UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

STATE OF FLORIDA, Plaintiff v. XAVIER BECERRA, Secretary of the Dep't of Health and Human Services, *et al.*, Defendant.	Case No. 8:21-cv-839-SDM-AAS

DECLARATION OF CAPTAIN AIMEE TREFILETTI
DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION

I, Aimee Treffiletti, declare as follows:

1) I am the Program Chief of the Centers for Disease Control and Prevention's (CDC) Vessel Sanitation Program (VSP). VSP is part of the Water, Food, and Environmental Health Services Branch (WFEHSB) in the National Center for Environmental Health's (NCEH) Division of Environmental Health Science and Practice at CDC. CDC is an agency within the U.S. Department of Health and Human Services (HHS). I hold the rank of Captain in the U.S. Public Health Service. The U.S. Public Health Service is one of the uniformed services of the United States.

Members of its Commissioned Corps hold service ranks equivalent to officers of the Navy and Coast Guard, along with corresponding in-service medical titles.

2) I received a Bachelor of Science in Geoscience from William Smith College and a Master in Public Health (MPH), *Environmental Health – Industrial Hygiene Concentration,* from the University of California, Berkeley, School of Public Health. I am also certified as a Registered Environmental Health Specialist (REHS) by the National Environmental Health Association. The REHS is a professional credential through the National Environmental Health Association, an association of environmental health professionals. The REHS credential signifies competency in a range of environmental health issues, including clean air, safe food and potable water, emergency response, vector control, sewage sanitation, occupational health, and hazardous material handling.

3) Prior to assuming my current position, I served in the VSP as Assistant Deputy Program Chief and an Environmental Health Officer. Between 2008 and early 2020, I conducted almost 700 cruise ship public health inspections and trained over 4,000 cruise ship managers and supervisors on maritime public health principles. I also worked as an Industrial Hygienist in CDC's Office of Health and Safety and as an Environmental Health Scientist in the Agency for Toxic Substances and Disease Registry within HHS.

4) VSP is an applied environmental health program with a clearly defined mission to help the cruise ship industry prevent and control the introduction, transmission, and spread of gastrointestinal illness on cruise ships in U.S. waters. The program's

environmental health officers review, inspect, and provide feedback on cruise ship sanitation, food safety, water safety, ventilation, and vector control activities during routine biannual ship inspections.

5) I have served as the Program Chief of the VSP since 2016. My duties include developing and maintaining partnerships with other Federal agencies and international agencies, including the U.S. Coast Guard, CDC's Division of Global Migration and Quarantine, the U.S. Food and Drug Administration, U.S. Customs and Border Protection, the National Sanitation Foundation, the World Health Organization, the European Union Ship Sanitation Program, the Public Health Agency of Canada's Travelling Public Program, the New South Wales, Australia Ship Sanitation Program, and the Caribbean Public Health Agency. I also routinely engage with international public health agencies, cruise lines, equipment manufacturers, shipyards, and public health consultants on matters relating to maritime public health.

6) Based on my years of experience with the VSP, I am familiar with the cruise ship industry's policies and practices to mitigate onboard illnesses and their response when outbreaks of illness occur on board cruise ships. VSP data shows that in the past 10 years (2009-2019), out of 2,338 public health inspections of cruise ships in U.S. waters, approximately 75 ships (3%) received a failing inspection score of 85 or below out of 100 points. Additionally, 140 ships (6%) received close to failing scores of between 86 and 89. These low and failing scores occurred despite the VSP's issuance of an Operations Manual that outlines minimum public health and

sanitation standards for cruise ships in U.S. waters, and VSP conducting six 2.5-day public health training courses per year for cruise ship managers and supervisors.

7) Between 2012 and 2019, there were 148 onboard outbreaks of acute gastroenteritis (AGE) cases (defined as when a cumulative percentage of AGE cases reaches 3% among passengers or 3% among crew) on cruise ships in U.S. waters and there were 100 onboard elevations of AGE cases (defined as when a cumulative percentage of AGE cases reaches 2% among passengers or 2% among crew, but not 3%). These elevations and outbreaks required VSP involvement and action, which ranged from remote monitoring and supervision of the cruise ship operator's response to an onboard, field response by VSP. Thus, even in regard to a well-understood, documented, and researched public health phenomenon on cruise ships, for which the cruise ship industry receives extensive instruction, training, and monitoring, breakdowns in cruise ship operators' health and safety protocols can be expected to occur.

8) Upon information and belief, on or about January 20, 2020, the *Diamond Princess* cruise ship departed Yokohama, Japan. On January 25, 2020, a symptomatic passenger departed the ship in Hong Kong, where he was later confirmed to have COVID-19. Upon the ship's return to Yokohama, Japanese authorities quarantined all passengers and crew on board the ship. Among the 3,711 *Diamond Princess* passengers and crew, 712 (19.2%) were subsequently confirmed to have COVID-19, 37 required intensive care, and nine died.

9) In January 2020, as part of its Coronavirus emergency response efforts, the CDC Emergency Operations Center created the Cruise Ship Task Force (CSTF) to manage the international *Diamond Princess* COVID-19 humanitarian crisis. The U.S. Government's response to this humanitarian crisis included, among other things, the repatriation and subsequent 14-day quarantine at U.S. Department of Defense facilities in Texas and California of approximately 329 U.S. citizens.

10) The CSTF was additionally tasked to respond to an increasing number of COVID-19 cruise ship outbreaks that were occurring both domestically and internationally. The CSTF, along with the U.S. Coast Guard and other components of the U.S. government, assisted in the emergency evacuation of over 40 cruise ships, aiding more than 260,000 passengers to safely disembark. After the conclusion of these operations, the CSTF was disbanded in April 2020 and superseded by the Maritime Unit, which is part of CDC's COVID-19 Global Migration Task Force (GMTF).

11) GMTF, as part of CDC's COVID-19 response, is composed of individual units that develop evidence-based international and domestic travel recommendations; protect the health of U.S.-bound travelers arriving at U.S. air, sea, and land ports of entry; coordinate contact investigations for ill or exposed travelers; provide technical assistance to cruise ships to prevent and control the spread of COVID-19 among passengers, crew, and shoreside communities; and develop and implement overseas and domestic guidance to prevent and mitigate COVID-19 in U.S.-bound refugees, immigrants, migrants, and globally mobile populations.

