number of resources that the cruise lines would have to pay for, while increasing the testing of employees and passengers on the ships.

III. Cruise Line Contracts with Hotels Should Gave Explicit Factors

The proposal does not make clear what the explicit partnership is between the cruise lines and the hotel organization they are working with the establish a quarantine protocol. In addition to mandating this relationship, Congress should add specific factors that each of these contracts include. Primary factors of this contract should be:

1. An explicit breakdown of costs covered by the cruise line should an outbreak require quarantine.

⁴⁴ *Florida v. Becerra*, NO. 8:21-cv-839-SDM-AAS, F. Supp. 3d, 1i -149, (M.D. Fla. 2021)

⁴⁵ U.S. Food and Drug Administration, *Pooled Sample Testing and Screening Testing for COVID-19*, (August 24, 2020), <https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/pooled-sample-testing-and-screening-testing-covid-19>.

- a. Cruise lines are currently offering to pay the cost of quarantine and any medical expenses on the ship; however, it seems that this agreement is intentionally vague in order to allow for cost-cutting tactics.⁴⁶
 - b. Fuller transparency will allow employees and passengers to make informed decisions as to whether or not they want to board the cruise ship.
 - c. The passenger ticket tax that is proposed below would account for some of these costs. Not every cruise will have to quarantine its passengers, this increase in revenue from the tax should be set aside to pay for quarantining costs of its employees and passengers.
 - i. Any remaining costs should be covered by cruise lines, as they are taking on the risks of opening cruises to the general public.
 - d. Because it is unreasonable to ask cruise lines to constantly block out and pay for hotel rooms for passengers, those passengers that test positive for COVID-19 could isolate onboard for ten days, per CDC guidelines, and then more to an available hotel for further quarantine should they need medical treatment.⁴⁷
2. A clause discussing the timeline of cost-coverage for such quarantine if extended care is needed.
- a. This would ensure that cruise lines are held accountable for the health and safety of their passengers, even through long-term treatment.

⁴⁶ Dave Sebastian, *Cruise Lines Budget for Extra Costs as They Prepare to Restart Sailings*, (May 21, 2021), <https://www.wsj.com/articles/cruise-lines-budget-for-extra-costs-as-they-prepare-to-restart-sailings-11621598402>.

⁴⁷ Center for Disease Control and Prevention, *When to Quarantine*, (March 12, 2021), <https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/quarantine.html>.

3. Employees of the cruise line should disembark alongside passengers and quarantine on land.
 - a. Though the cruises that had outbreaks in the Spring of 2020 quarantined on the ships, the current proposal allows for relationships to form between cruise lines and hotels in order to quarantine passengers if an outbreak occurs.
 - b. Studies have shown that quarantining on the cruise ship not only leads to higher rates of infection, but also takes an extreme toll on the mental health of employees.
 - c. Cruise ships should be docked, and employees should also be quarantined in those hotels with passengers. This would decrease the negative mental health side effects that the endless, unknown length of quarantining on a cruise line had on employers in the Spring of 2020.

IV. Congress Could Add a Tax to Cruise Lines That Allow Unvaccinated Passengers

As set forth in *South Dakota v. Dole*, marking that the government can use its spending power in pursuit of general welfare, within this proposed protocol Congress could add in the requirement of an additional tax on all passenger tickets.⁴⁸ Such a tax would be used to help alleviate the potential increased medical cost for those exposed to COVID-19. The primary use of this tax would be to discourage unnecessary travel that will create an unnecessary risk to the general welfare of U.S. Citizens. This tax would be to discourage cruise line travel all together. This tax would be similar to the government-imposed September 11th Security Fee that was imposed on all airline tickets to account for increase security in airports.⁴⁹ Also, it

⁴⁸ *South Dakota v. Dole*, 483 U.S. 203 (1987)

⁴⁹ Transportation Security Administration, *Security Fees*, (last visited June 30, 2021), <https://www.tsa.gov/for-industry/security-fees>.

enables cruise lines to get around the current Florida Executive Order No. 21-81 that bans asking for vaccine history as it would apply to all passengers.

Conclusion:

Cruise lines should continue to halt their voyages until the rate of infection, or the rate of vaccination has changed in the United States. In addition, the proposed phase in standards set out by congress should include additional collection of information, such as vaccine history.

Sincerely,

Erin Gannon
J.D. Candidate
Northeastern University School of Law
E-mail: gannon.e@northeastern.edu

Statement:

This public comment was prepared for a Northeastern University School of Law class: Problems in Public Health.

Jeffrey M. Zirger
Information Collection Review Office, Centers for Disease Control and Prevention
1600 Clifton Road NE, MS- D74
Atlanta, Georgia 30329

RE: Phased Approach to the Resumption of Cruise Ship Passenger Operations 2021-09094,
Docket No. CDC-2021-0011

June 30, 2021

EXECUTIVE SUMMARY

As the United States continues to navigate re-opening businesses and generally resuming operations across sectors, issues regarding travel have been at the forefront of conversation. Included in this dialogue is the end of restrictions placed on cruise operations. This comment addresses whether allowing cruise operations to resume is a good idea, what factors need to be considered in any decision making regarding possible restrictions, and recommendations for resuming cruise travel in a way that may mitigate at least some of the risk involved.

At a baseline, resuming operations may not be advisable at this time. Case numbers continue to remain steady, vaccination rates in the United States have stalled, and there is a severe lack of vaccine equity in the U.S. and globally. Resuming cruise travel would not only have potentially detrimental impacts on the home communities of returning passengers but would have significant impacts on destination nations who not only have incredibly low vaccination rates but would be devastated by a future outbreak. Any plan made without input from all stakeholders is therefore fundamentally unethical. Other considerations for planning include the increased prevalence of COVID-19 variants, the need to prioritize the use of limited CDC resources, and the impact of the recent Middle District of Florida decision on future planning and ability to regulate in this space.

If it fundamentally impossible to continue to halt operations; however, there are a number of requirements that could be put in place including capacity requirements, requiring cruises to provide crew with a way to be vaccinated prior to returning to work, and requiring at least some proportion of passengers and crew be vaccinated in order to make cruise travel safer.

BACKGROUND

In February and March of 2020, three cruise lines were connected to over 800 confirmed cases of COVID-19, including 10 deaths.¹ By mid-March, confirmed cases of COVID-19 could be traced to 25 cruise lines.² Cases directly linked to cruise travel were reported in 15 states and made up 17% of all COVID-19 infections at that point in the pandemic.³ Among those was the Grand Princess ship, which was quarantined off the coast of California because of a COVID-19 outbreak among the guests and crew.⁴ Following these incidents, the CDC issued a No Sail Order on March 14, 2020, suspending cruise operations from the U.S. for 30 days.⁵ This No Sail Order applied to vessels carrying over 250 passengers.⁶ The No Sail Orders were renewed in April of 2020, and extended again in July, September, and October, when the CDC finally stated that the order shall remain in place until either the expiration of the emergency declaration, the CDC Director rescinds or modifies the order, or November 1, 2021.⁷ The CDC began issuing and developing the framework that is the subject of this comment in October 30, 2020, with the most

¹ *Public Health Responses to COVID-19 Outbreaks on Cruise Ships – Worldwide, February-March 2020*, CDC (Mar. 27, 2020), <https://www.cdc.gov/mmwr/volumes/69/wr/mm6912e3.htm>.

² *Id.*

³ *Id.*

⁴ Bill Chappell & Vanessa Romo, *Coronavirus: Grand Princess Cruise Ship Docks Off California Coast*, NPR (Mar. 9, 2020), <https://www.npr.org/sections/health-shots/2020/03/09/813616982/coronavirus-u-s-has-564-cases-stricken-cruise-ship-to-dock-in-california>.

⁵ *CDC COVID-19 Orders for Cruise Ships*, CDC, <https://www.cdc.gov/quarantine/cruise/covid19-cruiseships.html> (last updated Mar. 5, 2021).

⁶ *Id.*

⁷ *Id.*

recent update on May 5, 2021.⁸ In the background of these developments is the fact that the United States has documented over 33 million confirmed cases of COVID-19 and 600,000 deaths.⁹

At present, much of the U.S. is going through the process of re-opening businesses and trying go back to some norms of pre-pandemic life, with many states lifting restrictions starting on May 20th.¹⁰ International travel destinations in Europe are once again starting to allow entry from the United States.¹¹ Airports such as Los Angeles International Airport are preparing for a 300% increase in daily air travel over the coming weeks.¹² Included in these recent developments; however, is the June 18, 2021 decision by the Middle District of Florida to issue an injunction against the proposed CDC framework for resuming cruise travel.¹³ This decision makes the current framework, essentially, a non-binding set of guidelines on ships sailing in and out of Florida as of July 18th.¹⁴

ANALYSIS

As an initial matter, it would be prudent to continue to delay the resumption of cruise ship operations. This assessment is based on a consideration of the increasing prevalence of COVID-19 variants, low global vaccination rates, and an eye toward issues of health equity.

Of critical concern when addressing the return of cruise lines, is the potential for the further spread and the potential continued development of COVID-19 variants. Currently, there are six

⁸ *Id.*

⁹ *United States of America Situation*, WHO, <https://covid19.who.int/region/amro/country/us> (last updated June 25, 2021).

¹⁰ Alaa Elassar, *This is where each state is during its phased reopening*, CNN (May 27, 2020), <https://www.cnn.com/interactive/2020/us/states-reopen-coronavirus-trnd/>.

¹¹ Forrest Brown & Brekke Fletcher, *Find out which countries are welcoming US tourists back*, CNN (June 30, 2021), <https://www.cnn.com/travel/article/us-international-travel-covid-19/index.html>.

¹² City News Service, *LAX bracing for 300% increase in international travel*, DAILY BREEZE (June 4, 2021), <https://www.dailybreeze.com/2021/06/04/lax-bracing-for-300-increase-in-international-travel/>.

¹³ Hannah Sampson, *Federal judge strikes down CDC cruise rules in 'major victory' for DeSantis*, WASHINGTON POST (June 18, 2021), <https://www.washingtonpost.com/travel/2021/06/18/florida-cruise-lawsuit-desantis/>.

¹⁴ *Id.*

COVID-19 variants being monitored in the United States.¹⁵ These variants spread more easily and quickly than other variants and are likely to lead to increased disease incidence.¹⁶ The Delta variant, responsible for increase case numbers in India and the United Kingdom, makes up at least 10% of cases reported in the U.S. as of June 2021.¹⁷ The World Health Organization is currently monitoring 11 variants that they consider to be variants of concern and variants of interest.¹⁸ The increasing number of variants needs to remain at the center of any conversation about reopening and returning to “normal life,” especially as we continue to evaluate the efficacy of existing vaccines and vaccines still in development.

The issue of variants, in addition to concern over the continued spread of the disease more generally, needs to be taken with a particular eye toward the fact that many of the Central American and Caribbean nations where cruises travel would be put at significant risk were cruise lines to continue operations. Vaccination rates in much of the world remain incredibly low.¹⁹ This includes in countries that serve as major travel hubs. Jamaica, for example, was visited by over 1.5 million cruise passengers in 2019 and currently has only been able to vaccinate 1.1% of its population.²⁰ Similarly, the Bahamas welcomed almost 5.4 million cruise passengers in 2019 and has only been able to vaccinate 4.6% of its population.²¹ At the same time, many of these nations are heavily dependent on the revenue derived from the cruise industry, making up as much as 5.9 percent of

¹⁵ *About Variants of the Virus that Causes COVID-19*, CDC, <https://www.cdc.gov/coronavirus/2019-ncov/variants/variant.html> (last updated June 28, 2021).

¹⁶ *Id.*

¹⁷ Stephanie Soucheray, *CDC: Delta variant now 10% of US COVID-19 cases*, CIDRAP (June 16, 2021), <https://www.cidrap.umn.edu/news-perspective/2021/06/cdc-delta-variant-now-10-us-covid-19-cases>.

¹⁸ *Tracking SARS-CoV-2 variants*, WORLD HEALTH ORGANIZATION, <https://www.who.int/en/activities/tracking-SARS-CoV-2-variants/> (last visited June 30, 2021).

¹⁹ Josh Holder, *Tracking Coronavirus Vaccinations Around the World*, NEW YORK TIMES, <https://www.nytimes.com/interactive/2021/world/covid-vaccinations-tracker.html> (last updated June 20, 2021).

²⁰ Garwin Davis, *Over 1.5 Million Cruise Passenger Arrivals in 2019*, Jamaica Information Service (Jan. 13, 2020), <https://jis.gov.jm/over-1-5-million-cruise-passenger-arrivals-in-2019/>; *supra* note 20.

²¹ Gay Nagle Myers, *Bahamas posts record arrivals numbers*, Travel Weekly (Jan. 24, 2020), <https://www.travelweekly.com/Caribbean-Travel/Bahamas-posts-record-arrivals-numbers>; *supra* note 20.

GDP in some Caribbean nations.²² This creates a scenario in which destination ports may feel intense pressure to accept tourists as cruise travel resumes, yet will be at significant risk for devastating COVID-19 surges as a result. As such, any plan needs to include input from these nations and consideration of the imbalance of power inherent in the existing relationship between cruise lines and their destination countries.

Also of consideration is the considerable resources required by the plan from the CDC. The plan as it exists requires a great deal of administrative labor on behalf of the CDC, including certification of Response Plans, issuing technical guidance, conducting inspections, reviewing appealed application denials, and conducting oversight of test voyages as well as future testing data collected during initial voyages. This represents thousands of hours by the CDC. The hours, also being spent at a time where only 45% of the country is fully vaccinated, the U.S. just surpassed 600,000 deaths from COVID-19, 7 million people remain uninsured due to the economic impacts of COVID-19 which will likely result in further health impacts from untreated illness and chronic disease, and schools and workplaces continue to struggle with how to get people back into their routines of daily living.²³ The CDC continues to address the domestic and global impact of the virus, including the issue of vaccine access, so the use of limited resources for this project is deeply out of step with those needs. The evidence strongly supports further delay of resuming activities like cruise ships until more pressing matters are addressed and the pandemic is actually under control.

If the June 18, 2021 decision from the United States District Court for the Middle of Florida is indicative of how other lawsuits may be decided, it lends additional credence to the idea that it

²² Monique Giese, *COVID-19 impacts on global cruise industry*, KPMG (July 23, 2020), <https://home.kpmg/xx/en/blogs/home/posts/2020/07/covid-19-impacts-on-global-cruise-industry.html>.

²³ Dylan Scott, *4 aftershocks of the coronavirus pandemic that will be felt for years*, VOX (May 11, 2020), <https://www.vox.com/2020/5/11/21254892/coronavirus-us-economy-primary-health-care-insurance>.

remains unsafe to conduct cruise operations. Under the decision, the proposed plan will become obsolete, leaving ships to travel without oversight from any kind of public health governing body.²⁴ By putting a preliminary injunction in place, the CDC is no longer able to resume operations is a dangerous and unwieldy decision which will likely have untold costs to communities both in the U.S. and in destination countries who, to date, have been left out of this dialogue. While the CDC can and should continue to challenge this action in court, there are also ways that the agency can try to give effect to at least some of the requirements of the challenged framework.

ACTIONS RECOMMENDED

At a baseline, cruise ships should not be able to resume at this point in time, especially without more serious input from destination countries. If cruise lines do resume operations; however, there are a number of additional precautions need to be taken to ensure the safety of not only the passengers, but the crew, service workers and citizens at ports of entry, and the health of countries and communities more broadly.

The existing framework appropriately requires cruise lines to have extensive plans for testing, providing care, and how to address potential positive cases. Admirably, the proposal also requires cruise lines to take into account the health care resources of local communities. These aspects could be made more stringent and require more resources from the cruise lines. That said, these aspects of the plan are generally strong and will not be the subject of my recommendations.

(1) Require cruise lines to continue to limit capacity among their vessels.

One of the major challenges with cruise ships generally is that they feature very tight quarters, making it difficult to control the spread of disease.²⁵ Fewer passengers also means fewer

²⁴ *Supra* note 13.

²⁵ *Supra* note 4.

crew members who likely also have fewer opportunities that passengers to social distance in shared quarters.

(2) Care for the crew must remain paramount.

As was learned following the COVID-19 outbreak on the Diamond Princess Cruise in February-March of 2020, the spread of COVID-19 was much more rampant among the crew than among the passengers.²⁶ In addition to requiring that cruise lines provide regular testing for crew members, it is essentially that companies also provide a way for all crew members to get fully vaccinated in advance of their return to work. This is essential for not only for preventing future outbreaks, but for advancing vaccine equity and the civil rights of crew members.

(3) Vaccination requirements may be too stringent.

The plan, as it currently exists, creates an incentive for vessels that have a 95% vaccination rate among staff and passengers to be able to set sail sooner.²⁷ This incentive; however, feels ineffectual. A more meaningful requirement may be that a certain percentage of passengers and crew must be vaccinated in order to be able to travel, potentially 70-75%. It is important to consider the ethical considerations at play when requiring vaccinations to participate in activities.²⁸ Some of these concerns may be mitigated; however, if vaccination is only required for a certain proportion of people on board.

(4) Obtain Congressional authorization to regulate in this space.

One of the central arguments in the Florida v. Becerra case was that the CDC had exceeded its statutory and regulatory authority in establishing these conditional sailing order.²⁹ The opinion

²⁶ *Supra* note 1; Eisuke Nakazawa et. Al., *Chronology of COVID-19 Cases on the Diamond Princess Cruise Ship and Ethical Considerations: A Report From Japan*, DISASTER MED. PUBLIC HEALTH PREP. (Mar. 24, 2020), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7156812/>.

²⁷ *Supra* note 13.

²⁸ *Vaccine passports: Benefits, challenges, and ethical concerns*, AMA (Apr. 22, 2021), <https://www.ama-assn.org/delivering-care/public-health/vaccine-passports-benefits-challenges-and-ethical-concerns>.