12) Because of VSP's vast experience on cruise ships and my role in managing the disinfection and crew quarantine of another Princess cruise ship, the *Grand Princess,* discussed below, I was asked to lead the CDC Maritime Unit in support of CDC's COVID-19 response on cruise ships. I have been leading the Maritime Unit since April 15, 2020.

13) In my capacity as Maritime Unit Lead, I oversee a staff of between 25 and 30 CDC personnel, including medical doctors, epidemiologists, laboratorians, public health officers, environmental health officers, health communicators, and administrative staff. These staff compose the Maritime Unit's various teams, which, among other duties, gather and compile epidemiologic and other data; review laboratory test results and assist cruise ship operators in building laboratory capacity; assist cruise ship operators with embarking and disembarking crew and responding to crew illnesses onboard; create COVID-19 surveillance systems for cruise ships; plan for future cruise ship operations; and assist with communications to media, interagency partners, cruise industry, and the public.

14) Since HHS/CDC's original No Sail Order, signed on March 14, 2020, CDC has worked to control COVID-19 on cruise ships that remained at sea, while protecting against further introduction and spread of COVID-19 into U.S. communities. As of April, 28, 2021, CDC has expended an estimated 100,000 person-hours on the cruise ship COVID-19 response since March 14, 2020—in addition to the thousands of hours invested by other HHS components, other U.S.

government agencies, and state and local authorities. CDC continues to have regular conversations by phone and email with cruise lines, often daily.

15) I additionally liaise with and provide updates to GMTF leadership, and collaborate with international, federal, state, and local partners. I also work closely with CDC's international maritime public health partners, who share concerns regarding the restart of cruise ship operations during a pandemic.

16) During February 7–23, 2020, the largest cluster of COVID-19 cases outside mainland China occurred on the *Diamond Princess* cruise ship, which was quarantined in the port of Yokohama, Japan. A scientific article published in the Journal of Travel Medicine by Rocklöv et al. later demonstrated that the *Diamond Princess* cruise ship experienced an onboard R_0 (basic reproduction rate) for COVID-19 of 14.8 before ship-wide quarantine was enacted.[1] This means that each case onboard the *Diamond Princess* transmitted COVID-19 to approximately 15 other people. This reproduction rate is approximately four times higher than the R_0 of the original epicenter of the outbreak in Wuhan, China, which was 3.7, meaning that each person with COVID-19 in the early days of the outbreak in Wuhan transmitted the disease to approximately four other people.

17) During February 11–21, 2020, the *Grand Princess* cruise ship sailed roundtrip from San Francisco, California, making four stops in Mexico (voyage A).

[1] Rocklöv J, Sjödin H, Wilder-Smith A. COVID-19 Outbreak on the Diamond Princess Cruise Ship: Estimating the Epidemic Potential and Effectiveness of Public Health Countermeasures. J. Travel Med. 2020; 18;27(3):taaa030. doi: 10.1093/jtm/taaa030.

Approximately, 1,111 crew and 68 passengers from voyage A remained on board for a second voyage that departed San Francisco on February 21 (voyage B), with a planned return on March 7. On March 4, a clinician in California reported two patients with COVID-19 symptoms who had traveled on voyage A, one of whom had positive test results for SARS-CoV-2. CDC notified the cruise line, which began cancelling group activities on voyage B. Additional cases of COVID-19 among persons who traveled on *Grand Princess* voyage A, but not on voyage B, were subsequently identified. One death was also reported at that time. On March 5, a U.S. Government response team was transported by helicopter to the ship (which was still on voyage B) to collect specimens from 45 passengers and crew with respiratory symptoms for SARS-CoV-2 testing; 21 (46.7%), including two passengers and 19 crew, had positive test results. The two *Grand Princess* voyages (voyages A and B) were ultimately associated with approximately 164 confirmed COVID-19 cases, including nine deaths.

18) I, along with other staff from VSP and WFEHSB, deployed to California to support the *Grand Princess* disinfection and crew quarantine and to conduct environmental assessments. Beginning on March 7, staff from WFEHSB deployed for a total of 112 person-days (i.e., number of personnel times number of days) to: support CDC's infection control team and international cruise ship team in the COVID-19 response; review ship disinfection and crew quarantine procedures and oversee implementation; collect environmental samples before and after disinfection to evaluate effectiveness; and conduct an environmental assessment of the ship,

including checking food operations, potable water, pest management, ventilation, and waste management.

19) A 14-day onboard quarantine for all *Grand Princess* crew members potentially exposed to the virus that causes COVID-19 began on March 21, 2020 and ended on April 4, 2020. I led a team of WFEHSB staff which boarded the ship daily to monitor implementation of the quarantine plan. During the *Grand Princess* mission, team members coordinated with a variety of agencies shoreside, including: Disaster Medical Assistance Teams, U.S. Public Health Service, U.S. Customs and Border Protection, the Port of San Francisco, U.S. Department of Health and Human Services/Assistant Secretary for Preparedness and Response, U.S. Department of State, U.S. Coast Guard, local law enforcement, and San Francisco Bar Pilots Association.

20) The COVID-19 outbreak onboard the *Grand Princess* cruise ship demonstrates the enormous logistical, operational, and financial burdens involved in placing just one cruise ship under quarantine. More than 2,000 U.S. persons were placed under federal quarantine on four U.S. Department of Defense facilities for 14 days. Persons requiring medical attention for other conditions or for symptoms consistent with COVID-19 were evaluated, tested for SARS-CoV-2 infection, and hospitalized if indicated. Repatriation flights for foreign nationals were organized by several governments in coordination with U.S. federal and California state government agencies. Foreign crew completed quarantine on board this ship under the supervision of the cruise company with technical assistance provided by public

health experts. Due to transfers of crew members from the *Grand Princess* to other ships before the voyage was halted, three other ships were ordered to return to port and were temporarily detained.

21) Between February and April 2020, CDC issued 27 separate notifications of COVID-19 outbreaks on cruise ships to international, state, and local health departments. This represents almost 11,000 cruise ship passengers who required contact tracing. Contact tracing is used by health departments to slow the spread of COVID-19 by letting people know that they may have been exposed and that they should self-quarantine or isolate if symptoms develop.

22) These approximately 11,000 cruise ship passenger contacts are significantly more than the nearly 3,000 contacts identified from flight investigations during the same timeframe. Medical evacuation efforts necessitated by these outbreaks required resource-intensive operations that involved multiple small boats to ferry contagious crew and passengers to shore and high levels of coordination between Federal, State, and local public health, maritime, and other governmental authorities.

23) These response efforts drew valuable resources away from the immense Federal, State, and local efforts to contain and mitigate the spread of COVID-19. State and local public health officials further stated that they faced an increasing burden supporting cruise ships attempting to make port with ill passengers or crew and struggled to repatriate passengers and crew while also protecting the limited medical assets available to their communities. The intensive care requirements for infected passengers and crew in need of life-saving critical care also greatly stressed

an already overtaxed healthcare system that at the time was facing shortages of masks, test kits, beds, and ventilators needed to respond to COVID-19.

24) Cruises vary in size with larger cruises involving populations of more than 6,000 passengers and crew who move in closed and semi-closed settings that facilitate transmission of COVID-19. Cruises include frequent events that bring passengers and crew close together, including group and buffet dining, entertainment events, and excursions. Cruise ship cabins are small, increasing the risk of transmission between cabinmates. Crew closely quarter in crowded spaces for eating and sleeping. Infection among crew members may lead to transmission on sequential cruises on the same ship because crew members may continue to work and live onboard the ship from one cruise to the next. Crew from one ship may in turn serve onboard multiple different ships for subsequent voyages, which can amplify transmission.

25) Travelers from different countries brought together in the often crowded, enclosed and semi-enclosed environments onboard ships can facilitate the spread of person-to-person, foodborne, or waterborne diseases. The most frequently reported cruise ship outbreaks involve respiratory infections, AGE infections (such as norovirus), and vaccine-preventable diseases other than influenza, such as varicella (chickenpox). Outbreaks on ships can be sustained for multiple voyages by transmission among crew members who remain onboard or by persistent environmental contamination.

26) Due to this increased transmission risk on cruise ships, on March 14, 2020, the CDC Director issued a *No Sail Order and Other Measures Related to Operations* directing cruise ships not voluntarily suspending operations to comply with certain measures (85 Fed. Reg. 16628). The CDC's March 14, 2020, Order followed a March 13, 2020, announcement by the Cruise Line International Association (CLIA), the leading industry trade group, that its members would voluntarily suspend cruise ship operations. On March 17, 2020, CDC issued a Level 3 Travel Health Notice warning all travelers to defer cruise travel worldwide based on widespread ongoing transmission of COVID-19. Despite the announcement by CLIA, the application of the March 14, 2020 Order, and the Level 3 Travel Health Notice, cruise ships continued to be associated with new COVID-19 outbreaks.

27) Between March 1 and April 15, 2020, confirmed COVID-19 outbreaks were reported on approximately 43 additional cruise ships with passengers including the *Costa Magica*, *Costa Favolosa*, *Celebrity Eclipse*, *Disney Wonder*, *Holland America Zaandam*, and *Coral Princess*. *Costa Magica* and *Costa Favolosa* reported at least 110 ill crew members, which required emergency medical evacuations, in coordination with U.S. Coast Guard and public health personnel. Six infected crew members on the *Magica* and seven from the *Favolosa* required emergency medical evacuations for life-critical care. The *Zaandam* cruise ship reported illness consistent with COVID-19 in at least 269 persons onboard, including 11 deaths with 10 deaths among passengers (one for non-COVID-19 related reasons). The *Eclipse* returned to San Diego, California, after being denied entry into other ports, with local health departments

left to deal with approximately 108 confirmed cases and 125 suspect cases. The *Disney Wonder* experienced a large outbreak of 292 cases, including 260 crew members and 32 passengers (including 3 passenger deaths).

28) These medical evacuation efforts were resource-intensive operations that required use of small boats to transport contagious crew to shore, U.S. Coast Guard air medical evacuation, and high levels of coordination between international, Federal, State, and local public health, maritime, and other governmental authorities. Moreover, safely evacuating, triaging, and repatriating cruise ship passengers and crew involved complex logistics, incurred financial costs at all levels of government, and diverted resources away from larger efforts to suppress or mitigate COVID-19.

29) Accordingly, to protect public health and safety and prevent the further introduction, transmission, and spread of COVID-19 into and throughout the United States, the CDC Director issued *No Sail Order and Suspension of Further Embarkation; Notice of Modification and Extension and Other Measures Related to Operations*, modifying and extending the previous March 14, 2020 Order, effective on April 15, 2020 (85 Fed. Reg. 21004).

30) Under the April 15, 2020 Extension, as a condition of obtaining controlled free pratique—that is, permission to enter U.S. ports, disembark, and operate under certain conditions—cruise lines were required to submit plans to prevent, mitigate, and respond to the spread of COVID-19 on board to ensure a safe work environment and disembarkation for crew members.

31) Following the April 15, 2020 Extension, CDC published its *Interim Guidance for Mitigation of COVID-19 Among Cruise Ship Crew* to assist cruise ship operators in preventing, detecting, and medically managing confirmed and suspected SARS-CoV-2 infections and exposures among crew members. CDC also established an enhanced surveillance process to provide a more complete picture of COVID-19 activity on cruise ships by requiring weekly submission of the "Enhanced Data Collection (EDC) During COVID-19 Pandemic Form (OMB Control Number 0920-0134, exp. 03/31/2022)." Since then, the EDC form has been used to conduct surveillance for COVID-19 among crew who remained on board cruise ships (85 Fed. Reg. 62732).