²⁹ *Florida v. Becerra*, No. 8:21-cv-839-SDM-AAS at 122-23 (M.D.Fl. June 18, 2021).

not only states that the CDC did not have expansive regulatory authority under Section 264(a), but such a grant would also likely be unconstitutional without an “intelligible principle to guide CDC’s exercise of authority.”³⁰ This does not disclose; however, the possibility that there is a permissible set of guidelines and principles under which Congress could constitutionally grant the CDC’s authority to promulgate such regulations as included in the challenged approach.

(5) Work to establish incentives to address compliance with CDC guidance.

The CDC could also try to accomplish some of their safety goals by working with Congress to develop a set of incentives under their powers to regulate interstate commerce and to tax and spend in order to incentivize health-promoting behaviors. This could include tax breaks or financial support program for companies whose vessels limit capacity, require masks on board, or provide vaccines to crew members. These programs could also look similar to those conditioning of funds such as those that connect the distribution of highway funds to raising the drinking age.³¹ Congress could consider conditioning some stream of existing funding or privileges on following a set of safety guidelines.

CONCLUSION

As the COVID-19 pandemic continues to pose a significant threat to global health, it is essential that the CDC maintain its steadfast commitment to public health and continue to try mitigating the effects to premature returns to normal operation could have on not only the United States, but the broader global community. It is with this commitment in mind that I urge the CDC to consider the above recommendations.

³⁰ *Id.*

³¹ *South Dakota v. Dole*, 479 U.S. 982 (1986).

Sincerely,

Jaclyn Blickley

Jaclyn Blickley, MPH

JD Candidate

Northeastern University School of Law

E-mail: blickley.j@northeastern.edu

Jeffrey M. Zirger
Information Collection Review Office, Centers for Disease Control and Prevention
1600 Clifton Road NE, MS- D74
Atlanta, Georgia 30329

RE: Phased Approach to the Resumption of Cruise Ship Passenger Operations 2021-09094,
Docket No. CDC-2021-0011

June 30, 2021

I. Executive Summary

The proposed project to collect information regarding the phased approach to the resumption of cruise ship passenger operations is necessary to ensure current and future safety for cruise ship crew members and passengers. However, the proposal does not adequately address the risk of cruise lines operating with unvaccinated crew or passengers or address other vaccination requirements. The proposal also does not effectively estimate accurate burdens for some respondents listed. Current practices by cruise lines are not addressed, and there are gaps in the information collection phases. This comment seeks to support the utility and importance of this project's different phases of information gathering that would support COVID-19 safety aboard cruise ships. However, it also seeks to point out lack of information and vagueness that should be addressed in order to attain maximum benefit from information gathering for cruise lines. Therefore, the proposal should be revised to address these issues before being finalized, by updating the project with current information, increasing the effectiveness and applicability of specific kinds of documentation, reallocating estimated burdens to reflect the labor needed to adequately create safe protocols and provisions for cruise ships reopening to the public, and creating space to analyze the collected information for determinations regarding the safety of resuming normal cruise line operations.

II. Background

After multiple cruise ships in different parts of the world became super-spreader events for COVID-19, the United States implemented the No-Sail Order (NSO) on March 14, 2020.¹ Individuals from multiple national backgrounds, including the United States, were unwittingly exposed due to the close quarter conditions of cruise ships, the transitory nature of crew and passengers during trips, and the lack of awareness and guidance to avoid spreading the disease. Due in part to substantial lobbying efforts by the cruise line industry,² the NSO was lifted at the end of October 2020, coinciding with the release of the CDC's Framework for Conditional Sailing Order. Vaccine rollout had not even begun, but with reduced capacity, strict hygiene and distancing guidelines, and emergency treatment measures in place, cruise lines were eager to revive their multi-billion-dollar industry. However, COVID-19 cases were on the rise throughout the winter of 2020, with new cases only starting to decline around the time vaccines began to be distributed and administered.³ A full lifting of the NSO would have been premature had cruise ships been fully reinstated then.

As of June 29, 2021, 46.4% of the United States population is fully vaccinated, and 54.2% of the population has received at least one dose.⁴ The CDC has relaxed restrictions on fully vaccinated individuals, lifting testing, quarantining, and mask wearing requirements and recommendations.⁵ However, the CDC's statistics do not reflect disparate vaccination rates in

¹ <https://www.cdc.gov/mmwr/volumes/69/wr/mm6912e3.htm>;

<https://www.federalregister.gov/documents/2020/03/24/2020-06166/no-sail-order-and-suspension-of-further-embarkation>

² <https://www.bloomberg.com/news/articles/2020-10-29/cruise-lines-lobby-trump-s-white-house-to-end-no-sail-order>

³ Daily cases spiked between October 2020 and January 2020 https://covid.cdc.gov/covid-data-tracker/#trends_dailytrendscases

⁴ <https://covid.cdc.gov/covid-data-tracker/#vaccinations>

⁵ <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated.html>

multiple states, and there are many communities with low vaccine rollout. The seriousness of contracting COVID-19 cannot be understated, as many people have and will suffer from long-term effects after recovery, such as difficulty breathing, chest pain, and prolonged organ damage, often as part of a collection of symptoms known as “long COVID.”⁶

The CDC maintains its recommendation that any person considering traveling on a cruise ship be fully vaccinated.⁷ However, until cruise lines are able to require vaccination for both staff and passengers, the risk of COVID-19 remains heightened. There have been multiple successful cruises that have taken place during COVID-19 outside of the U.S., but a key issue leading to outbreaks onboard is inadequate planning and risk management by the cruise line.⁸ For example, cruises in Europe found success by focusing on isolation and containment protocols⁹, and cruises in Singapore found success by partnering with risk management companies to strengthen safety measures, as well as by enforcing reduced capacity aboard ships.¹⁰ The outbreak and subsequent spread of COVID-19 that occurred on a Norwegian cruise ship in July 2020 had similar protocols for hygiene and reduced capacity.¹¹ However, the cruise ship, MS Roald Amundsen, became the source of an outbreak due to its failure to test its symptomatic crew members, and its lack of isolation protocols.¹² The contaminated crew from the first trip contributed to a second outbreak on the ship’s subsequent trip.¹³

⁶ <https://www.mayoclinic.org/diseases-conditions/coronavirus/in-depth/coronavirus-long-term-effects/art-20490351>

⁷ <https://wwwnc.cdc.gov/travel/notices/covid-3/coronavirus-cruise-ship>

⁸ <https://www.msn.com/en-us/news/world/super-spreader-cruises-may-give-biden-an-early-covid-19-test/ar-BB1bRTXN>

⁹ <https://www.travelweekly.com/Cruise-Travel/Cruise-lines-must-contain-Covid-Phocuswright-panel>

¹⁰ <https://www.tgasia.com/2020/11/13/first-person-cruising-in-a-covid-era/>

¹¹ <https://www.msn.com/en-us/news/world/super-spreader-cruises-may-give-biden-an-early-covid-19-test/ar-BB1bRTXN>

¹² <https://www.msn.com/en-us/news/world/super-spreader-cruises-may-give-biden-an-early-covid-19-test/ar-BB1bRTXN>

¹³ <https://www.msn.com/en-us/news/world/super-spreader-cruises-may-give-biden-an-early-covid-19-test/ar-BB1bRTXN>

The people at risk are not limited to cruise line staff or passengers. The local populations of islands or destinations that the cruise visits, the local hospital staff and patients when crew members or passengers need COVID-19 treatment, the staff at hospitality facilities that are made available to isolate and quarantine exposed cruise line members, and the family and friends that crew members and passengers return to are additionally at risk. Under this proposal, cruise lines are not incentivized to do more than the bare minimum needed to receive a COVID-19 Conditional Sailing Certificate, so it is imperative that those minimum requirements are thorough enough to require exemplary planning and measures for risk management.

III. Analysis

The following analysis addresses whether the proposed collection of information is necessary for the proper performance of the functions of the agency and if the information has practical utility; and if the agency's estimate of the burden of the proposed collection of information is accurate. The proposal's list of information to be collected is focused singularly on the actions of the cruise ship operator(s) and has minimal requirements of passengers, who will comprise the majority of a cruise line population at sea. Additional reporting requirements should be considered in terms of crew and passenger vaccination status, especially as states continue to challenge vaccine mandates and CDC orders. The proposal does not mention the option that cruise line ships may opt out of the Phase Two simulated voyage requirement if they show documentation that the crew and passengers for a planned cruise are 95% fully vaccinated. This should be included in the project proposal. Additionally, the cruise ship operator's agreement with the U.S. Port Authority and local health authorities is a key area of documentation for COVID-19 risk management and planning. It should be designated higher burden levels to

ensure that cruise lines are dedicated to creating effective plans for the health and safety of their crew and passengers.

A. This proposed collection of information is necessary and has practical utility, but it is missing important areas of information.

For cruise ships to safely carry passengers for multiple day trips, it is necessary to collect information on risk management, reporting, document retention, and voyage preparation. The proposal outlines a variety of information that will need to be collected. One important document is the No-Sail Order Response Plan. While this response plan may have less relevance now than it did in April 2020, it sets an important basis of health and safety to ensure a healthy work environment and promote safe practices that benefit crew members and the local health authorities where crew members disembark.¹⁴ However, there is no similar document required at present for cruise lines who have remained in U.S. waters and/or submitted a NSO Response Plan but have not embarked on commercial trips since last year. When reinstating a cruise ship for duty, a similar plan should be required that ensures the safety of crew members and the areas that the cruise line will necessarily effect. Otherwise, the utility of the NSO Response Plan will be low and the burden not applicable.

The simulated voyage phase is an excellent way to test a cruise ship's risk management and emergency protocol plans. However, it may be difficult to ascertain the details of the simulated voyage in the proposal. According to USA Today, the minimum number of days a simulated voyage must be is two, and with a minimum of 10% capacity.¹⁵ The majority of scheduled

¹⁴ <https://www.federalregister.gov/documents/2020/10/05/2020-22030/no-sail-order-and-suspension-of-further-embarkation-third-modification-and-extension-of-no-sail>

¹⁵ <https://www.usatoday.com/story/travel/cruises/2021/06/12/cruise-ship-return-us-ships-cdc-approved-sailings-test-cruises/7636627002/>

simulated voyages are only two days long.¹⁶ However, ships that have received certification and have approved trips with passengers are to set sail from four to seven days long.¹⁷ A two day simulated voyage, with a capacity percentage that is likely lower than the live voyage, cannot be used to adequately prepare for the health and safety deficiencies that the simulation is meant to discover. This kind of information needs to not only be readily available to the public, but the simulated voyage must be required to match average future voyages of the cruise ship. The After-Action report is an invaluable resource to handle safety problems in a controlled setting and adjust for deficiencies that arose during the simulation. However, it is not possible to have an accurate After-Action report if the simulated voyage is much shorter and with less passengers than future live voyages. The proposal should revisit the minimum voyage length and capacity percentage for simulated voyages.

Additionally, USA Today reports that a cruise ship operator may opt out of the simulated voyage if their crew is verified to be 95% vaccinated, and if they submit a plan to show how they will implement a mandatory vaccination rule for their future passengers.¹⁸ This was not included in the proposal and is an important area to collect information. If multiple cruise ship operators decide to opt for vaccinating at least 95% of the ship's occupants, that is vital data that should be tracked. There is no equivalent After-Action report to problem solve potential deficiencies, and so there may be an increase in burden needed for remote and in person inspections. After all, a 95% vaccinated ship is not full protection against COVID-19, as seen with the recent outbreak on Royal Caribbean Celebrity Ship on June 10, 2021.¹⁹ The ship's crew was fully vaccinated,

¹⁶ <https://www.usatoday.com/story/travel/cruises/2021/06/12/cruise-ship-return-us-ships-cdc-approved-sailings-test-cruises/7636627002/>

¹⁷ <https://www.usatoday.com/story/travel/cruises/2021/06/12/cruise-ship-return-us-ships-cdc-approved-sailings-test-cruises/7636627002/>

¹⁸ <https://www.usatoday.com/story/travel/cruises/2021/06/12/cruise-ship-return-us-ships-cdc-approved-sailings-test-cruises/7636627002/>

¹⁹ <https://www.cnn.com/2021/06/10/two-guests-onboard-a-royal-caribbean-cruise-test-positive-for-covid.html>

and all passengers older than sixteen were required to show proof of vaccination.²⁰ However, COVID-19 can still be spread by those sixteen and younger and can still be contracted by a fully vaccinated individual. While the Celebrity Ship used this small outbreak as a test of its health and safety protocols, it showcased that COVID-19 is not an escapable risk aboard a cruise ship. CDC spokesperson Caitlin Shockey stated that, “It’s not possible for cruising to be a ‘zero-risk activity’.” If this is the case, the proposal should require cruise ship operators to implement stricter requirements, such as frequent COVID testing, incentivized vaccine status disclosure, and rapid response quarantine protocols.

The proposal has little on vaccine requirements, including vaccination of crew members and passengers as part of the phases to resume cruise ship passenger operations. If cruise ships are allowed to opt out of the simulated voyage if they can show a 95% vaccinated crew and passenger list, then it is of great importance for this kind of information to be included in the proposed information collection. Additionally, for the cruise ship operators who do not opt to require 95% vaccination of their ship’s occupants, there is concern over the number of unvaccinated individuals present on a cruise and the capacity for COVID testing aboard. If an outbreak similar to the MS Roald Amundsen occurred (as discussed above), not only would passengers be at risk for contracting and spreading the disease, but crew members would be highly susceptible due to the nature of their jobs.²¹ The testing requirements outlined in the proposal will be essential, as well as reliable risk management protocols. It must be clear that a ship’s crew and passengers will need frequent COVID testing and access to adequate testing

²⁰ <https://www.cnn.com/2021/06/11/royal-caribbean-cruises-to-sail-despite-covid-cases-on-celebrity-ship.html>

²¹ <https://www.msn.com/en-us/news/world/super-spreader-cruises-may-give-biden-an-early-covid-19-test/ar-BB1bRTXN>

facilities, regardless of vaccination status. Additionally, there should be strong language incentivizing vaccination.

The CDC has and will likely face continued challenges from states regarding mandatory vaccination aboard cruise ships. This will impact cruise ship operators' decisions to mandate vaccination to their crew and require proof of vaccination from their passengers. Already, Florida and Texas have banned businesses from asking for proof of vaccination from customers²², and Florida has successfully received a preliminary injunction from a federal judge that allows the state to ignore the CDC's conditional sailing order.²³ While cruise lines still have the option to conduct simulated voyages prior to resuming commercial trips, they will likely choose not to when departing from Florida. If cruise ships cannot ask passengers for proof of vaccination, the need for COVID testing aboard cruise ships will increase, as will the burden to monitor and maintain safe and hygienic conditions on board and ensure adequate space for quarantine.

B. This proposed collection of information does not accurately estimate burdens.

The agreements with a Health Care Organization, Port of Entry, and Housing Facility are vital. However, the burden allocated to these agreements does not seem to be enough. Each agreement is assigned 130 respondents, with a total of 1,300 hours in burden. That accounts for approximately four hours of work per respondent. The allocation of burden that falls among the 130 respondents is unclear. However, it will likely require a substantial amount of time to receive and allocate designated spaces for a cruise line's passengers to enter a town, receive medical care, and to quarantine. It will require time to negotiate with each entity, allocate

²² <https://www.msn.com/en-us/news/us/royal-caribbean-nixes-vaccine-requirement-in-texas-and-florida/ar-AAKPVsR>

²³ <https://www.nbcmiami.com/news/local/judge-rules-in-floridas-favor-in-lawsuit-over-cdcs-no-sail-order-for-cruises/2476238/> ; <https://www.leagle.com/decision/infcco20210621722>

resources to pay each entity (especially a health care organization and housing facility), and to potentially organize these agreements for each town or locality that a cruise line may interact with and may need to use as a resource in case of an outbreak. The proposal should address the open-ended manner of these agreements, as it may affect the level of burden estimated if cruise ship operators need to negotiate to keep facilities ready or vacant in anticipation of potential future outbreaks.

The proposal does not mention the alternative option to the simulated voyage, and so there is no estimated burden regarding the verification of the cruise ship crew operators' vaccination status and of the plan to ensure vaccination of at least 95% of future passengers. The proposal also does not estimate burden for vaccine reporting in general. However, as proof of vaccines bans are passed in Florida and Texas, and the result of *Florida v. Becerra* essentially eliminates vaccine tracking on cruise ships in Florida, the proposal may need to create specific and varied guidelines or recommendations for Florida and Texas, as well as for states that do allow businesses to ask customers for proof of vaccination. This could include stricter requirements for on board testing facilities and testing mandates, requirements to partner with risk management agencies, or firm reduced capacity requirements.

C. Use collected information to create a report to track safety outcomes of current and future cruise ship operations to determine whether it is appropriate to resume normal cruise line operations.

As multiple variants of COVID-19 are being discovered and studied, the concern over resuming normal activities in public and commercial settings is valid. Isolated and close-spaced environments like cruise ships will be susceptible to outbreaks. The United States has barely

vaccinated half of its population²⁴, and there are a significant number of communities who remain unvaccinated. Vaccines are slowly becoming available to young adults, and young children cannot yet be inoculated. Even with the strictest of testing and hygiene protocols, there will always be the risk of an outbreak present during a cruise. As information is collected regarding the safety outcomes of cruise ships, it should be used to consider the overall risk of continuing normal cruise ship operations on a rolling basis. A report should be generated from this information that will advise on the sensibility and risk of current cruise ship operations.

IV. Recommended Actions

The following are recommended actions based upon the above analysis:

- A. *Create an NSO response plan equivalent to cruise line ships that have not set sail since the NSO was implemented and are planning to reenter U.S. and international waters.*

The NSO response plan was meant to create accountability to the cruise line and ship to ensure that the crew members could work and disembark in a manner that protected their health and safety. An equivalent plan should be required, even before a cruise ship begins the three phases of resuming passenger operations. This plan should detail not only safe disembarking guidelines but embarking guidelines that align with the requests to embark essential and non-essential crew. Additionally, there should be a request to embark passengers with intended capacity levels indicated.