32) To continue to protect public health and safety, and prevent the further introduction, transmission, and spread of COVID-19 into and throughout the United States, the CDC Director signed a *Second Modification and Extension of No Sail Order and Other Measures Related to Operations* on July 16, 2020, (85 Fed. Reg. 44085), and *Third Modification and Extension of No Sail Order and Other Measures Related to Operations* on September 30, 2020, (85 Fed. Reg. 62732). This last order, among other things, continued to suspend passenger operations on board cruise ships through October 31, 2020, pending cruise lines' submission of their COVID-19 response plans.

33) On October 30, 2020, CDC issued a *Framework for Conditional Sailing Order* (85 Fed. Reg. 70153). The CSO takes a phased approach to resuming cruise ship passenger operations in U.S. waters. There are four phases to the CSO: mass crew testing and lab capacity building for future travelers (passengers and crew) (Phase 1); preparation for simulated voyages (Phase 2A) and simulated voyages (Phase 2B);

applying for a COVID-19 Conditional Sailing Certificate (Phase 3); and restricted passenger voyages (i.e., revenue voyages with public health precautions in place to mitigate COVID-19 spread) (Phase 4).

34) This phased approach was adopted based on the best available science including epidemiology, surveillance data obtained from weekly submission of the EDC report from cruise ships, advancements in testing, laboratory analysis, and drug therapeutics. CDC also incorporated lessons learned from its review of cruise ship operators' No Sail Order (NSO) response plans submitted in response to the April 15, 2020 NSO Extension, passenger and crew disembarkations and repatriations that occurred early in the pandemic, and attempts to prematurely restart cruises in foreign jurisdictions.

35) In drafting the CSO, CDC carefully considered public comments submitted as part of a Request for Information (RFI) published in the Federal Register on July 20, 2020. That RFI, issued in conjunction with the July 2020 extension of the NSO, sought comment on 26 questions, many with multiple subparts, concerning cruise ship planning and infrastructure, resumption of passenger operations, and related topics (85 Fed. Reg. 44083). The 60-day comment period ended on September 21, 2020 and nearly 13,000 comments were received.

36) Comments received related to the reduction of number of passengers, the need for routine testing of passengers and crew, social distancing, coordination between CDC and the cruise industry, limiting ports of call to private islands, agreements with local public health and medical facilities, and the economic benefits of cruising.

37) The State of Alaska submitted comments that among other things stressed the need for cruise ship operators to work with local authorities and have in place prearranged shoreside contracts for housing, transportation, and other services for passengers and crew requiring evacuation from cruise ships. The Florida Ports Council, the Chief Executive and Port Director's Office for Port Everglades, and President and CEO of Tampa Port Authority, similarly submitted comments stressing the need for cruise ship operators to develop health and safety protocols relating to the use of local medical facilities and the safe evacuation and transportation of potentially infected cruise ship passengers in way that does not burden local resources. See Exhibit A (selected comments).

38) Approximately 74% of RFI respondents indicated that cruise ship passenger operations should immediately resume despite the surging pandemic, while 26% of respondents supported continuing the No Sail Order. However, about 98% of respondents supported cruise ship operators denying boarding to passengers with COVID-like illness or confirmed COVID-19 infection. Approximately 65% of respondents also supported denying boarding to passengers with known COVID-19 exposure in the previous 14 days before embarkation. A majority of respondents (74%) additionally supported requiring that cruise ship operators test passengers and crew prior to embarkation. Furthermore, approximately 90% of respondents supported cruise ship operators reducing passenger and crew loads to reduce the risk of COVID-19 transmission, while approximately 85% supported the wearing of face masks by passengers.

39) While CDC bases its public health determinations on the best available science and not on public opinion, public responses demonstrated a willingness to accept shipboard and shoreside measures to mitigate the risk of transmitting COVID-19 onboard cruise ships.

40) In drafting the CSO, CDC also considered alternatives. One alternative considered was allowing cruise ship operators to return to unrestricted passenger operations without any public health oversight. This alternative was deemed unacceptable because cruise ship travel is known to contribute to COVID-19 transmission and additional outbreaks would further burden ports and local communities.

41) For example, as late as July 2020, after the suspension of cruise ship operations in the United States in March, outbreaks on board cruise ships occurred in foreign countries that allowed cruise ships to resume operations. Upon information and belief, on the Hurtigruten cruise ship *MS Roald Amundsen*, 41 crew members and 21 passengers were confirmed to have COVID-19 after two voyages occurring between July 17–24 and July 25–31 in Norway. The ship had 209 passengers on the first voyage and 178 on the second. The cruise ship operator permitted passengers to disembark on July 31, before the announcement of the outbreak, potentially spreading the virus to dozens of towns and villages along Norway's western coast and setting off an effort by public health authorities to trace and locate the nearly 400 potentially exposed passengers. The protocols adopted by the Hurtigruten included new sanitation measures, elimination of self-serve buffet

dining, implementation of onboard social distancing procedures, operating at 50% capacity, a preboarding health questionnaire, and restricted shore excursions. Accordingly, simply relying on cruise ship operators to implement their own COVID-19 health and safety protocols was not seen as optimal as a careful, phased approach to resuming cruise ship passenger operations.

42) Another alternative considered was continuing to issue "No Sail Orders" as occurred between March 14 and September 30, 2020. However, this alternative was found to be less optimal than the CSO's phased approach, which takes into account the evolving state of the pandemic—in the United States and worldwide—and allows CDC to incorporate the best available science including advancements in vaccines and drug therapeutics. This approach also allowed cruise ship operators an opportunity to demonstrate the effectiveness of their health and safety protocols at mitigating COVID-19 through a government-supervised process.

43) In drafting the CSO, CDC further considered efforts by cruise ship operators to advance their public health response to COVID-19. For example, under the co-chairmanship of former Secretary of Health and Human Services Michael O. Leavitt, and former FDA Commissioner Dr. Scott Gottlieb, two cruise lines, Royal Caribbean Group and Norwegian Cruise Line Holdings, assembled a "Healthy Sail Panel" (HSP) of subject-matter experts from a variety of disciplines.