- B. *Include in Phase 2B the option to opt out of the simulated voyage and submit verification of crew vaccination status.*

²⁴ <https://covid.cdc.gov/covid-data-tracker/#vaccinations>

The proposal must include information about the vaccination alternative to the simulated voyage. This applies to states that have not banned vaccination status disclosure. Multiple cruise lines are likely to opt out of the simulated voyage, as it may allow them to begin passenger operations sooner than it would to conduct a simulated voyage and would likely be less of an expense. It would also be a safer alternative to ensure that crew members are fully vaccinated and protected in the event they need to service symptomatic passengers.

C. Include vaccination reporting in the project proposal and address states that ban proof of vaccine requirements.

While testing requirements and reporting will remain necessary and vital for all cruise line ships, more people will be partially or fully vaccinated over the coming months. Some people are not willing or able to take the vaccine for medical, religious, or personal reasons. It will be vital to find a way to keep track of vaccination status for crew members and passengers, as this will affect cruise ship activities, social distancing requirements, safety protocols, and testing requirements.

For the states that ban cruise lines from requiring passengers to disclose vaccine status, it would be beneficial to create guidelines that strongly recommend passengers to be fully vaccinated before embarking. If it is possible to allow passengers to voluntarily disclose their vaccination status²⁵ and offer incentives to do so, that may help soften the blow of Texas and Florida's ban on requiring vaccination status disclosure. If not, then all passengers will need to be treated as if they are unvaccinated, and the burden will increase for cruise ships to ensure they have adequate facilities for frequent and accurate testing.

²⁵ <https://www.msn.com/en-us/travel/news/first-us-cruise-in-15-months-stopped-by-florida-law-from-asking-patrons-covid-vaccine-status/ar-AAWrW3J>

D. Change estimated burdens based upon the additions above, and the work intensive nature of agreements with Health Care Facilities, Housing Facilities, and Ports of Entry.

The estimated burdens should be revisited to ensure that the correct number of respondents are attributed to a specific document, and that the potential amount of organizational labor entailed in submitted these documents is verified and accurate. Though preventing excessive burden is important, it may be necessary in this case to reconsider the amount of labor it will take to ensure the health and safety of all involved. The efficacy of the NSO response plan should be reconsidered, as a majority of ships in U.S. waters have submitted this plan, and an extended version of the NSO plan should be considered for implementation as part of health and safety protocol when cruise ships are re-entering U.S. and international waters. The various agreements that cruise ship operators need to make with local hospitals, hospitality facilities, and ports of entries should be revisited and the average of stops cruise ships make be compared to the hours attributed for each agreement. The number of respondents should also be addressed, or their number clarified, to prevent excessive attribution.

E. Collect information from cruise ship trips to create a report that would advise on the current safety of cruise line operations.

Cruise ships have already set sail and more trips are scheduled to embark. The proposal should include a provision that outlines the kinds of information needed from completed live voyages that would outline the safety outcomes of each trip. This could include the number of COVID tests performed, the number of positive tests, the number of passengers who were symptomatic regardless of test results, and the number of passengers who needed to be quarantined. Additionally, information should be collected on the amount of financial and

administrative resources needed to upkeep safety, hygiene, and risk management protocols. The information gathered after completed trips should be aggregated into a report. Following these sources of post-trip information will be essential in determining the ongoing safety and sensibility of continuing cruise line operations as normal.

V. Conclusion

The project proposal as it stands will likely be efficacious and contribute greatly to ensuring safety when resuming passenger operations on cruise ships. However, it still lacks current information and practices that will be vital to the continued safety of cruise ship operations. There is room to improve the proposal for efficiency and clarity in terms of key terms and allocation of labor. Particularly, the proposal should include requirements for reporting vaccination statistics, and clarify modes of action that support vaccinating crew members and passengers or address stringent and effective alternatives for states that ban vaccine requirements. With the additional changes proposed above, the kinds of information collected will be more useful when analyzing how well the phases of the Framework for Conditional Sailing Order protect cruise lines from COVID-19 outbreaks, and in deciding if the cruise line industry is ready to resume normal operations. Sincerely,

Maya Leggat
J.D. Candidate
Northeastern University School of Law
E-mail: leggat.m@northeastern.edu

Jeffrey M. Zirger
Information Collection Review Office, Center for Disease Control and Prevention
1600 Clifton Road NE, MS-D74
Atlanta, Georgia 30329

RE: Phased Approach to the Resumption of Cruise Ship Passengers Operations 2021-09094
Docket No. CDC-2021-0011

June 30, 2021

Executive Summary

The CDC has issued a Conditional Sailing Order (CSO) with guidance to cruise lines on what they must do before restarting cruises from U.S. ports. One option for the cruise lines is to “verify” that 95 percent of its passengers and crew are fully vaccinated prior to sailing. While the CDC is requiring that cruise lines obtain this information from passengers who wish to go on these “vaccinated” cruises, the CDC is not requiring submission of this data. Although Florida has a law preventing businesses from requiring customers to provide vaccine information and has won a preliminary injunction against the CSO, it appears that cruise lines will still be asking passengers to volunteer their vaccine status prior to cruise ship travel. Vaccines are the primary method of controlling and limiting the impact of COVID-19. Data on the efficacy of these vaccines is critical to determine their usefulness among various populations and against developing variants, as well as how the vaccines perform over time. In the case of a cruise ship outbreak, the data on which passengers or crew tested positive, which COVID-19 variant, and which vaccine they received, as well as when they received it, could all be very important in determining who is at highest risk for contracting the disease. Obtaining vaccine data from passengers and crew who voluntarily provide their information as a condition of participating in a specific cruise ship voyage would be one of the most valuable aspects of the CDC’s data collection program.

Background

Beginning in early 2020, cruise ships have been the source of heightened rates of transmission of COVID-19 among passengers and crew members. The *Diamond Princess* cruise ship, which was forced to quarantine in Yokohama, Japan after a symptomatic passenger departed the ship in February 2020, was the largest outbreak of COVID-19 outside of mainland China.¹ Research showed that the reproduction number of COVID-19 on the *Diamond Princess* was four times higher than in Wuhan, China before the cruise ship implemented countermeasures to slow transmission.² On March 4, 2020, passengers aboard the *Grand Princess* that was returning to San Francisco from Hawaii was ordered to quarantine on-board in their own rooms by the CDC after a passenger who died tested positive for COVID-19.³ Passengers quarantined on-board for five days before disembarking and were subsequently quarantined on land.⁴ Ultimately, there were at least 122 confirmed COVID-19 cases, including six deaths.⁵ These two early examples demonstrated the heightened risk that cruise ships pose for the transmission of COVID-19 and the difficulties in planning for the medical treatment and return of passengers and crew after a positive case was detected.

As COVID-19 cases rose in the U.S. in March 2020, the CDC issued increasingly strict warnings against cruise ship travel. On March 14, 2020, the CDC issued a No Sail Order that

¹ J. Rocklov et al., *COVID-19 outbreak on the Diamond Princess cruise ship: estimating the epidemic potential and effectiveness of public health countermeasures*, 27(3) J. of Travel Med. 1, 2 (2020).
<https://academic.oup.com/jtm/article/27/3/taaa030/5766334>

² Id.

³ Leah F. Moriarty et al., *Public Health Responses to COVID-19 Outbreaks on Cruise Ships – Worldwide, February-March 2020*, 69 Morbidity and Mortality Weekly Report 347-352(2020).
<https://www.cdc.gov/mmwr/volumes/69/wr/mm6912e3.htm>

⁴ Id.

⁵ Erin McCormick, *Grand Princess passengers grapple with Covid nightmare one year after ill-fated cruise*, The Guardian (Mar. 10, 2021) <https://www.theguardian.com/us-news/2021/mar/10/grand-princess-cruise-ship-coronavirus-one-year-later>

ordered any cruise ship with a capacity of over 250 persons to suspend operations.⁶ This order was extended on April 9, 2020 and July 16, 2020 and expired on October 31, 2020.⁷ In its place, the CDC issued a Framework for Conditional Sailing Order (CSO) which became effective on November 4, 2020.⁸ Despite repeated calls by the cruise industry demanding that the CDC release further guidance detailing the steps needed to restart cruise line operations, the CDC repeatedly refrained, saying as late as March 24, 2021, almost five months after they issued the CSO, that, “details for the next phase of the CSO are currently under interagency review.”⁹

Finally, after significant pressure from the cruise ship industry and others, in April 2021, the CDC began issuing the long-awaited further instructions which detailed the various steps that cruise ships need to follow in order to begin resuming regular activities (*e.g.* conducting trial voyages, establishing testing and quarantine protocols, and coordinating with local, state, and federal public health agencies).^{10,11} The cruise ship industry responded that these requirements were overly burdensome and inequitable especially given how the CDC was treating travel generally.¹² For example, the CDC announced on April 2, 2021 that fully vaccinated people can travel at low risk to themselves and that they could travel within the United States and

⁶ No Sail Order and Suspension of Further Embarkation, 85 Fed. Reg. 16628 (Mar. 14, 2020).

⁷ Center for Disease Control and Prevention, *Quarantine and Isolation: COVID-19 Orders for Cruise Ships* (May 5, 2021), <https://www.cdc.gov/quarantine/cruise/covid19-cruiseships.html>

⁸ *Id.*

⁹ Nicholas Reimann, *CDC Rejects Cruise Industry Push to Resume Sailing, Sending Stocks Tumbling*, Forbes (Mar. 24, 2021), <https://www.forbes.com/sites/nicholasreimann/2021/03/24/cdc-rejects-cruise-industry-push-to-resume-sailing-sending-stocks-tumbling/?sh=793e87dc4eb1>

¹⁰ Center for Disease Control and Prevention, *CDC Issues Next Phase of the Conditional Sail Order for Cruise Ship Operators* (April 2, 2021), <https://www.cdc.gov/media/releases/2021/s0402-conditional-sail-orders.html>

¹¹ Center for Disease Control and Prevention, *CDC Issues Phases 2B and 3 of the Conditional Sailing Order* (May 5, 2021), <https://www.cdc.gov/media/releases/2021/s0505-conditional-sailing-order.html>

¹² Cruise Lines International Association, *Cruise Lines International Association (CLIA) Issues Statement reiterating Its Call for the Lifting of the CDC's Conditional Sailing Order (USA)* (April 5, 2021) <https://cruising.org/en/news-and-research/press-room/2021/april/clia-issues-statement-reiterating-its-call-for-the-lifting-of-the-cdcs-conditional-sailing-order>

internationally without COVID-19 testing or post-travel self-quarantine.¹³ On April 28, 2021, the CDC recognized the significance of vaccines on the safety of cruising and stated, in a letter to industry leaders, that it would waive the simulated test sailing requirement in the CSO guidelines if the cruise ship had least 95 percent of passengers and crew fully vaccinated.^{14,15} This modification effectively created a second path to getting the CDC's authorization for cruises. The state of Florida objected to the protocols set forth in the CSO, and on April 8, 2021, Florida sued the CDC seeking a preliminary injunction against the CSO, arguing that the CSO exceeded the statutory and regulatory authority delegated to the CDC.¹⁶

On April 30, 2021, the CDC published notice CDC-2021-0011, which sought public comments on the Proposed Data Collection for the Phased in Approach to Resumption of Passenger Operations.¹⁷ Based on the Estimated Annualized Burden Hours in CDC-2021-0011, the time burden on the cruise lines to prepare the paperwork and collect the data does not seem unreasonable.¹⁸ Each passenger on the simulated voyages would have to spend sixty to ninety minutes filling out an Informed Consent and Medical Certification form.¹⁹ None of the other tasks listed seem to impose an unreasonable burden on the cruise line in terms of the number of respondents and the total number of hours required for collecting the data and preparing the paperwork. However, there is one glaring omission in the data collection proposed by the CDC: vaccination information for passengers and crew.

¹³ Center for Disease Control and Prevention, *CDC Updated Guidance on Travel for Fully Vaccinated People* (April 2, 2021), <https://www.cdc.gov/media/releases/2021/p0402-travel-guidance-vaccinated-people.html>

¹⁴ Center for Disease Control and Prevention, *Quarantine and Isolation: Technical Instructions for Simulated Voyages* (May 14, 2021), <https://www.cdc.gov/quarantine/cruise/ti-simulated-voyages-cso.html>

¹⁵ Hannah Sampson, *CDC outlines path for U.S. cruising to resume by mid-July*, The Washington Post (April 29, 2021) (this article states that the CDC would require 98 percent of crew to be vaccinated) <https://www.washingtonpost.com/travel/2021/04/29/cdc-cruise-vaccinated-passengers/>

¹⁶ *Florida v. Becerra*, No. 8:21-cv-839-SDM-AAS, 2021 U.S. Dist. LEXIS 114297 at *31 (M.D. Fla. June 18, 2021).

¹⁷ Phased Approach to the Resumption of Passenger Operations, 86 Fed. Reg. 22964 (proposed Apr. 30, 2021).

¹⁸ *Id.*

¹⁹ *Id.*

Analysis

The CDC’s protocols—as set forth in the CSO and subsequent guidance—impose a significant burden on the cruise lines and did not initially appear to take into account the impact of vaccinations on the safety of cruise ship travel. Ultimately, the CDC agreed to waive the simulated test sailings if 95 percent of the crew and passengers are fully vaccinated prior to sailing.²⁰ The result of this change is that several cruise lines have received permission to conduct “vaccinated” cruises out of U.S. ports and other cruise lines have received relatively fast approval for their simulated cruises, which would put them on track for having regular cruises with paying customers.²¹

Unfortunately, there is controversy over whether cruise lines should be allowed to require proof of vaccination in order to certify that they have met the CDC requirement of vaccination rates of 95 percent for the crew and passengers. Florida has passed a law prohibiting businesses from requiring customers to provide their vaccine status.²² On June 18, 2021, a District Court in Florida granted a preliminary injunction against the CSO enjoining the CDC from enforcing the CSO against any cruise ship arriving in or departing from Florida.²³ The Court stayed the effective date of the injunction until July 18, 2021 and allowed the CDC to propose a narrower injunction that would allow cruise ships to sail and remain within the CDC’s authority as interpreted by the Court’s Order.²⁴ As of the date of this submission, the CDC has not indicated

²⁰ Center for Disease Control and Prevention, *Quarantine and Isolation: Technical Instructions for Simulated Voyages* (May 14, 2021), <https://www.cdc.gov/quarantine/cruise/ti-simulated-voyages-cso.html>

²¹ Johanna Jainchill, *CDC approves 10 cruise ships for test and revenue sailings*, Travel Weekly (June 3, 2021) <https://www.travelweekly.com/Cruise-Travel/CDC-approved-more-cruise-ships-for-sailings>

²² Fla. Stat. §381.00316 (2021).

²³ *Florida v. Becerra*, No. 8:21-cv-839-SDM-AAS, 2021 U.S. Dist. LEXIS 114297 at *148 (M.D. Fla. June 18, 2021).

²⁴ *Id.*

whether it will propose a narrower injunction. If it does not, as of July 18, 2021, the CSO will be treated a non-binding recommendation or guideline.²⁵

Regardless of whether the CDC opts to propose narrower guidelines or if the CSO becomes a recommendation instead of a requirement for the cruise lines (at least with respect to cruises from Florida), it appears that most cruise lines will still be seeking vaccination information from passengers and crew. For its Florida departures, Royal Caribbean will ask, but not require, that fully vaccinated guests provide documentation of vaccination before boarding in order to accommodate Florida's law preventing businesses from requiring that its customers provide vaccine information.²⁶ A passenger who does not provide documentation of vaccination will be considered unvaccinated and must undergo COVID-19 testing and adhere to all additional health protocols.²⁷ Celebrity Cruises is also requiring vaccinations, except for cruises departing from Florida, and passengers who do not provide proof of vaccination will be subject to additional costs and restrictions.²⁸ Norwegian Cruise lines and Carnival Cruise lines are also requiring vaccines and have not yet indicated their position on Florida cruises.^{29, 30} Thus, it seems clear that most cruise lines will be obtaining vaccine information on a voluntary basis from a significant number of passengers. Indeed, a recent survey of more than 5,000 readers of a popular cruise review site found that 80 percent of respondents preferred to sail on a ship with a

²⁵ Id.

²⁶ Royal Caribbean International, *Frequently Asked Questions: Do I need a COVID-19 vaccine to cruise? What documents count as proof of vaccination? How far in advance do I need to get my vaccine?* <https://www.royalcaribbean.com/faq/questions/do-i-need-a-covid-vaccine-to-cruise-what-counts-as-proof>

²⁷ Id.

²⁸ Wells Dusenbury, *Celebrity Cruises changes vaccination policy for Florida*, South Florida Sun Sentinel (June 24, 2021) <https://www.sun-sentinel.com/business/fl-bz-cruises-vaccine-requirement-20210624-e2e3fjvq2vh3deh4jnsi2gxwli-story.html>

²⁹ Norwegian Cruise Line, *Sail Safe: Safety for Guests & Crew* (last viewed June 28, 2021) <https://www.ncl.com/sail-safe#t4m1>

³⁰ The Associated Press, *Norwegian Cruise plans Fla. Sailings, stands by vaccine requirement*, The Atlanta Journal-Constitution (June 8, 2021) <https://www.ajc.com/news/nation-world/norwegian-cruise-plans-fla-sailings-stands-by-vaccine-requirement/MLIFSPT62FDJNEKDNAKQIG4HY/>

vaccine requirement, and only thirteen percent preferred one without such a mandate, suggesting that many passengers will likely volunteer to provide their vaccine information to the cruise lines.³¹

This vaccine data on passengers and crew is relevant to the CDC's effort to collect important useful data from the cruise lines. According to CDC 2021-0011, Enhanced Data Collection is the second most significant burden in complying with the CSO, in terms of anticipated hours necessary to complete.³² Presumably, Enhanced Data Collection refers to the requirement that cruise ships prepare daily reports on the frequency of COVID-19 cases and illnesses.³³ Preparing these reports is anticipated to take fifteen minutes per day for 130 crew members.³⁴ This requirement seems reasonable and is likely to be helpful in terms of understanding how successful the various protocols are in minimizing the incidence of COVID-19 on cruise ships. However, CDC 2021-0011 does not require collection and reporting of the vaccine status of the crew and passengers.

Vaccination is the most important means of controlling and minimizing the impact of COVID-19.³⁵ Determination of the efficacy of the various vaccines over time, in different populations, and against developing variants is a critically important area of study.³⁶ Although the CDC recognizes that vaccines can dramatically alter the safety of cruise ship travel, the CDC

³¹ Arian Campo-Flores, *Cruise Lines Wrestle With Florida Ban on Vaccine Passports*, The Wall Street Journal (June 13, 2021) <https://www.wsj.com/articles/cruise-lines-wrestle-with-florida-ban-on-vaccine-passports-11623587416>

³² Phased Approach to the Resumption of Passenger Operations, 86 Fed. Reg. 22964 (proposed Apr. 30, 2021).

³³ Center for Disease Control and Prevention, *CDC Issues Next Phase of the Conditional Sail Order for Cruise Ship Operators* (April 2, 2021), <https://www.cdc.gov/media/releases/2021/s0402-conditional-sail-orders.html>

³⁴ Phased Approach to the Resumption of Passenger Operations, 86 Fed. Reg. 22964 (proposed Apr. 30, 2021).

³⁵ Vivek Shinde et al., *Efficacy of NVX-CoV2373 Covid-19 Vaccine Against the B.1.351 Variant*, 384 New England J. of Med. 1899, 1899 (2021) (stating that vaccination remains the “cornerstone” of COVID-19 control strategies). <https://www.nejm.org/doi/full/10.1056/NEJMoa2103055>

³⁶ Shabir A. Madhi et al., *Efficacy of the ChAdOx1 nCoV-19 Covid-19 Vaccine against the B.1351 Variant*, 384 New England J. of Med. 1885, 1885 (2021). <https://www.nejm.org/doi/full/10.1056/nejmoa2102214>

will not be collecting data on which passengers are vaccinated and with which vaccine.³⁷ In the event of a shipboard outbreak, the data on which passengers and crew tested positive for which variant and which vaccine they received could be vitally important and would enable the ship to isolate those who may be less protected. Not only will this data improve safety on the ship, but it is essential to our general understanding of the efficacy of different vaccines.

Actions Recommended

The challenges of detecting and controlling a potential lethal outbreak of COVID-19 justify the collection and analysis of data regarding transmissibility, methods of combatting an evolving viral threat, and the efficacy of the various vaccinations currently in use. The CDC has recognized that vaccines can significantly improve the safety of cruise ship travel and that a “vaccinated” cruise poses a much lower safety risk than a cruise with unvaccinated crew and passengers.³⁸ Because it appears that a large number of cruise lines will still be requiring proof of vaccination, the CDC should alter its data collection plan to include information about the vaccine status of those who voluntarily provide their vaccine data to the cruise company. The information gathered about which vaccines were administered and when could provide essential information about the effectiveness of the various vaccines against any variants that may be contracted aboard the ship and knowing when people were vaccinated could provide information about the effectiveness of the various vaccines over time.³⁹ The CDC would not be requiring anyone to get vaccinated and would only be collecting the information that passengers

³⁷ Center for Disease Control and Prevention, *COVID-19: Myths & Facts* (June 3, 2021) <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/facts.html>

³⁸ Center for Disease Control and Prevention, *Quarantine and Isolation: Technical Instructions for Simulated Voyages* (May 14, 2021), <https://www.cdc.gov/quarantine/cruise/ti-simulated-voyages-cso.html>

³⁹ Shabir A. Madhi et al., *Efficacy of the ChAdOx1 nCoV-19 Covid-19 Vaccine against the B.1351 Variant*, 384 *New England J. of Med.* 1885, 1885 (2021). <https://www.nejm.org/doi/full/10.1056/nejmoa2102214>

voluntarily chose to provide in order to be permitted to go on a “vaccinated” cruise. Given that only those who provide this information voluntarily to the cruise line would be affected, this policy would not unduly impinge on the privacy rights of the public at large.

To accomplish this data collection, the CDC would need to make an exception to its current policy that it does not monitor or maintain records of vaccine status for those who voluntarily choose to provide their vaccine information to the cruise line in order to go on a specific cruise.⁴⁰ The CDC would have to provide assurances that the information collected would only be used for legitimate public health purposes and would be treated confidentially. If necessary, the CDC could assure the public that the vaccine information would only be used if there was an outbreak on their ship. The actual time involved in collecting the data and preparing the paperwork for the CDC would be relatively minimal since the cruise lines will have already received this information from passengers and crew. Given the importance of collecting all available data about the efficacy of the vaccines and the spread of COVID-19, the CDC should ensure that it receives passenger and crew vaccine information as part of its data collection.

Sincerely,

Madeleine Minke
J.D. Candidate
Northeastern University School of Law
Email: minke.m@northeastern.edu

⁴⁰ Center for Disease Control and Prevention, *COVID-19: Myths & Facts* (June 3, 2021) <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/facts.html>

Jeffrey M. Zirger
Information Collection Review Office, Centers for Disease Control and Prevention
1600 Clifton Road NE, MS- D74
Atlanta, Georgia 30329

RE: Phased Approach to the Resumption of Cruise Ship Passenger Operations 2021-09094,
Docket No. CDC-2021-0011

June 30, 2021

Executive Summary

The Proposed Rule, “Phased Approach to the Resumption of Cruise Ship Passenger Operations 2021-09094.” (Docket No. CDC-2021-0011) does not extend far enough to protect the health and safety of cruise ship crew members by failing to address variable vaccination coverage rates. While the CDC does provide ample protection by way of on-board laboratory testing for all crew members on at a minimum of a weekly basis, vaccination of both staff and passengers would be the most effective risk reduction method. Currently, the Proposed Rule recommends that cruise ship lines merely encourage their crew members to receive a vaccine when eligible. This fails to address the various geographic locales of cruise ship crew members and their access to FDA-approved vaccines. The interests of cruise ship lines, passengers, and cruise ship members would best be served by stronger provisions for the vaccination of cruise ship crew members and passengers.

Background

A few days after the CDC’s No Sail Order expired, the CDC released a Conditional Sailing Order on November 4, 2020. The Order outlines a phased-in approach to resuming cruise ship passenger operations in accordance with CDC guidelines. The CDC requires that cruise ships undergo three phases of capacity building and training before being eligible to apply for a COVID-19 Conditional Sailing Certificate, under which cruise ships will be allowed to

commence restricted passenger operations. Phase 1 requires cruise ships to develop mass testing and laboratory capacity to be able to test both crew and passengers at time periods recommended by the CDC. Phase 2 allows cruise ships to conduct simulated voyages with volunteers as passengers. During these simulated voyages, cruise ships are to submit an action report noting the results of tests conducted during the simulation and any deficiencies that arose. During the final phase, cruise ships may apply for a Conditional Sailing Certificate and, upon approval, commence restricted passenger voyages limited to seven days.

Cruise ships who have received approval to commence passenger operations must sail within the limitations outlined by the Conditional Sailing Order. In terms of laboratory tests, cruise ships must test every crew member for COVID-19 on a weekly basis, or as otherwise required by the CDC. Furthermore, all passengers and crew must be tested on the day of embarkation and on the day of disembarkation. All confirmed COVID-19 infections or exposures must be immediately notified and isolated. Besides receiving approval from the CDC, cruise ships must also receive approval of the US ports, as well as the local health authorities at those locations. Such approval with ports and local authorities includes three components: 1) a medical care agreement, 2) a housing agreement, and 3) a port agreement. The medical care agreement ensures that onshore hospitals are available to admit passengers and crew with COVID-19 and in need of care. Similarly, a housing agreement establishes a designated on-shore facility for the quarantine of passengers and crew with COVID-19, or those that have been in close contact. Lastly, the port agreement between the cruise ship and the port authority ensures that a single jurisdiction will not be overburdened by a possible COVID-19 outbreak.

Since January 2020 COVID-19 outbreak on the Diamond Princess and the February 2020 outbreak on the Grand Princess, public health scholars and infectious disease specialists have

paid special attention to the spread of COVID-19 aboard cruise ships. The outbreaks aboard both the Diamond Princess and the Grand Princess provide many invaluable lessons that should be considered in any proposed rule for the resumption of cruise ship passenger operations.

Analysis

In light of on-going infectious disease and public health studies, the Proposed Rule affords inadequate protections to cruise ship crew members. The health and well-being of crew members is paramount, and also dependent on the vaccination status of passengers. COVID-19 outbreaks on cruise ships will have a significant impact on a large portion of crew members' ability to work and maintain their livelihood, possibly even beyond the incubation period. Beyond placing the health of the crew members at risk, inadequate mandates requiring the vaccination of both crew members and passengers can place multiple, subsequent voyages at risk. Effectively protecting crew members also protects the interests of cruise lines – ensuring adequate staffing, limiting outbreaks between consecutive voyages, and protecting passengers. These reasons should compel cruise lines to mandate vaccination of their staff and to mandate vaccination of all passengers.

Studies of the COVID-19 outbreaks on the Diamond Princess and the Grand Princess also support the critical impact that crew member safety has on the spread of infectious disease aboard cruise ships. Subsequent studies of the Diamond Princess outbreak revealed that crew members continued to work during their quarantine and could not be isolated, despite close contact with the index patient,² meaning that potentially infected crew members continued to interact with other crew members and passengers. Based on these findings, scholars have

² Yasuharu Tokuda, et al., *COVID-19 outbreak on the Diamond Princess Cruise Ship in February 2020*, JOURNAL OF GENERAL AND FAMILY MEDICINE, July 29, 2020, <https://doi.org/10.1002/jgf2.326>.

recommended having a reserve staff or other crew relief available for future voyages.³ Ample staff availability would allow cruise lines to maintain the quality of the voyage for their passengers, while continuing to prioritize the health of their crew members. Such an intervention is not addressed by the current Proposed Rule, but could be implemented to serve the mutual interests of both passengers and crew members.

Other scholars have raised concerns about the risk of spreading an outbreak across multiple voyages via crew members who remain on board from one voyage to another.⁴ Studies of the outbreak on the Grand Princess have revealed that crew members who were likely infected on voyage A then transmitted COVID-19 to passengers on voyage B (a subsequent cruise).⁵ While the Proposed Rule is not explicit in barring the transfer of crew members across different ships or in requiring an interim between subsequent voyages, the recommendation that cruise ships conduct laboratory testing of all crew on both the day of disembarkation and day of embarkation may help in mitigate the transmission of infection across voyages. Vaccination of all crew members and passengers would likely prove to be the most effective intervention to reduce the risk of outbreaks among crew members.

The Proposed Rule does not currently contain provisions requiring that cruise ships vaccinate its crew members. The CDC does recommend that cruise ships explore vaccinating their crew and has amended its framework to permit cruise ships to skip Phase 2 if the cruise line attests that 98 percent of its crew and 95 percent of its passengers are fully vaccinated. However, the CDC also recommends that cruise ships encourage their crew to receive the COVID vaccine when eligible and available. These recommendations overlook the fact that a majority of cruise

³ Id.

⁴ Leah F. Moriarty, et al., *Public Health Responses to COVID-19 Outbreaks on Cruise Ships – Worldwide, February-March 2020*, CDC, March 23, 2020. <https://www.cdc.gov/mmwr/volumes/69/wr/mm6912e3.htm>

⁵ Id.

ship crew members are foreign workers.⁶ Public health scholars have raised concerns about the negative impact that a variety of vaccines will likely have on risk reduction attributed to vaccination.⁷ Since many crew members are foreign workers, many may not have had access to FDA-approved vaccines, and are either unvaccinated or have received non-FDA-authorized vaccines in their home countries. With an average crew size of several hundred⁸, such a number falling in either of these categories is likely significant. Scholars have also emphasized that the congregation of crew members and passengers from multiple countries with “varying burdens of COVID-19, variable vaccination coverage rates with a variety of vaccines, and SARS-CoV-2 variants of concern” will likely impact the effectiveness of vaccination on cruises.⁹

Actions Recommended

Require that cruise lines facilitate the vaccination of all foreign-crew members with an FDA-authorized vaccine.

This intervention would effectively address the variable vaccination coverage rates that would likely arise from allowing crew members without vaccines, or with non-FDA-authorized vaccines, aboard to interact with passengers and other crew members. This would be a one-time cost to cruise ship lines and could utilize onshore vaccination sites at major U.S. ports. Utilizing onshore vaccination sites could become part of the health agreements suggested by the CDC under the Proposed Rule. A similar strategy is already underway at the Port of San Diego, where on May 19, 2021, hundreds of crew members of Holland America Line’s Koningsdam received

⁶ John Frittelli, *COVID-19 and the Cruise Ship Industry*, CONGRESSIONAL RESEARCH SERVICE, March 16, 2020, <https://crsreports.congress.gov/product/pdf/IN/IN11245/2>.

⁷ Sarah Anne J Guagliardo, et al., *Cruise ship travel in the era of COVID-19: A summary of outbreaks and a model of public health interventions*, CLINICAL INFECTIOUS DISEASES, May 12, 2021, <https://doi-org.ezproxy.neu.edu/10.1093/cid/ciab433>.

⁸ Supra note 6.

⁹ Supra note 7.

their first dose of the Pfizer vaccine.¹⁰ This would require further negotiations between cruise ship lines and ports before applying for a Conditional Sailing Certificate. Alternatively, port authorities could explore converting major US ports into mass vaccination sites for crew members of various cruise lines. This conversion could be a joint effort between the CDC and the major cruise lines that dock in US ports. The utilization of US ports to vaccinate crew members and un-vaccinated passengers may be effective because of US ports' interest in resuming passenger cruise operations in U.S. waters. US ports will likely be willing to invest space, staffing and cost into developing a vaccination site, as demonstrated by the fact that vaccination sites are already operational at ports in Miami, Port Canaveral and Galveston.¹¹

Addressing the wide timeframe between receiving the first vaccination dose and full vaccination (a maximum of six weeks) will require cruise lines to weigh the risks of running simulation voyages with partially-vaccinated crew members, or utilizing on-shore housing to quarantine crew members during the interim period. Royal Caribbean has elected to pause all operations until crew members are fully vaccinated, after which they will begin training their crew on COVID-related protocols and practices.¹² This strategy is likely to be the most effective for resuming passenger operations as quickly and safely as possible. The CDC should amend the Proposed Rule to reflect the vaccination practices that many cruise lines have begun to adopt. In summary, this would involve expanding port agreements and health agreements under the Order to include provisions for vaccination facilities that are capable of serving the mass vaccination of cruise crew members.

¹⁰ Karla Rendon-Alvarez and Audra Stafford, *Cruise Ship Members Getting COVID-19 Vaccine at Port of San Diego*, NBC SAN DIEGO, May 19, 2021, <https://www.nbcsandiego.com/news/local/cruise-ship-crew-members-getting-covid-19-vaccine-at-port-of-san-diego/2608910/>

¹¹ Cruise Lines Vaccinate Thousands of Crew at US Ports, Hoping for July Restart, Airguide Online, May 9, 2021, https://link.gale.com/apps/doc/A661376565/ITOF?u=mclin_b_northeast&sid=bookmark-ITOF&xid=09127d09

¹² *Id.*

Strongly encourage cruise lines to mandate the vaccination of all passengers with an FDA-authorized vaccine.

A vaccination mandate for all passengers would also effectively address the inadequate protections currently afforded cruise crew members under the Proposed Rule. Cruise staff must interact with a large number of passengers, who have traveled from variety of geographic locations, in spaces that do not often afford social distancing precautions. Furthermore, passengers often constitute the vast majority of a voyage's capacity. Unvaccinated passengers, therefore, pose a significant risk to both the health and safety of cruise staff, as well as the ability of cruise lines to safely operate on a long term basis.

In light of *Florida v. Becerra*, individual cruise lines will likely have to enact their own passenger vaccination mandates. Florida's on-going legal battle against the CDC and the federal government has resulted in a preliminary injunction blocking the federal government from enforcing pandemic-related restrictions on the cruise industry, set to go into effect July 18, 2021.¹³ It is possible that other states will join in seeking such an injunction, as Alaska and Texas have strongly backed Florida in this battle. This injunction does not impact the ability of cruise lines to enact pandemic-related restrictions on their own voyages. However, depending on the jurisdiction cruise lines may face challenges in enforcing vaccination mandates – as it will likely depend on the jurisdiction. New York, for example, has advised that individual businesses may add additional guidelines to the state and CDC guidelines¹⁴ – this has spurred many NYC bars and restaurants to require that patrons be vaccinated. Florida, however, has passed state

¹³ *Florida v. Becerra*, No. 8:21-cv-839-SDM-AAS, 2021 U.S. Dist. LEXIS 114297 (M.D. Fla. June 18, 2021)

¹⁴ Governor Cuomo, New York State to Adopt New CDC Guidance on Mask Use and Social Distancing for Fully Vaccinated Individuals, May 17, 2021.

legislation barring businesses from requiring customers to be vaccinated. In light of this law, Governor DeSantis has also stated that he will fine cruise ships that require vaccinations \$5,000 per passenger. While it is unclear whether DeSantis will act on this threat, it poses a serious challenge for cruise ship lines seeking to require vaccinated passengers.

Despite these challenges, the CDC should continue to strongly encourage cruise lines to institute vaccination mandates for their passengers. To provide for any potential vaccination mandates, the CDC should also expand US port vaccination sites to include vaccinating passengers for future voyages. While this may not be a feasible option for passengers traveling great distances to US ports, these vaccination sites could service locally-based passengers through a one-shot vaccination. In summary, to protect the well-being of cruise crew members the CDC should revise the Proposed Rule to include strong recommendations for cruise lines regarding passenger vaccinations, these revisions should include updated jurisdictional laws, as well as an expansion of the port and health agreements to include provisions for vaccinating passengers.