44) CDC sent two observers to the HSP meetings who, while not acting as participants, engaged in dialogue, and exchanged information with other subject-matter experts. The CDC Maritime Unit reviewed the documents from these

meetings and the HSP's final recommendations. While the Maritime Unit agreed that some approaches identified in the HSP's recommendations, including contact tracing, sanitation, in-cabin medical visits, and education of passengers and crew about COVID-19, could help improve traveler comfort and public health outcomes, it found them inadequate to sufficiently mitigate the introduction, transmission, and amplification of COVID-19 on cruise ships and to U.S. communities. Accordingly, more emphasis was needed on actions to mitigate potentially infected travelers from boarding ships in the first instance so that fewer government resources would be needed from local, state, and federal agencies—as well as onshore medical facilities—to manage cases and outbreaks.

45) In drafting the CSO, the Maritime Unit agreed with the HSP that a "phased approach" to resuming passenger operations was needed, including simulated voyages. In addition, the Maritime Unit agreed with the panel's recommendation that cruise ship operators plan for "small-, moderate-, and large-scale debarkation scenarios in advance of cruising."

46) Phase 1 of the CSO consisted of testing and additional safeguards for crew members and the building of additional laboratory capacity by cruise ship operators to test future passengers. The CSO originally required that cruise ship operators with ships in U.S. waters complete this first phase by December 29, 2020 (60 days after the effective date of the CSO). Cruise ship operators were expected to collect clinical specimens for SARS-CoV-2 testing from all crew currently onboard their cruise ships

and arrange for the transportation and testing of those specimens at a shoreside laboratory facility.

47) To assist cruise ship operators in meeting the requirements of Phase 1 of the CSO, CDC's Maritime Unit established a Laboratory Team with four to five full-time experts in multiple disciplines led by laboratory subject matter experts. This Laboratory Team and its subject matter experts met with cruise line and manufacturer representatives to discuss equipment supply concerns and worked with individual cruise lines to address technical issues, provided consultations regarding which testing instruments to procure, and helped them identify shoreside laboratories and laboratory equipment manufacturers. The Maritime Unit's Laboratory Team has conservatively expended over 5,000 personnel-hours on these efforts.

48) By December 29, 2020, cruise ship operators with ships in U.S. waters, in coordination with CDC, were also expected to implement onboard testing capabilities to be able to test all symptomatic travelers (crew and future passengers) and their close contacts for SARS-CoV-2. However, cruise ship operators informed CDC that, because of supply issues for procuring onboard laboratory equipment, not all cruise ships operating in U.S. waters were able to procure necessary equipment. Accordingly, on December 23, 2020, CDC announced that it would exercise enforcement discretion for Phase 1 of the CSO to allow cruise ship operators additional time to comply with the crew testing and lab capacity requirements.

49) As of April 26, 2021, 95% of cruise ships under the jurisdiction of the CSO (56 out of 59 cruise ships) have performed mass screening testing of all crew.

Additionally, 97% (57 out of 59 ships) have had their plans for onboard point-of-care laboratory assays, instruments, and reagents approved by CDC. However, while 92% (54 out of 59 ships) have procured testing supplies as specified by the manufacturer of their testing instruments, only 80% (47 out of 59 ships) have had those testing instruments installed on their ships. Cruise lines have also reported that most onboard medical staff have been trained on specimen collection and the use of their onboard testing instruments. Accordingly, as of April 26, 2021, 80% (47 out of 59 ships) have fully completed Phase 1, the largest limiting factor being installation of onboard testing instruments and are ready to proceed to Phase 2.

50) On April 2, 2021, CDC released the technical instructions for Phase 2A of the CSO. The approximately 3-month delay between December 29, 2020 (the date by which most cruise ship operators were expected to complete mass crew testing) and April 2, 2021 (the date the Phase 2A guidance was issued), can be attributed to the additional time needed for cruise ship operators to conduct mass crew testing and procure testing instruments and supplies for future embarkations of passengers and crew. Delay can also be attributed to the need to draft the additional new guidance, consult with federal and local partners, and the change in Administration on January 20, 2021, which involved a change in CDC and other federal leadership, as well as the need to advise and brief these individuals on the history and workings of the CSO.

51) During Phase 2A, cruise ship operators will work to establish agreements at ports where they intend to operate that must be approved by port authorities and

local public health authorities. These agreements will ensure that the necessary infrastructure is in place in the event of an outbreak of COVID-19 onboard cruise ship operators' ships, including healthcare capacity and housing to isolate infected people and quarantine those who are exposed. It must also include a plan and timeline for vaccination of cruise ship crew and seaport personnel prior to resuming passenger operations. Under these agreements, port authorities and local public health authorities may determine the maximum number of ships and travelers permitted to operate out of their ports considering their medical and other capacity in the event of a significant outbreak of COVID-19.

52) On April 28, 2021, CDC issued a "Dear Colleague" letter (Exhibit B) to cruise line industry representatives based on the results of twice weekly meetings with those representatives and other federal agencies. This letter provides important clarifications regarding CDC's previously issued Phase 2A technical instructions and greater flexibility regarding how cruise ship operators choose to comply with CDC's requirements, including through entering into multi-jurisdictional port agreements instead of agreements with individual port jurisdictions. It also reiterates the CDC's commitment to the phased resumption of passenger operations around mid-summer.

53) The intent of Phase 2A is to provide port and local health authorities with an opportunity to determine to what extent they wish cruise ship travel to resume in their own communities. Phase 2A does not impose requirements on port and local health authorities, but rather requires the cruise ship operator to demonstrate that they have conferred with these authorities prior to conducting a simulated voyage or

engaging in restricted passenger voyages. Port and local health authorities are under no obligation to deliberate or enter into a Phase 2A agreement with a cruise ship operator. Under the recent "Dear Colleague" letter, if a port or local health department desires to enter into a Phase 2A agreement with a cruise ship operator but concludes that it lacks sufficient medical and housing capacity in the event of an outbreak, the cruise ship operator would be authorized to enter into a "multi-jurisdictional" agreement with multiple port authorities to ensure sufficient capacities are in place provided that all relevant jurisdictional authorities agree to this arrangement.

54) In developing the Phase 2A technical instructions, CDC consulted with representatives from international, federal, state, and local partners, including European Union's Healthy Gateways Maritime Transport team, World Health Organization's Border Health Risk Dissemination Unit, Caribbean Public Health Agency, U.S. Coast Guard, Florida Department of Health, Alaska Department of Health and Social Services, and Port Canaveral, Florida.