Sincerely,

Amanda L'Esperance
J.D. Candidate
Northeastern University School of Law
Email: lesperance.a@northeastern.edu

Jeffrey M. Zirger
Information Collection Review Office, Centers for Disease Control and Prevention
1600 Clifton Road NE, MS- D74
Atlanta, Georgia 30329

RE: Phased Approach to the Resumption of Cruise Ship Passenger Operations 2021-09094,
Docket No. CDC-2021-0011

June 30, 2021

Executive Summary¹

As cruise ships resume normal operations, the CDC intends to avoid the issues that arose at the beginning of the pandemic (e.g. infected and quarantined passengers stranded at sea, cruise ships being rejected from ports) by issuing its Framework for Conditional Sailing Order (“CSO”).

The CSO outlines a phased approach to resuming operations consisting of three phases. The first phase requires cruise ships to establish mass testing on their ships. The second phase requires cruise ships to establish agreements with local ports, healthcare facilities, and residential facilities in case of a COVID-19 outbreak and for cruise ship operators to undergo “simulated voyages.” Finally, phase three requires cruise ship operators to apply for a conditional sailing certificate, after which cruise ship operators will be allowed to resume passenger operations.

This comment recommends that the CDC guidance (1) delineate clear rules, (2) provide transparency to passengers, and (3) ensure that compliance is not prohibitively expensive. This comment appreciates the CDC’s commitment to protecting public health and believes that the CSO’s requirements of mass-testing and contingency plans with local facilities are necessary as cruise ships resume operations. This comment recommends, however, that to improve public

¹ This document was prepared for a law school class will be added to the final comment prior to submission.

safety, the CDC recommend that cruise ships vaccinate their entire crews. Also, for transparency, cruise ships should make publicly available their agreements with local ports, healthcare facilities, and residential facilities. Finally, this comment recommends that the CSO eliminate the “simulated voyage” requirement of Phase 2B as a means of conforming with the recent ruling in *State of Florida v. Becerra*.

Background: The Cruise Ship Industry and the COVID-19 Pandemic

On March 5, 2020, cruise ships became the flashpoint of the COVID-19 pandemic when a passenger on The Grand Princess became the first known person to die of COVID-19 in California.² Governor Gavin Newsom subsequently declared a state of emergency to control the novel virus and protect the citizens of California as The Grand Princess, which was carrying around 2,500 passengers and over 1,000 crew members, was held in limbo off the coast of California.³ As the initial stages of pandemic were unfolding, it became clear that there was no established playbook to address the COVID-19 crisis. The lack of plan left cruise ship operators out to sea with regard to managing their businesses and their passengers stranded on cruise ships.

On March 14, 2020, the CDC provided clarity to cruise ship operators by issuing its No Sail Order (NSO).⁴ The NSO was a blunt instrument that prevented cruise ship companies from operating their businesses without permission from the United States Coast Guard.⁵ The CDC advised that the NSO was warranted because the risk of COVID-19 transmission was elevated on

² Bill Chappell, *Coronavirus: Cruise Ship in Limbo Off California After A Former Passenger Died*, NPR, (Mar. 5, 2020), <https://www.npr.org/sections/health-shots/2020/03/05/812456413/coronavirus-cruise-ship-in-limbo-off-california-after-former-passenger-died>.

³ *Id.*

⁴ CENTERS FOR DISEASE CONTROL AND PREVENTION, NO SAIL ORDER AND OTHER MEASURES RELATED TO OPERATIONS (2020)

⁵ *Id.* at 7.

cruise ships and cruise ship travel had the potential to introduce, transmit, and spread COVID-19, especially among vulnerable populations.⁶

After the CDC issued its NSO, cruise ship operators⁷ and states initially confronted grim financial realities.⁸ Spectators wrote that cruise ship operators should not receive bailout funds from the federal government because the industry pays almost nothing in federal income taxes⁹ and that the bankruptcy process would be the best way for the cruise ship industry to navigate COVID-19 related hardships. The cruise ship industry was able to largely avoid bankruptcies, however, through the Federal Reserve's intervention into credit markets and its Primary Market Corporate Credit Facility.¹⁰ As such, with the help of the federal government, cruise ship operators were able to add enough capital to their balance sheets through bond offerings to weather the COVID-19 pandemic.

⁶ *Id.* at 5.

⁷ See Veronica Brezina-Smith, *Port Tampa Bay takes financial hit from extension of no-sail order for cruise lines*, TAMPA BAY BUSINESS JOURNAL (Jun. 17, 2020), <https://www.bizjournals.com/tampabay/news/2020/06/17/port-tampa-bay-takes-a-financial-hit-from-cruises.html>

⁸ See, e.g., *The state-budget train crash*, THE ECONOMIST (Jun. 20, 2020), <https://www.economist.com/united-states/2020/06/18/the-state-budget-train-crash> (noting that in 2020 state tax revenues in Louisiana declined by 43% and in New York by 67%. In California, income-tax receipts fell by 85%); see also Louise Sheiner & Sophia Campbell, *How much is COVID-19 hurting state and local revenues?*, BROOKINGS (Sept. 24, 2020), <https://www.brookings.edu/blog/up-front/2020/09/24/how-much-is-covid-19-hurting-state-and-local-revenues/> (projecting that state and local government revenues would decline by \$155 billion in 2020, \$167 billion in 2021, and \$145 billion in 2022); see also Cruise Lines International Association, *Cruise Industry Economic Impact: Florida*, CLIA (2021), <https://cruising.org/-/media/Infographics/Enhanced%20Public%20Health%20Measures/2019%20Economic%20Impact%20Key%20Stats/Florida> (illustrating the economic impact of the cruise ship industry in states like Florida, in which the industry contributes \$9.04 billion in direct spending and \$8.06 billion in wages to the state economy).

⁹ Alex Harris & Taylor Dolven, *'A cruise ship is not a riskier environment' for coronavirus*, *Carnival CEO tells Axios*, MIAMI HERALD (Mar. 22, 2020), <https://www.miamiherald.com/news/coronavirus/article241395861.html>; see also Sean O'Kane, *Don't bail out the cruise industry*, THE VERGE (Mar. 23, 2020), <https://www.theverge.com/2020/3/23/21187076/cruise-line-industry-bailout-trump-coronavirus-us-companies-tax> (contending that cruise ships pay effectively nothing in federal income taxes, fail to incorporate as US companies, pollute the environment, and provide a non-essential service).

¹⁰ Matt Wirz, *How Fed Intervention Saved Carnival*, WALL ST. J. (Apr. 26, 2020), <https://www.wsj.com/articles/how-fed-intervention-saved-carnival-11587920400>; see also David Dierking, *Fed Buys \$1.3 Billion In Bond ETFs; Here's The Breakdown*, THE STREET (Jun. 4, 2020), <https://www.thestreet.com/etffocus/market-intelligence/fed-buys-1-3-billion-in-bond-etfs-heres-the-breakdown> (not only did the Federal Reserve unfreeze credit markets by communicating its intention to buy corporate bonds in general, the Fed later would support the cruise industry by buying bonds of companies like Carnival Corporation & PLC—albeit in relatively small amounts-- through ETFs such as the junk bond ETF “JNK”).

Today the NSO is still in effect, but the successful development and distribution of vaccines has reduced the transmission risks that initially supported its creation. As of June 29, 2021, 46.5% of individuals in the United States have been fully vaccinated and governors across the country are reopening their state economies.¹¹ Given the changed circumstances, the CDC has issued its Framework for Conditional Sailing Order (“CSO”), which provides technical instructions to the cruise industry on resuming normal operations.¹² The CSO is intended to protect public health by prohibiting cruise ship operators from resuming operations until cruise ship operators comply with the CDC’s phased approach to returning to passenger operations.

Framework for Conditional Sailing Order (“CSO”) Summary

The CSO’s phased approach to resuming passenger operations consists of the following. First, cruise ship operators must commit to mass testing their crews and building the requisite testing facilities to test their passengers and crew upon the return to normal operations.¹³

The second phase of the CSO requires cruise ship operators to establish agreements with port operators, local hospitals, and shoreside residential facilities.¹⁴ Cruise ship operators and port operators must have agreements in place to ensure local ports are not overburdened during voyages. Cruise ship operators must also have agreements with local hospitals and residential facilities to ensure that passengers and crew will have access to adequate medical care and

¹¹ See *U.S. COVID-19 vaccine tracker*, MAYO CLINIC (Jun. 29, 2020), <https://www.mayoclinic.org/coronavirus-covid-19/vaccine-tracker>; See *Reopening Plans and Mask Mandates for All 50 States*, N.Y. TIMES (Jun. 29, 2020), <https://www.nytimes.com/interactive/2020/us/states-reopen-map-coronavirus.html>.

¹² Phased Approach to the Resumption of Passenger Operations—Existing Collection in use without an OMB Control Number—National Center for Emerging and Zoonotic Infectious Diseases, 86 Fed. Reg. 22965 (proposed Apr. 30 2021).

¹³ *Id.*

¹⁴ *Id.*

available space to quarantine in case of covid transmission. During this phase cruise ships must report daily on individuals who are in quarantine.

In Phase 2B, cruise ship operators must request permission to embark on a “simulated voyage” thirty days prior to such voyage to prove their ability to mitigate COVID-19 risk. After approval, cruise ship operators must identify and document any deficiencies in health and safety in an “after-action report.”

The third (and final) phase consists of cruise ship operators successfully completing a conditional voyage and then submitting to the CDC a COVID-19 Conditional Sailing Certification Application 60 days prior to any proposed restricted voyage.

Analysis of the CSO

As it currently exists, the CDC’s CSO optimizes the safety of passengers, which should be the guiding principle behind public health related interventions. There are, however, instances where the CSO may be overly burdensome without providing added public health benefits, and there are sections that require more clarification.

The CDC’s mission is to protect the United States from health, safety, and security threats and much of the CSO does just that. For example, the mandatory testing of the crew and passengers on cruise ships is essential to keeping individuals on (and off) cruise ships safe. In theory, the testing will allow cruise ships to quickly identify a COVID-19 outbreak on any given ship and immediately mitigate the transmission and spread of the virus.

The requirement that cruise ship operators develop agreements with local port authorities, hospitals, and residential facilities is also crucial to preventing the spread of COVID-19. At the onset of the COVID-19 outbreak, it was evident that cruise ship operators did not have

contingency plans for a public health emergency such as a pandemic. Ensuring that agreements are in place prior to resuming normal operations will eliminate uncertainty and ensure that passengers will not be stranded on ships in the event of an outbreak. Such planning will serve to protect the health of individuals on cruise ships.

The requirement that cruise ships perform “simulated voyages,” however, seems unnecessarily burdensome and provides limited public health benefits. Conceptually, simulated voyages would seem to provide an opportunity for cruise ships to address problems that might arise during regular operations in a lower-stakes setting. Absent clarification from the CDC though, it is difficult to understand how simulated voyage will adequately prepare cruise ships for emergencies if such voyages do not involve a representative simulation of regular operations.

If the simulated voyages involve passengers, then it would suggest that cruise ship operators are prepared to resume normal operations. If simulated voyages do not involve passengers, then it is doubtful that they will serve the purpose of preparing cruise ship operators for passenger-related emergencies or informing the CDC of potential public health risks when passenger travel restarts in earnest. Instead, the decision to resume operations seems binary: either cruise ship operators are prepared to accept passengers or they are not.

Moreover, the entire legal viability of the CSO has come under scrutiny after the decision in *State of Florida v. Becerra*, which recently ordered that the CDC’s conditional sailing order likely exceeds the scope of the CDC’s authority.¹⁵ The district court reasoned that the CDC strayed from its historically “limited application of inspection, sanitation, and isolation” and is likely exercising an unconstitutionally expansive power in shutting down the entirety of a multi-

¹⁵ *State of Florida v. Xavier Becerra et al.*, No. 8:21-cv-839-SDM-AAS (M.D. Fla. Jun. 18, 2021) (order granting preliminary injunction).

billion-dollar industry.¹⁶ The court seems most concerned with the CDC infringing on the power of the legislature and the CDC's claiming an "unbounded" power to regulate industries and individuals.¹⁷ Accordingly, the court granted Florida's motion for a preliminary injunction against the CSO and allowed the CDC to propose a narrower sailing guidance backed by scientific evidence and full disclosure.¹⁸

Removing the simulated voyages would undercut much of the Florida's argument against the CSO and eliminate unnecessary bureaucracy. If the CDC chooses to submit an amended CSO to the district court in Florida, it will be difficult for a judge to hold unconstitutional a CSO that does not include multi-month delays to resuming operations. Even so, if the court affirms its injunction, on appeal the Supreme Court might be receptive to upholding the constitutionality of the amended CSO (similar to its recent decision related to the CDC's eviction moratorium).¹⁹ Litigation might be inevitable considering that certain states have not been receptive to any COVID-19 safety measures (no matter how reasonable or carefully designed). Nevertheless, removing simulated voyages (and the subsequent delay of normal operations) might avoid future litigation from other states and prevent district courts from transforming the entire CSO into a non-binding document. Even without the simulated voyages, public health will likely be protected if cruise ships meet the criteria of Phases 1 and 2 of the CSO while also required to producing "After Action Reports" analyzing the return to normal operations detailed in Phase 3.

¹⁶ *Id.* at 50.

¹⁷ *Id.* at 74.

¹⁸ *Id.* at 122-123.

¹⁹ *Alabama Association of Realtors, et al. v. Department of Health and Human Services, et al.*, 594 U.S. __ (2021) (in which the Supreme Court recently upheld the CDC's national eviction moratorium after *multiple* district court judges held that the CDC's order was unconstitutional. On appeal, the Supreme Court might not be as hostile to federal public health related interventions as expected).

Actions Recommended: Vaccinations, More Transparency, and No Simulated Voyages

The CDC guidance is comprehensive and demonstrates the agency's commitment to protecting public health. Nevertheless, the CDC should consider the following recommendations to create a framework that (1) delineates clear rules, (2) provides transparency to passengers, and (3) ensures that compliance is not prohibitively expensive.

One of the most effective means of limiting the transmission of COVID-19 is vaccinations. Vaccines have high efficacy rates and have proven to drastically reduce the spread of COVID-19.²⁰ If the intent of the CSO is to eliminate the risk of COVID-19 transmission, then the CDC should publicly recommend that all crew and passengers be vaccinated (absent extraordinary circumstances). While the CDC cannot force employers to require vaccinations as a condition of employment, including a vaccine recommendation will at least put public pressure on cruise ship operators.

Although politicians such as Governor Ron DeSantis have passed state level ordinances pushing back against vaccines passports making it difficult to ensure that passengers are vaccinated,²¹ employers are well within their rights to require that employees be vaccinated.²² More recently, the Southern District of Texas dismissed the allegations of workers who argued that their employer, Houston Methodist Hospital, was illegally coercing them to receive

²⁰ *Largest CDC COVID-19 Vaccine Effectiveness Study in Health Workers Shows mRNA Vaccines 94% Effective*, CENTERS FOR DISEASE CONTROL AND PREVENTION (May 14, 2021), <https://www.cdc.gov/media/releases/2021/p0514-covid-19-vaccine-effectiveness.html>; Heidi Ledford, *Six months of COVID vaccines: what 1.7 billion doses have taught scientists*, NATURE (Jun. 4, 2021), <https://www.nature.com/articles/d41586-021-01505-x>.

²¹ Media Office of Governor Ron DeSantis, *Governor Ron DeSantis Signs Landmark Legislation to Ban Vaccine Passports and Stem Government Overreach*, FLGOV.COM (May 3, 2021), <https://www.flgov.com/2021/05/03/governor-ron-desantis-signs-landmark-legislation-to-ban-vaccine-passports-and-stem-government-overreach/>.

²² *See What You Should Know About COVID-19 and the ADA, the Rehabilitation Act, and Other EEO Laws*, EEOC (Jun. 28, 2021), <https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws> (noting that Federal Equal Employment Opportunity laws do not prevent employers from requiring all employees be vaccinated so long as employers comply with the accommodation provisions of the Americans with Disabilities Act and Title VII of the Civil Rights Act of 1964).

vaccines.²³ The court in Texas unequivocally held that “every employment includes limits on the worker’s behavior in exchange for his remuneration” and such limits may include vaccinations.²⁴ Although the outcome of hypothetical litigation is always indeterminate, courts will likely find that similar employer mandated vaccine programs are legal, so the CDC should recommend that cruise ships implement analogous vaccine mandates.

Cruise ship operators also should aim for as much transparency as possible such that passengers can make informed decisions prior to embarking on cruises. As such, cruise ship operators should make the details of their agreements with port authorities, local hospitals, and shoreside facilities open to the public so that passengers can make informed decisions when purchasing cruise tickets. To the extent that cruise ships can incorporate the technology into their operations, cruise ships also should make daily testing information available to all passengers and “After Action Reports” should be publicly available. With transparency regarding agreements with local facilities and daily testing, passengers can make informed decisions about the risks of traveling on cruise ships. As a legal matter, the demand for increased transparency is almost certainly within the CDC’s power under 42 U.S.C. §264(a) because it is non-burdensome and a standard use of the CDC’s authority to prevent the spread of communicable diseases.

Finally, the CSO should not require cruise ships to undergo simulated voyages. The public health value of the simulated voyages likely does not outweigh their costs. Presumably cruise ship operators want to reopen because passengers are demanding it. As explained above, the removal of simulated voyages has the added benefit of possibly bringing the CSO in

²³ *Jennifer Bridges, et al. v. Houston Methodist Hospital, et al.*, No. 4:21-cv-01774 (S.D. Tex. Jun. 12, 2021) (order on dismissal).

²⁴ *Id.* at 4 (explaining that “as a matter of law, it is also necessary to clarify that Bridges has not been coerced.... [an employee] can freely choose to accept or refuse a COVID-19 vaccine; however, if she refuses, she will simply need to work somewhere else”).

compliance with the Southern District of Florida’s preliminary injunction too. Ultimately, transparency is the best way to protect passengers and allow them to make informed decisions.