55) During these discussions, port and local health authorities—including Florida, Alaska, California, Washington, and Louisiana—expressed the following concerns: 1) unease over cruise ship operators introducing COVID-19 into local communities by prematurely resuming cruise ship passenger operations during an ongoing pandemic; 2) need for cruise ship operators to share individual patient data with local public health partners to ensure timeliness and transparency; 3) estimate of the approximate number of persons embarking and disembarking on any given day for

community planning purposes; 4) routine testing of crew and port partners to protect the public health; 5) need for advance agreement on all aspects of medical care (including disembarkation, transportation, and facilities); and 6) cruise ship industry identification of housing facilities for travelers who need to be isolated and quarantined. Lastly, partners stressed the need to have these details in writing and agreed to by all parties.

56) The Maritime Unit includes a team of laboratory subject matter experts to keep up to date on the latest testing advancements. During initial phases of the CSO, antigen testing was not recommended because vaccines were not yet available and this testing is more likely to miss cases of SARS-CoV-2 infection (i.e., lower sensitivity) when compared to reverse transcription polymerase chain reaction (RT-PCR) testing. CDC has several studies being performed that compare antigen screening testing to RT-PCR and, sometimes, viral culture. Preliminary data has shown that, when used for screening purposes, antigen testing is both less sensitive (i.e., more false negatives) and less specific (i.e., more false positives) than when used for diagnostic purposes (i.e., for symptomatic or exposed persons).

57) Because the cruise environment represents a high-risk, residential congregate setting, the most accurate (i.e., most sensitive and specific) test should be used during Phases 1 and 2 of the CSO. However, CDC's April 28, 2021 "Dear Colleague" letter (Exhibit B) clarifies that based on lessons learned from the initial phase of crew testing, advancements in laboratory testing in the U.S., and greater availability and

more widespread use of vaccines, the Maritime Unit will be updating technical instructions to include all forms of viral testing, including antigen.

58) In the next phase (2B), simulated (trial) voyages will allow cruise ship operators, crew, and seaport personnel to practice their COVID-19 operational procedures with volunteers simulating the role of passengers before ships sail with paying passengers. Simulations will help cruise ship operators to identify practices that are successful at mitigating COVID-19 on board their ships, as well as any deficiencies in their health and safety protocols that need to be addressed prior to resuming passenger operations. Phase 3 will include an application process to certify ships for restricted passenger voyages. On May 5, 2021, the documents for Phase 2B and Phase 3 were finalized, posted to CDC's website,[2] and made available to cruise ship operators (Exhibits C, D). These documents include:

- Eligibility criteria and requirements for the simulated voyage;
- Guidance for CDC inspections of cruise ships during simulated and restricted passenger voyages; and
- Operational procedures to assist cruise ship operators in mitigating the risk of spreading COVID-19, including requirements and recommendations on prevention measures, surveillance for COVID-19 on board, laboratory testing, infection prevention and control, face mask use, social distancing, passenger interactive experiences, and embarkation and disembarkation procedures.

[2] https://www.cdc.gov/quarantine/cruise/covid19-operations-manual-cso.html and https://www.cdc.gov/quarantine/cruise/ti-simulated-voyages-cso.html

With the release of this guidance, cruise ship operators have the information they need to move through Phases 2 and 3 and ultimately commence passenger operations.

59) COVID-19 vaccines will play a critical role in the safe resumption of passenger operations and plans to vaccinate crew and seaport personnel are an important part of returning to passenger operations. However, while some cruise lines have publicly stated that they intend to require passengers to be vaccinated, others have announced that they do not plan to require vaccinations or have announced no plans. Some passengers, notably children, are also not currently eligible to get a COVID-19 vaccine. Furthermore, cruise lines have not indicated how they intend to seek and confirm information about passenger vaccinations. CDC intends to update testing and quarantine requirements for passengers and crew to closely align with CDC's guidance for fully vaccinated and not fully vaccinated persons.

60) As part of its ongoing discussions with cruise line representatives, CDC has reviewed a purported vaccination statement submitted by these representatives outlining the industry's proposed vaccination goals. (Exhibit E) Upon information and belief, cruise lines are in discussion with several Governors' offices in States in which cruise ship operators plan to operate, for such states to provide the necessary supply of surplus vaccine to vaccinate crew, and are working to arrange a mutually agreed path forward. While CDC supports States using surplus vaccine supplies to vaccinate cruise ship crew, potential barriers to this plan exist. This includes perceptions of prioritizing foreign cruise ship workers over States' residents and other

competing priority groups; logistics and time involved in administering a 2-dose vaccine with a 21- to 28-day wait in between doses; whether both doses will be administered by the same jurisdiction; and unresolved issues regarding whether cruise ship operators will reimburse States for cost of the vaccines and their administration. While the Johnson & Johnson vaccine is a one dose vaccine that could expedite vaccination of cruise ship crew, there is high demand for use of this vaccine among other population groups, including the unhoused, college students, and other difficult to reach populations.

61) Furthermore, based on previous experience relating to vaccination for the influenza vaccine, a vaccine that is inexpensive and widely available, there is reason to doubt that many cruise ship operators will be able to fully vaccinate crew. In discussions with the Maritime Unit, senior cruise line executives have pointed to voluntary influenza vaccination rates for crew being an indicator for expected voluntary COVID-19 vaccination rates. CDC analyzed the influenza vaccination rates among cruise ship crew from the 63 influenza outbreaks on cruise voyages between 1/1/2019 and 3/31/2020. Eighteen (29%) of those outbreak voyages had crew vaccination rates of less than 50%. The average crew vaccination rate among those voyages was 61%. This is despite CDC's online guidance for cruise ships on influenza outbreak management and outreach to individual cruise ships that meet outbreak status. These percentages are concerning due to the high vaccine coverage needed to prevent COVID-19 outbreaks.

62) Preliminary CDC modeling data also indicates that to avoid significant outbreaks of COVID-19, cruise ship operators will need to conduct voyages with a high percentage of vaccinated passengers and crew, use a highly effective vaccine, test all passengers and crew for COVID-19 on their day of embarkation, and immediately quarantine newly-embarking crew for 14-days.

63) If a cruise ship has crew that originate from a community with a medium prevalence of COVID-19 and 50% of those crew are fully vaccinated for COVID-19 with a vaccine that is 90% effective, the modeling data estimates that the crews' risk of introducing COVID-19 onto the ship has been reduced by 99.9%. However, this model assumes that all crew are tested for COVID-19 on their day of embarkation and immediately enter a 14-day quarantine. Under this model, most of this risk reduction can be attributed to day-of-embarkation testing and 14-day quarantine. Absent the protection afforded by the 14-day quarantine, a rate of vaccination significantly higher than 50% would be needed to achieve an equivalent level of COVID-19 risk reduction. Based on wider vaccine availability, CDC does not expect to require a 14-day quarantine of embarking crew once cruise ship operators resume restricted passenger voyages.

64) If passengers originate from a community with a medium prevalence of COVID-19 and 50% of those passengers are fully vaccinated for COVID-19 with a vaccine that is 90% effective, the modeling data estimates that the passengers' risk of introducing COVID-19 onto the ship has only been reduced by 62.8%. Under this model, most of this risk reduction can be attributed to vaccination and day-of-

embarkation testing. This model assumes that a 14-day quarantine of all passengers would be impractical and thus not occur.

65) This model additionally estimates 4 cases of COVID-19 infections will be introduced onto a ship sailing with 2,000 passengers, despite day-of-embarkation testing, and that additional transmission of COVID-19 on this ship will occur 67% of the time. There will be an average of 6 additional infections by day 4 of the voyage. In some situations, using the same model parameters, there can be up to 16 additional infections by day 4 of the voyage. This is based on a model of 2,000 passengers and 1,000 crew, a voyage duration of 7 days, and a reproductive value (R_0) of 5.

66) CDC continues to evaluate the impact of vaccinations. This includes how long vaccines protect individuals, including older adults, persons with weakened immune systems, or who take immunosuppressive medications. In addition, research is still ongoing regarding how well COVID-19 vaccines keep people from spreading the disease to others. The need for and timing of COVID-19 booster doses have also not been established, although vaccine manufacturers have indicated in recent media reports that there may be a need for a booster vaccine between 6 and 12 months. CDC is still recommending that fully vaccinated people should avoid indoor large-sized in-person gatherings for these reasons.

67) However, based the above referenced CDC modeling data, CDC's April 28, 2021 "Dear Colleague" letter (Exhibit B) indicated that in lieu of conducting a Phase 2B simulated voyage, cruise ship operators' responsible officials, at their discretion,

may sign and submit to CDC an attestation under 18 U.S.C. § 1001 that 98% of crew are fully vaccinated and submit to CDC a clear and specific plan and timeline to limit cruise ship sailings to voyages where 95% of passengers have been verified by the cruise ship operator as fully vaccinated prior to sailing. Cruise ship operators that chose to do so may proceed directly to Phase 3 and apply for a COVID-19 Conditional Sailing Certificate to resume passenger operations.

68) CDC continues to evaluate how well vaccines protect against emerging SARS-CoV-2 variants and how these variants will affect infection prevention and control recommendations. An emerging variant of interest requires additional laboratory and epidemiological investigation to assess how easily the virus spreads to others, the severity of disease, the efficacy of therapeutics, and whether currently authorized vaccines offer protection. Early data show the vaccines currently available in the United States may work against some variants but could be less effective against others.

69) Vaccination of cruise ship crew continues to be a concern for the resumption of passenger operations. Cruise ship crew are primarily foreign nationals and many of their countries of origin (including the Philippines, Indonesia, and India) have very low rates of vaccination for COVID-19. Upon information and belief, Royal Caribbean Cruise Lines have halted their hiring of foreign nationals from India based on surging rates of COVID-19 in that country. Additionally, the efficacy of non-FDA authorized and non-WHO listed vaccines that are currently available to foreign-based crew members in their home countries have not been fully demonstrated.

70) Upon information and belief and based on discussions with cruise ship operators, at this time most plan to encourage crew to be vaccinated on a voluntary basis as vaccines become more widely available. This is because vaccines are currently not commercially available and can only be obtained through government resources. Recent media reports confirmed that the cost to governments of the two-dose COVID-19 vaccines currently authorized for use in the U.S. cost between $19.50 to $37 per dose ($39 to $74 for the complete series). Vaccine manufacturers have noted in media reports that they may increase these prices when they offer the vaccine commercially.

71) By comparison, per CDC's Vaccine Price List, the adult influenza vaccine costs between $17.89 to $26.39 per dose in the private sector. The CDC Vaccine Price Lists provides current vaccine contract prices and lists the private sector vaccine prices for general information. Contract prices are those for CDC vaccine contracts that are established for the purchase of vaccines by immunization programs that receive CDC immunization cooperative agreement funds (i.e., state health departments, certain large city immunization projects, and certain current and former U.S. territories). Private providers and private citizens cannot directly purchase vaccines through CDC contracts. Private sector prices are those reported by vaccine manufacturers annually to CDC. Based on the above information, cruise ship operators may face a significant cost when vaccinating their own crew with commercially available vaccines.

72) Even when travelers are vaccinated, protective public health measures—such as testing, mask use, and physical distancing—will still be important because of concern over variants and continuing research regarding how well vaccines provide full protection against the virus, particularly in regards to older adults or those who are immunosuppressed.

73) CDC acknowledges that it is not possible for cruising to be a zero-risk activity for spread of COVID-19. While cruising will continue to pose some risk of COVID-19 transmission, CDC is committed to ensuring that cruise ship passenger operations are conducted in a way that protects crew members, passengers, and port personnel, particularly with emerging COVID-19 variants of concern. This is consistent with CDC's statutory obligations to "prevent the introduction, transmission, and spread of communicable diseases" under 42 U.S.C. § 264.