To make compliance more economically feasible, the CSO should consider having cruise ships require passengers to sign waivers of liability. It is likely that cruise ship operators already require passengers to sign waivers prior to embarking on cruises, so inserting COVID-19 related language should not be overly burdensome. The legal standard that *might* invalidate a COVID-19 liability waiver is the concept of “substantive unconscionability,” which has been debated in the context of forced arbitration. Given the direction of contract-based unconscionability litigation, it is likely that, if challenged, COVID-19 related travel waivers would survive.²⁵ Liability waivers should theoretically make operations less expensive and signal to passengers that they are traveling at their own risk.

The federal government and taxpayers have made it possible for the owners of cruise ships to weather the COVID-19 pandemic so cruise ship operators should be expected to conform to reasonable CDC regulations, particularly with the above-outlined edits to the CSO.

²⁵ See, e.g., *AT&T Mobility LLC v. Concepcion*, 563 U.S. 333 (2011) (the seminal case in which the Supreme Court indicated its unwillingness to hold forced class arbitration unconscionable. Although waivers are distinct from forced arbitration, it seems that the Supreme Court is not predisposed to invalidate waivers of liability as unconscionable)

Jeffrey M. Zirger
Information Collection Review Office, Centers for Disease Control and Prevention
1600 Clifton Road NE, MS- D74
Atlanta, Georgia 30329

RE: Phased Approach to the Resumption of Cruise Ship Passenger Operations 2021-09094,
Docket No. CDC-2021-0011

June 30, 2021

Executive Summary

The Framework for Conditional Sailing Order issued by the Centers for Disease Control and Prevention (CDC) is a useful mechanism for containing the ongoing COVID-19 pandemic, as well as a necessary data collection project for the proper performance of the functions of the CDC. Cruise ships are especially susceptible to a threat like COVID-19 and therefore, the CDC must be able to regulate their activities during this time and collect information it can use to assess the viability of cruise ship operations during the pandemic. However, in order to maximize the efficiency and effectiveness of the data collection, the CDC should consider allowing cruise ship operators to submit the required information electronically and sending CDC personnel to some or all of the simulated voyages. Additionally, the legality of the Order itself is currently in dispute. As such, the CDC should consider bolstering the legality of the Order by changing the Order, proving certain arguments, and lobbying Congress.

Background

On March 14, 2020, in response to the COVID-19 pandemic, the CDC issued a No Sail Order (NSO) for all recreational cruise ships, effective immediately.¹ This order was renewed or

¹ Center for Disease Control and Prevention, <https://www.cdc.gov/quarantine/cruise/covid19-cruiseships.html> (last visited Jun. 20, 2021).

extended several times, shutting down the American cruise line industry from March 2020 through October 2020.²

Then, on October 30, 2020, the CDC issued the Framework for Conditional Sailing Order (CSO). Although this order did not allow cruise ships to immediately restart activities, it did provide a process cruise ships would need to follow in order to resume activities. The CSO is currently in effect until the earliest of (1) the expiration of the Secretary of Health and Human Services' declaration that COVID-19 constitutes a public health emergency, (2) the CDC Director rescinds or modifies the order based on specific public health or other considerations, or (3) November 1, 2021.³

Additional details were released on April 2, 2021, and May 5, 2021.⁴ These updates provided cruise ship operators with the “last” requirements and recommendations they needed to go through the process of obtaining conditional sailing certificates, which allow cruise ship operators to conduct restricted passenger (or “simulated”) voyages.⁵ These instructions outline the information that cruise ship operators must submit, including the cruise ship operator's port, medical care, and housing agreements with U.S. port authorities and local health authorities, and data collected from simulated voyages.⁶

As of June 4, 2021, the CDC had port agreements for twenty-two ships and had scheduled nine ships to begin simulated voyages, most of which begin in July or August of 2021.⁷ Of the estimated fifty-nine eligible cruise ships, only two ships have received conditional

² Id.

³ Id.

⁴ Id.

⁵ Id. These instructions may not in fact be the last set issued because the CDC has the power to issue adjustments based on changing circumstances, new public health information, and other considerations.

⁶ Id.

⁷ Florida v. Becerra, No. 8:21-cv-839-SDM-AAS (M.D. Fla. 2021).

sailing certificates, both for “highly vaccinated voyages” (at least ninety-eight percent of the crew and ninety-five percent of the passengers are fully vaccinated).⁸

Meanwhile, the COVID-19 pandemic has begun to come under control thanks in part to the successful development of several vaccines, but much of the world has yet to reach vaccine rates necessary to achieve herd immunity,⁹ which scientists estimate requires anywhere from sixty to eighty-five percent of the population to be fully vaccinated.¹⁰ This includes many parts of the United States, including Florida, the home of the three busiest cruise ports in the world, which has only fully vaccinated forty-four percent of its population.¹¹

Analysis

A. Importance of the Order

The Order is a valuable tool for containing the ongoing COVID-19 pandemic as well as a necessary data collection project for the proper performance of the functions of the CDC.

Because cruise ships are a major COVID-19 concern, the CDC must be able to regulate cruise ships activities and be able to obtain information that it can use to assess cruise ships’ activities during the pandemic.

Cruise ships inherently present a myriad of issues regarding COVID-19. Cruise ships may host thousands of geographically diverse passengers, have many crowded and/or enclosed spaces, make several port visits, and typically have limited medical resources.¹² Each of these factors alone could increase the likelihood of transmission, but together they create an especially

⁸ Id.

⁹ The point at which so much of the population has been fully immunized that the likelihood of further transmission is dramatically decreased.

¹⁰ <https://www.yalemedicine.org/news/herd-immunity>

¹¹ Cruise Industry News, <https://www.cruiseindustrynews.com/cruise-news/17487-the-busiest-cruise-ports.html> (last visited Jun, 21, 2021); USAFacts, <https://usafacts.org/visualizations/covid-vaccine-tracker-states/state/florida> (last visited Jun. 21, 2021).

¹² Center for Disease Control and Prevent, <https://wwwnc.cdc.gov/travel/yellowbook/2020/travel-by-air-land-sea/cruise-ship-travel> (last visited Jun. 20, 2021).

perilous situation.¹³ Additionally, there tends to be large amounts of alcohol consumption, on cruise ships.¹⁴ Alcohol consumption not only weakens the immune, it also relaxes inhibitions, which could in turn lead passengers to ignore social distancing measures and other COVID-19 safety guidelines. Cruise ship passengers also tend to skew older, which could mean on average cruise ship passengers are more likely to catch and spread COVID-19 than the general population.¹⁵ However, since older populations are the most vaccinated, it could in fact mean the opposite. Finally, a cruise ship with a confirmed outbreak of COVID-19 can present serious legal issues. The most extreme example of this was when the English *Diamond Princess* cruise ship, with its international clientele, was quarantined by the Japanese government, which triggered a minor international incident.

Given all these concerns regarding cruise ships and the COVID-19, it is evident that the CDC needs not only to strictly regulate the activities of cruise ships during the pandemic, but also needs information in order to help guide cruise ships operators during this time. The port, medical care, and housing agreements, despite their potential to inconvenience the non-cruise ship party, are all extremely important for the CDC to have, not only because they confirm that a single cruise ship operator is taking the necessary steps, but also because collectively, they help the CDC see and understand the larger picture of how all of these cruise ships will be interacting, and which resources will require additional support.

The information to be collected from the simulated voyages is also especially valuable. By collecting data from many simulations conducted by different ships, the CDC will be able to

¹³Kenichi Azuma, U Yanagi, Naoki Kagi, Hoon Kim, Masayuki Ogata & Motoya Hayashi, Environmental factors involved in SARS-CoV-2 transmission: effect and role of indoor environmental quality in the strategy for COVID-19 infection control, *Env't Health and Preventive Med.*, Nov. 2020, at 66.

¹⁴ *Cruiseline.com*, <https://cruiseline.com/advice/cruising-101/all-about-cruising/shipfaced> (last visited Jun. 20, 2021).

¹⁵ *Cruise1st*, <https://www.cruise1st.co.uk/blog/cruise-holidays/how-old-is-the-average-cruise-passenger> (last visited Jun. 20, 2021); Center for Disease Control and Prevention, <https://www.cdc.gov/COVID-19/2019-ncov/need-extra-precautions/older-adults.html> (last visited Jun 20., 2021).

discern what issues are common among cruise ships, what practices are and are not effective, and what scenarios all ships need to prepare for, such as what to do when onboard testing facilities are overwhelmed, how to manage resources and potentially unruly passengers during a confirmed outbreak onboard, and how to effectively separate unhealth passengers from health passengers. The simulations would also, in and of themselves, be beneficial to the cruise ships, as simulations have been shown to help mitigate errors, finetune procedures, and prepare individuals for unlikely situations.¹⁶ The simulations will of course take additional time and money to properly implement, but the benefits obtained through a simulation may be difficult to obtain through a different process.

B. Legality of the order

As of July 18, 2021, the CDC will be enjoined from enforcing the Order due to a preliminary injunction stemming from Florida v. Becerra.¹⁷ One way the CDC can stave off the injunction is if it proposes a sufficiently narrowed order by July 2, 2021.¹⁸

Among many complex legal issues raised during the case, one of the central themes highlighted several times by U.S. District Court Judge Steven Merryday was the allegedly unprecedented nature of the CDC's action. Judge Merryday opined that the CDC has never implemented measures "as extensive, disabling, and exclusive as those under review in this action," asserting that the CDC has never (1) detained a vessel for more than fifteen months, (2) implemented a widespread or industry-wide detention of a fleet of vessels in American waters, (3) "conditioned pratique as extensively and burdensomely as the conditional sailing order," (4)

¹⁶ Fatimah Lateef, Simulation-based learning: Just like the real thing, J. of Emergencies, Trauma, and Shock. 66, Oct. – Dec. 2010, at 348-352.

¹⁷ Florida v. Becerra, No. 8:21-cv-839-SDM-AAS (M.D. Fla. 2021).

¹⁸ Id.

imposed restrictions that essentially dismiss the effectiveness of state regulation, and (5) halted a multi-billion dollar industry nationwide for such an extended period of time.¹⁹

Additionally, Judge Merryday found that not only did the CDC exceed its statutory limits, but also that the statutory limits argued by the CDC would likely be “an unconstitutional delegation of legislative power to CDC because the delegation fails to convey any ‘intelligible principle’ to guide CDC’s exercise of authority.”²⁰

Actions Recommended

A. How to improve the data collection aspect

There are several actions the CDC should consider adopting in order to improve the efficiency and effectiveness of the data collection component of the Order.

First, the CDC should ensure that all the information they are collecting can be submitted electronically. Electronic delivery is generally faster, easier, cheaper, and more reliable than mail or in-person delivery. Furthermore, the CDC should determine if website or mobile applications could be utilized for this project, especially for the simulated voyages. Website and mobile applications can streamline data collection projects by turning long, sterile forms into manageable, interactive guides. If the CDC decided to utilize website or mobile applications, it would also need decide which type of applications would be best. Mobile applications tend to be faster, safer, and more versatile than website applications, but website applications are typically cheaper to build and maintain, and do not need to be approval by the application store or downloaded by the consumer.²¹ The drawback to these actions would be the cost of developing

¹⁹ Id.

²⁰ Id.

²¹ Sagara Technology Idea Lab, <https://sagaratechnology.medium.com/mobile-apps-vs-web-apps-which-is-the-better-option-868106c88730> (last visited Jun. 20, 2021).

the electronic tools and training personnel to provide services to cruise ship operators who have problems with the platforms.

Second, the CDC should consider sending their personnel to some or all of the simulated voyages. This action would, first and foremost, help to ensure that cruise ship operators are reporting accurate information. Additionally, having CDC officials at some of the simulated voyages, especially the early ones, would enable the CDC to see for itself what is and is not working in these simulations, and whether there is additional information it should be collecting. Lastly, having CDC officials in-person may help to foster trust, especially since the simulations are, for the cruise ship operators, highly important and therefore stressful situations. The obvious drawback to this action is the time and money inherent in sending personnel to these time-consuming simulations, which could conceivably be conducted dozens if not even hundreds of times before the order is no longer in effect.

B. How to enhance the legality of the Order

The CDC must take action to ensure that its Order is legally enforceable.

First, the CDC should attempt to narrow its Order, but only if it can do so without narrowing the Order to the point of uselessness, which would be a self-defeating endeavor.

Second, the CDC should attempt to demonstrate that the Order is not unprecedented. Proving this would undercut a significant amount of the reasoning undergirding Judge Merryday's decision, potentially so much so that the decision must be overturned. The CDC could, for instance, argue that the Order is not unprecedented in a world in which its eviction moratorium order, an equally massive intervention into commerce, has been implemented and thus far legally upheld.

Third, if the CDC cannot prove that the Order itself is unprecedented, then it should argue that the cruise industry is unique. As demonstrated above, cruise ships intrinsically and typically feature a number of aspects that make them highly susceptible to an airborne disease such as COVID-19. In fact, there is already evidence to suggest that even with the CDC protocols in place, the possibility of outbreaks on cruises ships have not been eliminated.²² If the CDC can prove that the cruise industry demands particularized regulation, then the Order or something like it could be sustained.

Fourth, if the CDC cannot prove that the cruise industry is unique, then it should argue that the COVID-19 pandemic is unique. Demonstrating that COVID-19 is more contagious, deadly, and uncontrollable than previous pandemic diseases would prove the need for stepped-up measures. However, the viability of this strategy is unknown since comparing pandemics is a challenging if not impossible task.²³

Fifth, the CDC should attempt to persuade Congress, ideally through legislation, to confirm the CDC's interpretation of its statutory limits. This would imbue the CDC with the power it needs.

Sixth, if the CDC cannot convince Congress to adopt the CDC's interpretation, the CDC should lobby Congress to pass discrete legislation granting the CDC the powers it needs to address this issue. This option is admittedly undesirable because of its low likelihood of success. The degree of control government agencies have over private business has long been a contentious topic in Congress and the COVID-19 pandemic (along with the absurd politicization of the pandemic itself) has further expanded this gap. Additionally, even if Congress were

²² Victoria Forster, Cruises Just Restarted And Passengers Are Already Testing Positive For COVID-19 Again, Forbes (Jun. 10, 2021), <https://www.forbes.com/sites/victoriaforster/2021/06/10/cruises-just-restarted-and-passengers-are-already-testing-positive-for-covid-19-again/?sh=49950ad02ada>

²³ Silvio Daniel Pitlik, COVID-19 Compared to Other Pandemic Diseases, Rambam Maimonides Med. J., 11, Jul. 2020, at 20.

somehow able to find common ground that encouraged greater agency oversight, such legislation is unlikely to be ratified and implemented any time soon; by the time the CDC has the power it needs, the COVID-19 pandemic could be effectively over, the cruise industry could have set and disseminated its own standards, or any number of other mitigating events could occur.

Sincerely,

Jeffrey Robinowitz
J.D. Candidate
Northeastern University School of Law
E-mail: robinowitz.j@northeastern.edu

Jeffrey M. Zirger
Information Collection Review Office, Centers for Disease Control and Prevention
1600 Clifton Road NE, MS- D74
Atlanta, Georgia 30329

RE: Phased Approach to the Resumption of Cruise Ship Passenger Operations 2021-09094,
Docket No. CDC-2021-0011

June 30, 2021

Executive Summary

The coronavirus disease 2019 (COVID-19) changed the daily lives of people globally starting in early 2020. The cost of the pandemic has been high, with the loss of life and livelihood being unimaginable. With increasing vaccination rates, life is slowly returning to a semblance of normal in the United States (U.S.). The cruise ship industry poses unique safety challenges and risks to its employees and patrons. In response, Centers for Disease Control and Prevention (CDC) instituted a framework for the restart of cruise ship operations, titled *Framework for Conditional Sailing and Initial Phase COVID-19 Testing Requirements for Protection of Crew*. This framework sets out various guidelines for cruise lines concerning port agreements, testing requirements, and evacuation standards, among others. This comment will highlight concerns surrounding the current testing and evacuation guidelines set forth by the CDC while raising questions about the lack of guidance for ventilation standards while on cruise ships. This comment will ultimately recommend that the CDC increase the testing cadence of both patrons and crew while on board, require more port agreements to allow for immediate evacuation of sick individuals, institute vaccination standards for patrons and crew, and to incorporate ventilation standards for cruise ships.

Background

The month of March 2020 will be remembered in the minds of the United States (U.S.) and global populace for years to come. Although COVID-19 already had a strong foothold

across the globe, the World Health Organization (WHO) officially declared that COVID-19 was a pandemic on March 11, 2020.¹ The cost of this pandemic has been high; as of June 15, 2020, the confirmed death toll of the pandemic in the U.S. sits over 600,000; the confirmed death toll globally sits over 3.8 million.² In the U.S., the spring of 2021 has been marked by decreasing incidence of COVID-19 and increasing vaccination efforts. The new case average in June 2021 was the lowest it has been since late March of 2020, and nearly 44% of the U.S. population is currently fully vaccinated.^{3,4} In response to these encouraging signs, many states have begun to ease COVID-19 restrictions and have done away with mask requirements altogether.⁵ With life returning to some semblance of normal for much of the country, some activities and industries still give cause for concern, and likely need heightened precautions to keep participants healthy and safe.

One of these activities and industries is cruise ships. The danger of cruise ships during the COVID-19 pandemic first captured national headlines when the *Diamond Princess* and its over 3700 multinational guests and crew were forced to quarantine in a Japanese port beginning in early February of 2020, ultimately leading to over 700 positive cases and multiple deaths.^{6,7} A

¹ WHO, *WHO Director-General's opening remarks at the media briefing on COVID-19 – 11 March, 2020* (2020), <https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020?>

² Scott Neuman, *The U.S. Has Hit over 600,000 COVID Deaths, More Than Any Other Country*, NPR (Jun. 15, 2021), <https://www.npr.org/sections/coronavirus-live-updates/2021/06/15/1006186695/the-u-s-has-hit-600-000-covid-deaths-more-than-any-other-country>.

³ Google, *Cases, United States* (last updated Jun. 14, 2021), <https://news.google.com/covid19/map?hl=en-US&mid=%2Fm%2F09c7w0&gl=US&ceid=US%3Aen>.

⁴ Audrey Carlson, *Coronavirus by the Numbers: How Is The COVID-19 Vaccination Campaign Going in Your State?* NPR (last updated Jun. 15, 2021), <https://www.npr.org/sections/health-shots/2021/01/28/960901166/how-is-the-covid-19-vaccination-campaign-going-in-your-state>.

⁵ Neuman, *supra* note 2.

⁶ Eilif Dahl, *Coronavirus (COVID-19) outbreak on the cruise ship Diamond Princess*, 71 INT. MARIT HEALTH 5, 5 (2020), https://journals.viamedica.pl/international_maritime_health/article/view/IMH.2020.0003/50489.

⁷ Dave Sebastian, *As Cruises Resume, a Positive Covid-19 Case Doesn't Spell the End of a Voyage*, THE WALL ST. J. (Jun. 11, 2021), <https://www.wsj.com/articles/as-cruises-resume-a-positive-covid-19-case-doesnt-spell-the-end-of-a-voyage-11623441869>.

recent study of this event shows just how uniquely problematic the cruise ship environment is. Using January 21, 2020 as the date of the first infected patient onboard, this study found the initial basic reproduction number, the number of secondary infections arising from this each case on the ship, to be almost 15.⁸ This reproduction number was around 4 times higher than Wuhan, China, the original epicenter of the pandemic.⁹ This study posits that this high rate of COVID-19 transmission is likely due to the incredible population density on board a cruise ship.¹⁰ With the Delta variant recently being identified as a variant of concern with increased virulency and risk of hospitalization, it is likely that the transmission rate could increase even more on cruise ships as this variant becomes prevalent in the U.S.^{11,12}

Upon identification of the dangers posed by cruise ships and their continued operation, on March 14, 2020 the CDC instituted a *No Sail Order and Suspension of Further Embarkation* for all cruise ships that had not already voluntarily suspended their operations, halting all operations of cruise ships for an indeterminate amount of time.¹³ Subsequent modifications and extensions of this order halted the operation of cruise ships until at least October 21, 2020.¹⁴ The CDC has since proposed a framework for the resumption of cruise ship voyages titled *Framework for*

⁸ Rocklöv et al., *COVID-19 outbreak on the Diamond Princess cruise ship: estimating the epidemic potential and effectiveness of public health countermeasures*, 27 J. OF TRAVEL MED. 1, 2-3 (2020), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7107563/pdf/taaa030.pdf>.

⁹ *Id.* at 4.

¹⁰ Nearly 25,000 people were confined on the Princess Diamond per km². *Id.*

¹¹ Jen Christensen, *CDC now calls coronavirus Delta variant a 'variant of concern'*, CNN (updated Jun. 15, 2021), <https://www.cnn.com/2021/06/15/health/delta-variant-of-concern-cdc-coronavirus/index.html>.

¹² WHO, *Tracking SARS-CoV-2 variants* (updated May 31, 2021), <https://www.who.int/en/activities/tracking-SARS-CoV-2-variants/>.

¹³ Centers for Disease Control and Prevention, *No Sail Order and Suspension of Further Embarkation*, 85 FR 16628, 16628-29 (2020), <https://www.federalregister.gov/documents/2020/03/24/2020-06166/no-sail-order-and-suspension-of-further-embarkation>.

¹⁴ Center for Disease Control and Prevention, *Framework for Conditional Sailing and Initial Phase COVID-19 Testing Requirements for Protection of Crew* (Oct. 30, 2020), https://www.cdc.gov/quarantine/pdf/CDC-Conditional-Sail-Order_10_30_2020-p.pdf.

Conditional Sailing and Initial Phase COVID-19 Testing Requirements for Protection of Crew (“Framework for Conditional Sailing”).¹⁵

Analysis

As part of the Framework for Conditional Sailing, the CDC sets out that the cruise ship operator tests all the ship’s patrons and crew “on the day of embarkation and the day of disembarkation.”¹⁶ The only other mention of onboard testing is when a symptomatic individual

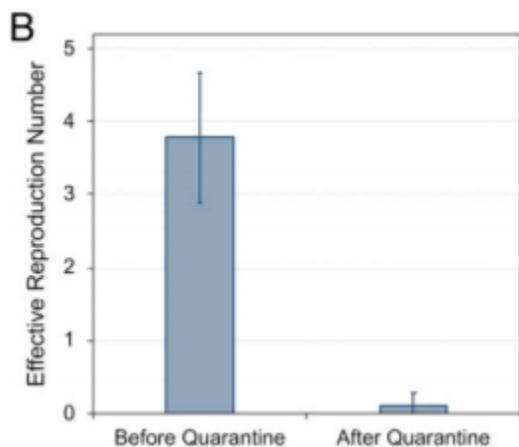


Fig. 1. Effective reproduction rate of COVID-19 before and after quarantine on a cruise ship.

shows symptoms of COVID-19.¹⁷ Nearly fifteen months after COVID-19 was first labelled a pandemic, we have known for quite some time that asymptomatic individuals are still able to shed a viral load and infect others.¹⁸ Not having regular testing standards while patrons and crew are on board is a set up for more severe outbreaks aboard cruise ships. Several studies have shown that

quarantining is an effective mechanism in halting and ultimately stopping the spread of COVID-19 while on cruise ships by lowering the number of infections individuals can infect (Fig. 1, 2).^{19,20} A higher testing cadence would likely allow a cruise ship operator to identify the start of an outbreak sooner and limit its scope.

¹⁵ *Id.*

¹⁶ *Id.* at 25.

¹⁷ Center for Disease Control and Prevention, *Technical Instructions for Simulated Voyages by Cruise Ship Operators under CDC’s Framework for Conditional Sailing Order* (updated May 21, 2021), <https://www.cdc.gov/quarantine/cruise/ti-simulated-voyages-cso.html>.

¹⁸ Azimi et al., *Mechanistic transmission modeling of COVID-19 on the Diamond Princess cruise ship demonstrates the importance of aerosol transmission*, 188 PNAS 1, 1 (2021), <https://www.pnas.org/content/pnas/118/8/e2015482118.full.pdf>.

¹⁹ *Id.* at 1, 5.

²⁰ Rocklöv, *supra* note 8 at 1.

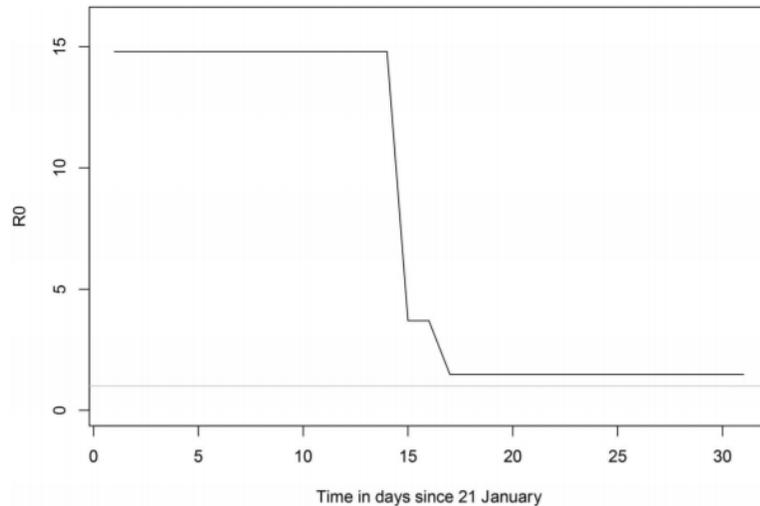


Fig. 2. Effective reproduction rate of COVID-19 drops after the institution of a quarantine on a cruise ship.

The CDC has also identified the efficacy and importance of isolation and quarantine in controlling the spread of COVID-19 on cruise ships. The CDC requires that once a patron is identified as having active COVID-19, they should be quarantined in a single-occupancy cabin for the

remainder of their illness and/or the remainder of the cruise, whichever comes first.²¹ Removing sick patrons from the ship in current guidance is only required when a cruise ship operator believes it to be medically necessary.²² A recent study has shown the importance of evacuation of sick patients in conjunction to quarantine. Modeling a ship around the size of the *Diamond Princess*, and assuming immunity rates of 70% and 50% for the patrons and crew, respectively, quarantining sick individuals slowed but did not stop new COVID-19 infections.²³ Only after the removal of sick individuals did the infection rate onboard quickly reach zero and extinguish (Fig. 3).²⁴

²¹ Center for Disease Control and Prevention, *Interim Guidance for Ships on Managing Suspected or Confirmed Cases of Coronavirus Disease 2019 (COVID-19)* (last reviewed Jan. 26, 2021), <https://www.cdc.gov/quarantine/maritime/recommendations-for-ships.html>.

²² *Id.*

²³ Batista et al., *Minimizing disease spread on a quarantined ship: A model of COVID-19 with asymptomatic infections*, 329 *MATHEMATICAL BIOSCIENCES* 1, 8-9 (2020), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7413099/pdf/main.pdf>.

²⁴ *Id.*

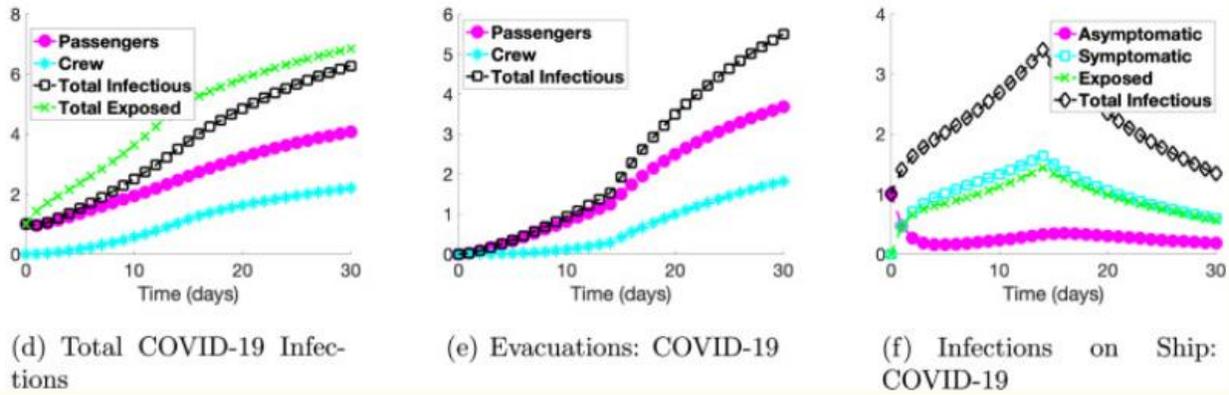


Fig. 3. Showing the effect that quarantine and removal of COVID-19 positive individuals have on infection rate. (d) shows total infections over a 30-day period, (e) shows the evacuations of individuals with COVID-19, (f) shows the subsequent drop in infections due to the evacuations of COVID-19 positive individuals.

Somewhat concerning, the Framework for Conditional Sailing makes no mention of cruise ship ventilation standards. Other CDC guidance, however, highlights that improved

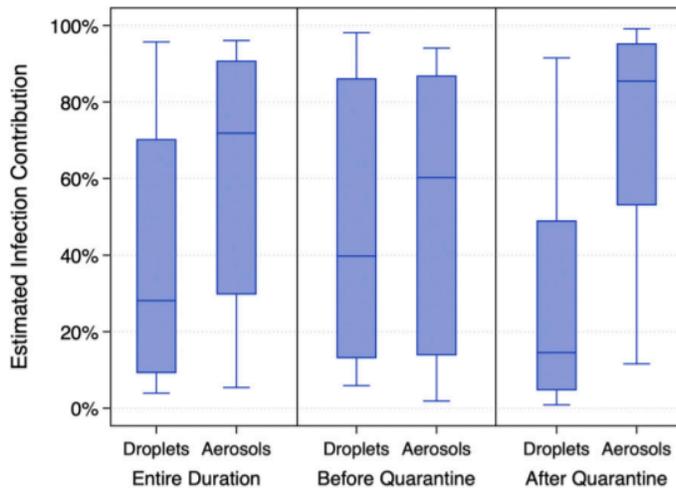


Fig. 4. Model of the *Diamond Princess* COVID-19 outbreak showing the primary modes of infection over the entirety of the voyage, before quarantine, and after quarantine.

ventilation can be an important tool in reducing and diluting potential COVID-19 particles.²⁵ This guidance is directly in line with several studies showing the primary mode of spread of COVID-19 is through air particles. One such study, modelled after the *Diamond Princess* outbreak, found that droplets and aerosols were likely the primary mode of transmission for COVID-19 onboard (Fig

4).²⁶ Again highlighting the importance of both proper ventilation and removal of infectious

²⁵ Centers for Disease Control and Prevention, *Ventilation in Buildings* (updated Jun. 2, 2021), <https://www.cdc.gov/coronavirus/2019-ncov/community/ventilation.html>.

²⁶ Azimi, *supra* note 18 at 6.

passengers, aerosols were still found to be a significant infectant even after quarantine was put into place.²⁷ An initial study performed on *Oasis of the Sea* does show encouraging signs for the effectiveness of cruise ship ventilation.²⁸ Minimal to no movement of aerosols were observed between spaces connected only through the ship's ventilation systems.²⁹ Aerosol movement was observed between connected public spaces, but most of the aerosol dispersed within 15 minutes of its release.³⁰ Although the results are preliminarily positive, there are a number of causes for concern. The study recommends the instillation of improved air filtration, such as MERV-13, as a further precaution.³¹ Additionally, because this study was done on a vacant ship, it is unclear what effect the introduction of cruise ship patrons and crew will have on the transmission of aerosols through the ship.

Actions Recommended

To properly protect cruise ship patrons and crew, I recommend that the CDC update their testing protocol for all individuals on board to follow a more frequent cadence. The CDC currently recommends that all unvaccinated individuals get tested 1-3 days before they travel.³² I therefore see this as an appropriate testing cadence to implement for all individuals on board for the totality of their time on board. Following the current CDC cruise ship guidance of required testing on embarkation, disembarkation, and showing of symptoms has the very real possibility of missing asymptomatic individuals and creating more severe outbreaks.³³ Increasing the testing

²⁷ *Id.*

²⁸ Santarpia et al., *Aerosol and Surface Contamination From Controlled Aerosol Releases in the Cruise Ship Environment to Simulate the Spread of Infectious Disease*, ROYAL CARIBBEAN GROUP, UNIV. OF NEB. MED. CTR., AND NAT'L STRATEGIC RSCH. INST. (Feb. 2, 2021), <https://www.royalcaribbeangroup.com/wp-content/uploads/2021/02/UNMC-Aerosol-study-findings.pdf>.

²⁹ *Id.*

³⁰ *Id.*

³¹ *Id.*

³² Centers for Disease Control and Prevention, *Domestic Travel During COVID-19* (updated Jun. 10, 2021), <https://www.cdc.gov/coronavirus/2019-ncov/travelers/travel-during-covid19.html>.

³³ Azimi, *supra* note 18 at 1.

frequency will give the cruise ship operator the wealth of data that they need to identify any infectious individuals properly and quickly on board, put them in isolation, and begin contact tracing to limit the scope of an outbreak as much as possible. In the uniquely dense environment of a cruise ship, quick institution of the isolation of infected individuals and quarantine of potentially infected individuals is especially important in decreasing the extremely high initial reproduction rate of COVID-19 in this setting.³⁴ I therefore find the current testing cadence proposed by the CDC to be inadequate and ineffective in properly protecting cruise ship patrons and crew and recommend that all individuals on board be tested at least every 3 days.

I also recommend that the CDC institute stricter guidelines for the evacuation of sick patrons or crew members in conjunction with the expansion of the required port city agreements. As construed, sick individuals on a cruise ship only need to be evacuated when they need serious medical attention.³⁵ This will likely be inadequate to protect other patrons and crew from the spread of COVID-19, as studies have shown isolating COVID-19 positive individuals is not enough to adequately stop the spread of the disease, even if high numbers of individuals on board have immunity.³⁶ Studies have also shown the time lag between presentation of symptoms and hospitalization is somewhere between 3 and 11 days, depending on the population and age cohort.³⁷ The upper limit of this range currently exceeds the allowable 7 day cruise limit imposed by the Framework for Conditional Sailing.³⁸ I therefore recommend that an individual with a confirmed COVID-19 case should be removed from the cruise ship within 1-3 days to limit the

³⁴ Rocklöv, *supra* note 8 at 1-3.

³⁵ Centers for Disease Control and Prevention, *supra* note 21.

³⁶ Batista, *supra* note 23 at 8-9.

³⁷ Faes et al., *Time between Symptom Onset, Hospitalization and Recovery or Death: Statistical Analysis of Belgian COVID-19 Patients*, 17(20) INT. J. ENV'T RSCH. & PUB. HEALTH at 1, 4-6 (Oct. 2020), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7589278/pdf/ijerph-17-07560.pdf>.

³⁸ Centers for Disease Control and Prevention, *supra* note 14 at 32.

potential scope of COVID-19 outbreaks on cruise ships. This is especially important to protect the crew, as they are typically the ones who need to interact with sick patrons while keeping the ship running properly.³⁹ To properly follow this guidance, I would also require that cruise ships enter into port agreements not only with their home port, as the current guidance requires, but also with ports they will have access to in 1-3 day increments along their planned itineraries.⁴⁰ I would also require that on a cruise ship's simulated voyage, it makes one of these diversions or stops during its itineraries, regardless of whether the ship has a positive COVID-19 individual on board.