74) CDC is further committed to working with the cruise industry and seaport partners to resume cruising following the phased approach outlined in the CSO. In support of that goal and to ensure transparency, CDC, DHS, and U.S. Department of Transportation senior leadership have recently hosted multiple meetings with key cruise industry leaders. The objective of these meetings is to discuss top priority issues of the cruise industry, including the impact of vaccines and other scientific developments since the Order was issued in October 2020. This goal aligns with the desire expressed by many major cruise ship operators and travelers for the resumption of passenger operations in the United States by mid-summer.

75) It is my professional judgment, based on nearly 20 years of professional experience and the science gathered regarding SARS-CoV-2 transmission, that absent the protections afforded by the CSO's phased approach, allowing cruise ship operators to immediately return to unrestricted passenger travel (i.e., travel subject only to voluntary measures to address the threat of COVID-19) would likely exacerbate and amplify the spread of SARS-CoV-2, the virus that causes COVID-19. Data from CDC's crew surveillance system from November 30, 2020 through April 25, 2021, demonstrates the enormous difficulty in identifying and preventing COVID-affected persons from boarding cruise ships. Out of 131 crew cases identified on board cruise ships, 43% (56) were identified during the initial 14-day ship quarantine mandated by CDC. This shows the difficulty of attempting to prevent COVID-19 cases from boarding ships through pre-embarkation testing plus exposure and symptom screening.

76) Cruise ships, unlike other forms of voluntary recreation or travel such as theaters, amusement parks, and aviation, present a unique setting that is particularly conducive to transmission of the virus that causes COVID-19. Cruise ships bring diverse passenger and crew populations together in close proximity for many days, leading to potential transmission of respiratory illness. Cruise ships also have a high population density on board, which are typically more densely populated than cities or most other living situations. Factors that facilitate the significantly heightened spread of SARS-CoV-2 on cruise ships may include:

- Comingling of travelers from multiple geographic regions.

- Closed nature of the cruise ship environment.
- Older passenger population who frequently make cruise voyages and are at increased risk for serious complications.
- Crew members who transfer between ships and voyages can perpetuate transmission across multiple voyages and ships.
- The passenger population represents an older demographic, some of whom have underlying medical conditions that put them at higher risk for severe complications of COVID-19.
- Quarantine and isolation measures are difficult to implement effectively onboard a cruise ship and only occur after an infection has already been identified.

77) While CDC has not prohibited persons from flying overseas to engage in cruise ship travel, CDC has recommended that all people avoid travel on cruise ships, including river cruises, worldwide. Furthermore, while CDC does not have data indicating what percentage of airline travelers may choose to go oversees to engage in cruise travel contrary to CDC's recommendations, experience and common sense suggests that this number is significantly less than those passengers who would choose to cruise from a port in the United States if cruise ship operations were to immediately resume outside of the CSO's phased approach. CDC also lacks the ability to track the itineraries of individual travelers to know which travelers may choose to go on a cruise after flying overseas.

78) While some cruise ship operators have claimed to have successfully engaged in cruising with hundreds of thousands of passengers in foreign markets, including Asia, with no or only limited transmission of COVID-19, this is not an equivalent comparison to cruising in the United States. Many of these claims are based on the country of Singapore—a small island nation with a consistently low prevalence of SARS-CoV-2 infection and federal authority over its travel industry. Since November 2020, Singapore has experienced only a handful of locally transmitted new cases each day (between zero and five cases/day). Its cruise voyages have been open only to Singapore residents on itineraries that only port within Singapore and at a reduced capacity. Ironically, this nation's Tourism Board has employed similar regulatory measures to what CDC has detailed in the CSO, including a "Health Safety Framework" and a "Cruise Safe Certification" which all cruise operators must obtain before they can sail (and requires mandatory testing, physical distancing, and disease response planning). The low prevalence of disease in Singapore combined with its federally mandated protocols and assistance would be analogous to those measures detailed in the CSO when accompanied by a highly vaccinated cruise population in the United States.

79) Similarly, some cruise ship operators have claimed to have successfully engaged in cruising in the Europe. However, these cruises have not been without incident. From September to November 2020, media sources reported several outbreaks occurred on European river cruise ships where approximately 100 persons were infected, including 8 travelers on CroisiEurope's *Vasco da Gama* cruise ship in

September, 60 passengers on the *MS Swiss Crystal* and 13 travelers on the *MS Vista Serenity* in October, and 10 crew members on the *MS Thurgau Chopin* in November. Many other river cruise voyages in Europe were cancelled due to the threat of COVID-19.

80) From July 2020 to February 2021, outbreaks were reported on European non-river cruise ships with over 100 persons infected, including 71 travelers on Hurtigruten's *MS Roald Amundsen*, 10 crew on AIDA cruise line, and 5 crew on the Mein Schiff 1 in July; three travelers on the *MS Finnmarken* in September; 13 travelers on the Le Jacques-Cartier, 8 on the Costa *Diadema*, and 1 on the MSC *Grandiosa* in October. In February of this year, four guests tested positive for COVID on the *Mein Schiff 2*.

81) Furthermore, while the cruise industry has claimed to have successfully prevented the introduction and transmission of COVID-19 on board and into communities in Europe, this claim cannot be substantiated without results from laboratory testing of disembarking passengers or crew and further follow-up with travelers post-cruise. Such testing and follow-up do not occur in these foreign markets. Local and national public health authorities in Europe also do not routinely collect or mandate collection of these data. Unlike in the United States, which has federally-mandated requirements on cruise ships to report illness and death to CDC-staffed Quarantine Stations at major ports of entry, European countries do not have similar systems in place to track cruise ship-related cases or outbreaks. Based on this lack of testing and data collection, potential failures in cruise ship industry protocols

and practices cannot be reliability recognized because cases can only be identified within a community and not linked to a cruise ship exposure.

82) Accordingly, it is my professional judgment based on all the information available to CDC, that it is necessary to continue the phased approach and protections of the CSO to protect the public's health.

83) In accordance with 28 U.S.C. § 1746, I declare, under penalty of perjury, that the above information is true and correct to the best of my knowledge and belief.

Signed this 5th day of May 2021.

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Aimee Treffiletti, MPH, REHS (CAPT, USPHS)
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