The CDC should also institute stricter guidance on the vaccination requirements of cruise ship patrons and crew. I believe this to be the most effective way to protect all individuals on board, especially the crew. Therefore, all cruise ship crew members should be required to be vaccinated, notwithstanding any medical or religious exemptions, and that cruise ship companies provide these vaccines. Vaccination requirements have already been upheld in several contexts, lending support for this position by the CDC.^{41,42} Although requiring vaccinations for patrons would be the best way to ensure the safety of the crew, it is unclear whether the CDC has the authority to promulgate such a requirement and if cruise ship companies have the power to enforce them, especially in the context of recent litigation.⁴³

³⁹ Dahl, *supra* note 6 at 7.

⁴⁰ Centers for Disease Control and Prevention, *supra* note 14 at 23-24.

⁴¹ Requiring the vaccination of employees is not violative of the ADA. U.S. Equal Employment Opportunity Commission, *What You Should Know About COVID-19 and the ADA, the Rehabilitation Act, and Other EEO Laws* (last updated Jun. 28, 2021), <https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws>.

⁴² A COVID-19 vaccination mandate by a hospital system was upheld. *Bridges v. Houston Methodist Hosp.*, Civil Action H-21-1774, 2021 U.S. Dist. LEXIS 110382, at *5-8 (S.D. Tex. Jun. 12, 2021).

⁴³ Discussed further below in the section **Potential Cause for Concern – Florida v. Becerra**.

My final recommendation would be for the CDC to include guidance on ventilation standards for cruise ships. Ventilation has been shown to be instrumental in reducing the spread of COVID-19 through the filtering of droplets and aerosols, the primary way COVID-19 is spread.^{44,45} Having no guidance for baseline levels of ventilation systems on cruise ships and their effectiveness could make COVID-19 outbreaks more likely and more severe. Adding a requirement for an aerosol study, like the one performed by the *Royal Caribbean Group*, for each cruise ship without individuals on board and during a simulated journey is necessary to determine if the ventilation system is adequate to properly protect patrons and crew members. Potential air filtration deficiencies would need to be recorded and then remedied. Only major deficiencies would likely require full overhaul of a cruise ship's ventilation system and most minor deficiencies could be remedied with the introduction of In-Room Air Cleaners, which typically include high efficiency HEPA filters.⁴⁶

Potential Cause for Concern – *Florida v. Becerra*

Recent litigation stemming from Florida has thrown into question the entire Framework for Conditional Sailing. Decided in *Florida v. Becerra*, a Florida district court has found that the CDC has exceeded its authority in enacting and enforcing the Framework for Conditional.⁴⁷ Additionally, this court found that the CDC did not follow established guidelines when enacting this rule and that the Framework for Conditional Sailing is “arbitrary and capricious.”⁴⁸ Furthermore, this court found that if the Framework for Conditional Sailing is allowed to

⁴⁴ Centers for Disease Control and Prevention, *supra* note 25.

⁴⁵ Azimi, *supra* note 18 at 6.

⁴⁶ American Society of Heating, Refrigerating, and Air-Conditioning Engineers, *In-Room Air Cleaner Guidance for Reducing COVID19 in Air in Your Space/Room* (Jan. 21, 2021), <https://www.ashrae.org/file%20library/technical%20resources/covid-19/in-room-air-cleaner-guidance-for-reducing-covid-19-in-air-in-your-space-or-room.pdf>.

⁴⁷ *Fla. v. Becerra*, No. 8:21-cv-839-SDM-AAS, 2021 U.S. Dist. LEXIS 114297, at * 109 (M.D. Fla. Jun. 18, 2021).

⁴⁸ *Id.* at *113, *121, 128-131.

continue the state of Florida would experience “a substantial likelihood of irreparable injury” in forms of the loss of around 160,000 jobs and lost income to the state in upwards of \$8 billion.⁴⁹ As a result, the court has granted a preliminary injunction which enjoins the CDC from enforcing the Framework for Conditional Sailing and any accompanying guidance against ships arriving, departing, or already in the state of Florida.⁵⁰ This injunction will be stayed on July 1, 2021 at 12:01 am EDT, at which point the Framework for Conditional Sailing and any accompanying guidance will be “non-binding... ‘guideline[s].’”⁵¹ The CDC does, however, have the ability to move to introduce narrower restrictions while also allowing cruise ships to resume service, but any new measures must be introduced before July 2, 2021.⁵²

This court order largely curtails the power the CDC has in promulgating and enforcing their proposed framework for cruise ship and my even stricter recommendations in the state of Florida. This is likely the first of much litigation surrounding this topic; now that the state of Florida has succeeded in obtaining this injunction, many other states with extensive cruise ship operations will likely follow suit. In the end, it is unclear what the CDC will be able to enforce or require of the cruise ship industry. Even so, I highly stress that the CDC takes a crew-centric model in reviewing and updating their Framework for Conditional Sailing. As seen in past outbreaks, the crew is the most at risk for infection while also being responsible for keeping the ship operational.⁵³ The CDC’s focus therefore must be on protecting this vulnerable population while on-board. I believe that my recommendations surrounding testing cadence, increased port agreements, vaccination requirements, and ventilation standardization would be major steps in

⁴⁹ *Id.* at *137.

⁵⁰ *Id.* at *148.

⁵¹ *Id.*

⁵² *Id.*

⁵³ Dahl, *supra* note 6 at 7.

protecting the crew. Even if the CDC is no longer able to propose binding framework, I believe that these measures should still be put forth as highly recommended to all cruise ship companies to ensure that all individuals on cruise ships are properly protected from the continuing dangers of COVID-19.

Sincerely,

Alan Perrotti
J.D. Candidate
Northeastern University School of Law
E-mail: perrotti.al@northeastern.edu

Jeffrey M. Zirger
Information Collection Review Office, Centers for Disease Control and Prevention
1600 Clifton Road NE, MS– D74
Atlanta, Georgia 30329

RE: Phased Approach to the Resumption of Cruise Ship Passenger Operations 2021-09094,
Docket No. CDC-2021-0011

June 30, 2021

I. Executive Summary

In November 2020, the Centers for Disease Control and Prevention (CDC) issued a Framework for Conditional Sailing Order to resume cruise ship operations in U.S. ports. The Framework utilizes a phased approach for cruise line operators to thoughtfully implement COVID-19 mitigation on board passenger vessels. The CDC offers a set of guidelines and recommendations to aid cruise ship operators in their COVID-19 mitigation efforts. To ensure further protection the CDC should adjust guidelines and reporting requirements to mandate vaccinations among crew and passengers, extend weekly testing to passengers, and simplify protocols by not distinguishing between vaccinated and unvaccinated passengers.

II. Background

COVID-19 has affected every country in the world, the devastating outcomes of which we will see for years to come. As of June 30, 2021 the global impact of COVID-19 has been significant with over 181 million confirmed cases of COVID-19 and 3.9 million deaths.¹ In the United States, as of June 30, 2021, there have been over 33 million cases of COVID-19 and

¹ WHO Coronavirus (COVID) Dashboard, World Health Organization, <https://covid19.who.int/> (last visited June 11, 2021)

approximately 601,808 deaths as a result of COVID-19.² Despite the availability of several effective vaccines, COVID-19 still remains an active threat to public health and safety.

Early in the COVID-19 pandemic, cruise ship travel was a vehicle for significant global transmission of the virus. In February 2020, the Diamond Princess cruise ship had over 3,700 passengers with 712 of confirmed cases of COVID-19 leading to a six-week quarantine on-board the vessel.³ The timeline of infections among the passengers and crew indicated that most of the infections happened while aboard the cruise ship.⁴ Ultimately, the quarantine was more effective for the passengers than it was for the crew, who were still tasked with servicing the cruise ship's needs.⁵ Due to the high density of passengers in close proximity, cruise ships were deemed a serious public health risk for the transmission of COVID-19.

On March 14, 2020, the CDC issued a No Sail Order for cruise ships to suspend operations from U.S. ports--the order remained in effect until October 2020.⁶ In the interim, the CDC continued to provide resources and guidelines for cruise ship operators regarding COVID-19 exposure, detection, and management. As COVID-19 cases declined in the United States, the CDC proposed restricted cruise ship operations with a Framework for Conditional Sailing Order, which was published in the Federal Register on November 4, 2020.

The Framework for Conditional Sailing Order offers a multi-phase approach to obtain a COVID-19 Conditional Sailing Certificate as a step towards commencing regular cruise ship passenger operations. The first phase of the Framework establishes requirements for the testing

² *Trends in Number of COVID-19 Cases and Deaths in the US Reported to CDC*, by State and Territory, Centers for Disease Control and Prevention, https://covid.cdc.gov/covid-data-tracker/#trends_dailytrendscases (last visited June 30, 2021).

³ Chris Baraniuk, *What the Diamond Princess Taught the World About COVID-19*, BMJ, <https://www.bmj.com/content/369/bmj.m1632> (April 27, 2020)

⁴ *Id.*

⁵ *See id.*

⁶ *CDC COVID-19 Orders for Cruise Ships*, Centers for Disease Control and Prevention, <https://www.cdc.gov/quarantine/cruise/covid19-cruiseships.html> (last visited June 30, 2021).

of crew and future passengers. The second phase authorizes simulated voyages to evaluate cruise ship operators' COVID-19 mitigation procedures with volunteers. Deficiencies in safety protocols must then be documented and addressed. Medical care agreements with health care providers and housing agreements for quarantine purposes are also required prior to applying for a Conditional Sailing Certificate. The third phase of the Framework entails the application for the Conditional Sailing Certificate and, once obtained, cruise ships can resume restricted passenger travel.

III. Analysis

The COVID-19 pandemic is the largest crisis that the cruise ship industry has ever faced with hundreds of ships carrying infected passengers and crew prior to suspension of operations.⁷ The severe economic strain that the cruise ship industry has experienced due to the grounding of ships has also impacted local and global economies as the cruise industry is an international business that supplements hotel, restaurant, airline, and tourism industries. The cruise industry, while still operating in other countries, needs the economic stimulus of travelers from the United States after experiencing more than a 70% revenue decrease following the CDC No Sail Order.⁸

The resumption of cruise ship operations in the United States impacts the health of a wide array of populations including the passengers, crew, general U.S. population, and international populations. While approximately 60% of the U.S. population has been fully vaccinated there is still a large subsection of the population that is still at risk of contracting the COVID-19 virus.⁹ Moreover, COVID-19 vaccines are not readily available in many other countries, with only 0.9%

⁷ Ana Lucia Rodrigues da Silva, *An Overview of the Impact of COVID-19 on the cruise industry with Considerations for Florida*, 10 *Transportation Research Interdisciplinary Perspectives* 1 (2021).

⁸ *Id.*

⁹ *Trends in Number of COVID-19 Cases and Deaths in the US Reported to CDC, by State and Territory*, Centers for Disease Control and Prevention, https://covid.cdc.gov/covid-data-tracker/#trends_dailytrendscases (last visited June 30, 2021).

of people in low-income countries having received one dose of the vaccine as of June 30, 2020.¹⁰ At this time, leisure travel poses the greatest risk to low-income countries that do not have the resources to address another COVID-19 outbreak.¹¹

While it is important to the global economy to resume cruise ship operations, the outstanding public health concerns make unrestricted cruise travel unfeasible. The CDC's Framework for Conditional Sailing Order is thorough in providing public health oversight with testing, sanitation, and reporting protocols. The benefits of the framework include that the phased approach provides opportunities for evaluating the efficacy of proposed public health measures implemented by cruise line operators. The simulated voyages are beneficial in this approach to reduce risk of errors during real-time cruise trips. The Framework is also flexible in allowing cruise operators to develop their own procedures, as long as they are effective in mitigating COVID-19 outbreak and transmission. Further, the Conditional Sailing Order requires cruise ships to have pre-determined agreements with health care entities and housing facilities in the case an evacuation or quarantine needs to occur.

During Phase II of the Framework, the CDC requires cruise ships to perform daily reports of symptomatic case counts and diagnostic testing of all crew and passengers onboard, which presents a higher annual burden than other requirements at an estimated 11,863 hours.¹² The sum of all the reporting requirements mandated by the Framework creates an annual burden of 20,780 hours for cruise ship operators.¹³ While this can be perceived as cumbersome and costly for

¹⁰ *Statistics in Research Coronavirus (COVID-19) Vaccinations*, Our World in Data, <https://ourworldindata.org/covid-vaccinations> (last visited June 30, 2021).

¹¹ See Mary E. Wilson & Lin H Chen, *Re-starting Travel in the Era of COVID-19: Preparing Anew*, 27 J Travel Med 1 (2020).

¹² Department of Health and Human Services; Phased Approach to the Resumption of Cruise Ship Passenger Operations, 86 Fed. Reg. 22,964 (April 30, 2021).

¹³ *Id.*

cruise line operators, this is a necessary cost to ensure the health and safety of the general public. Most of the reporting requirements are staggered in the initial phases and singular in nature to obtain the Conditional Sailing Certification. Once cruise line operators obtain their Conditional Sailing Certificate, the annual burden of reporting requirements is sure to decrease and will be offset by the increased revenue from resumed operations.

Although the Framework for Conditional Sailing Order imposes a long list of minimum requirements on cruise line operators, it is silent on other areas of concern that could risk the health of passengers and crew. Cruise lines have been operating in other countries and future voyages will likely travel between the United States and other countries. One feature of cruises is that passengers get to explore the mainland when the cruise docks in a destination, and during this time, passengers can be exposed to or spread COVID-19. Moreover, if passengers are infected and asymptomatic, it will lead to greater transmission once they embark onto the cruise ship and come into close contact with other passengers. Using the Diamond Princess as a case study, the rate of transmission onboard the ship was four times higher than on land.¹⁴ With the use of social distancing, mask enforcements, and on-site testing the rate of transmission may be decreased but not eliminated.

The Framework for Conditional Sailing Order is efficient in limiting the burden of all stakeholders involved, but needs further safeguards to protect not only the crew and passengers onboard the ship but also the general public. Especially as countries are struggling to contain COVID-19 resurgences, it is a responsibility of the CDC and the United States to avoid contributing to that burden by introducing strict protocols for leisure travel. Thus far, the

¹⁴ J Rocklov et al., *COVID-19 Outbreak on the Diamond Princess Cruise Ship: Estimating the Epidemic Potential and Effectiveness of COVID-19 Countermeasures*, 27 J. Travel Med. 1 (2020).

Framework mandates minimum requirements with recommendations which can be altered for maximum public health caution.

IV. Actions Recommended

To further prevent the transmission and resurgence of COVID-19, the CDC should implement additional reporting and safety guidelines. At this point in time, the CDC currently recommends that cruise line operators “explore options to vaccinate crew for COVID-19.”¹⁵ Now that multiple COVID-19 vaccines are readily available to the public in the United States, this should be a highlighted priority, if not a mandatory requirement from the CDC. This guideline should also apply to passengers. At the minimum, cruise line operators should collect data on vaccination patterns among passengers to calculate the potential risk of infection while the ship is in transit.

In response to the Framework for Conditional Sailing Order, the state of Florida sued the CDC alleging, among other things, that the Conditional Sailing Order is arbitrary and capricious and exceeds the scope of the CDC’s authority.¹⁶ On June 18, 2021, a Florida District Court granted a preliminary injunction in Florida’s favor temporarily blocking the CDC’s restrictions on resumption of cruise ship passenger operations.¹⁷ In determining whether the Framework is arbitrary and capricious, Florida argued that the CDC did not take into account the development of vaccines in the Conditional Sailing Order.¹⁸ To overcome these legal challenges while still regulating cruise ship operations the CDC should mandate vaccinations for all cruise ship passengers and crew. By mandating vaccinations, the CDC can eliminate several of the protocols

¹⁵ *Technical Instructions for Mitigation of COVID-19 Among Cruise Ship Crew*, Centers for Disease Control and Prevention, <https://www.cdc.gov/quarantine/cruise/management/technical-instructions-for-cruise-ships.html> (last visited June 16, 2021).

¹⁶ *Florida v. Becerra*, No. 8:21-cv-839-SDM-AAS (M.D. Fla. June 18, 2021).

¹⁷ *Id.*

¹⁸ *Id.*

listed in the Framework to ease the cumbersome burden that Florida alleges the CDC is imposing on the cruise line industry.

CDC guidelines distinguish testing and quarantine protocols for fully vaccinated and unvaccinated passengers and crew. This may create a burden for cruise line operators in keeping track of individuals who are vaccinated and applying procedures accordingly. To simplify the testing and quarantine process, the CDC should apply procedures uniformly across vaccinated and unvaccinated passengers and crew. According to CDC updates, vaccinated individuals may still be susceptible to SARS-CoV-2 variants and should be monitored.¹⁹ Creating uniform procedures may also ameliorate the risk of individuals who are unwilling to comply with protocols.

The Framework, as currently proposed, mandates weekly laboratory testing for crew only. With travel and disembarking at various geographical locations, it would increase safety precautions if mandatory weekly testing was extended to passengers. Viral mutations of SARS-CoV-2 may interfere with the efficacy of COVID-19 tests and pose a greater risk if not detected and contained prior to an infected individual's contact with other passengers, crew, or people in port cities. If passengers and crew are tested on a regular basis COVID-19 potential mutations can be identified and proper quarantine protocols can be implemented. The CDC can also mandate that cruise ships do not allow passengers to disembark at port stops to reduce the risk of infection from unknown sources. The Framework currently advises minimal shore leave but does not entirely restrict the activity.

¹⁹ What You Should Know About the Possibility of COVID-19 Illness After Vaccination, Centers for Disease Control and Prevention, <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/effectiveness/why-measure-effectiveness/breakthrough-cases.html> (Apr. 21, 2021).

The CDC's Framework for Conditional Sailing Order is a step in the right direction of regulating passenger ship operations. As the pandemic continues, there are many uncertainties about what the future may look like for public health and safety. To further protect public health, the CDC should adjust the Framework to include more stringent requirements for vaccinations and testing instead of leaving it to cruise operators' discretion.

Sincerely,

Bavani Sridhar
J.D. Candidate
Northeastern University School of Law
E-mail: sridhar.b@northeastern.edu