

ALL HANDS ON DECK: CDC’S LEGAL RESPONSE TO THE COVID-19 PANDEMIC ONBOARD CRUISE SHIPS

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INTRODUCTION	121
I. LEGAL AUTHORITIES AND STRUCTURE	123
II. EVACUATIONS AND REPATRIATIONS IN RESPONSE TO COVID-19	127
III. CDC ISSUES AND EXTENDS NO SAIL ORDER (NSO)	131
A. CDC Issues Nationwide NSO — March 14, 2020	131
B. CDC Modifies and Extends NSO — April 15, 2020	134
C. CDC Modifies and Extends NSO for a Second Time — July 16, 2020	137
D. CDC Modifies and Extends NSO for a Third Time — October 1, 2020	139
IV. CDC TRANSITIONS TO CONDITIONAL SAIL ORDER (CSO).....	142
V. CDC ISSUES TECHNICAL INSTRUCTIONS AND GUIDANCE UNDER THE CSO.....	146
VI. FEDERAL DISTRICT COURT ENJOINS CDC FROM ENFORCING CSO IN FLORIDA.....	151
VII. CDC MOVES FOR AN EMERGENCY STAY PENDING APPEAL	155

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VIII. COURT DENIES EMERGENCY STAY AND PRELIMINARY INJUNCTION ENTERS INTO EFFECT	158
IX. CDC TEMPORARILY EXTENDS AND MODIFIES CSO AND TRANSITIONS TO A VOLUNTARY PROGRAM.....	161
X. LEGAL ANALYSIS AND CONSIDERATIONS FOR FUTURE ACTION.....	164
CONCLUSION.....	174

ABSTRACT

The Centers for Disease Control and Prevention took the unprecedented step during the COVID-19 pandemic of suspending all cruise ship activity in the United States. The CDC extended this suspension several times before it allowed cruise ship operators to resume operations in phases over several months through a new set of public health requirements. The State of Florida subsequently sued the CDC, culminating in the federal district court's issuance of a preliminary injunction in *Florida v. Becerra*. 544 F.Supp.3d 1241 (M.D. Fla. 2021). The preliminary injunction converted the CDC's public health requirements into nonbinding recommendations for cruise ships in Florida. Despite the existence of the preliminary injunction, cruise ship operators in Florida and elsewhere continued to comply with the CDC's public health requirements. The CDC later implemented a fully voluntary program for all cruise ships operating out of U.S. ports that ended on July 18, 2022.

This Article provides a legal analysis of the CDC's response to the challenges of COVID-19 onboard cruise ships. Considering the need to prepare for future public health emergencies, including possible pandemics, policymakers should consider further clarifying the CDC's legal authorities as they relate to its maritime public health activities. Such actions could include amending section 361 of the Public Health Service Act (42 U.S.C. § 264) and new rulemaking. New regulations could also be based on section 366 of the PHS Act (42 U.S.C. § 269), which authorizes regulations requiring ship operators to obtain and deliver a "bill of health" to the public health authority upon arrival at a U.S. port. Requiring a ship's operator to produce and comply with the terms of a bill of health is a historic maritime public health practice that the CDC could reintroduce to respond to future pandemics and other public health emergencies.

INTRODUCTION

On March 14, 2020, the Centers for Disease Control and Prevention (“CDC”), an agency within the Department of Health and Human Services (“HHS”), took the extraordinary step of suspending all cruise ship activity in the United States in response to the COVID-19 pandemic.¹ This suspension was extended several times before the CDC allowed cruise ships to resume operations in phases over several months.² The State of Florida subsequently filed suit against the CDC.³ As a result, the federal district court issued a preliminary injunction in *Florida v. Becerra*.⁴ The preliminary injunction converted CDC’s requirements into nonbinding recommendations for cruise ships in Florida.⁵ Despite the preliminary injunction, cruise ship operators in Florida continued to comply on a voluntary basis with the CDC’s requirements for a phased reopening of operations.⁶ The CDC later implemented a fully voluntary program for all cruise ships operating out of U.S. ports that ended on July 18, 2022.⁷

This Article provides a description and legal analysis of the CDC’s response to the challenges of COVID-19 onboard cruise ships that were

¹ No Sail Order and Suspension of Further Embarkation, 85 Fed. Reg. 16628 (March 24, 2020). Throughout the COVID-19 pandemic, CDC defined “cruise ships” as “commercial, non-cargo, passenger-carrying vessels operating in international, interstate, or intrastate waterways and subject to the jurisdiction of the United States with the capacity to carry 250 or more individuals (passengers and crew) with an itinerary anticipating an overnight stay onboard or a twenty-four (24) hour stay onboard for either passengers or crew.” *Id.* at 16628-29.

² See *id.*; No Sail Order and Suspension of Further Embarkation; Notice of Modification and Extension, 85 Fed. Reg. 21004 (April 15, 2020); No Sail Order and Suspension of Further Embarkation; Second Modification and Extension, 85 Fed. Reg. 44085 (July 21, 2020); No Sail Order and Suspension of Further Embarkation; Third Modification and Extension, 85 Fed. Reg. 62732 (Oct. 5, 2020); and Framework for Conditional Sailing and Initial Phase COVID-19 Testing Requirements for Protection of Crew, 85 Fed. Reg. 70153 (Nov. 4, 2020).

³ See *Florida v. Becerra*, 544 F. Supp. 3d 1241 (M.D. Fla. 2021).

⁴ *Id.* at 1305.

⁵ *Id.*

⁶ See *State Argues CDC Violated Cruise Case Injunction*, FLORIDA POL. (July 28, 2021), <https://floridapolitics.com/archives/444093-state-argues-cdc-violated-cruise-case-injunction/>.

⁷ See *Cruise Ship Travel During COVID-19*, CDC, <https://www.cdc.gov/coronavirus/2019-ncov/travelers/cruise-travel-during-covid19.html#faq> (Nov. 3, 2022); Allie Hubers, *CDC Ends Covid-19 Program for Cruise Ships*, ROYAL CARIBBEAN BLOG (July 18, 2022) <https://www.royalcaribbeanblog.com/2022/07/18/cdc-ends-covid-19-program-cruise-ships>.

undertaken based on legal authorities found in section 361 of the Public Health Service Act (hereinafter, “PHS Act”).⁸ Although a pandemic on the scale of COVID-19 is a rare event of unpredictable occurrence but major consequence, this Article suggests that policymakers consider further clarifying the CDC’s role and legal authority in maritime public health as it prepares for future public health emergencies, including possible pandemics. Such actions could include amending the PHS Act, as well as the CDC engaging in additional rulemaking to clarify the CDC’s authority under section 361.⁹ As further explained in this Article, additional rulemaking could also be based on section 366 of the PHS Act, which authorizes regulations requiring vessels to obtain and deliver a “bill of health.”¹⁰ Although requiring a ship to obtain and deliver a bill of health is an archaic practice that has fallen into disuse, it could be revived and revitalized to respond to pandemics and other public health emergencies declared by the HHS Secretary.

I. LEGAL AUTHORITIES AND STRUCTURE

The CDC’s legal authority for its maritime public health activities is found primarily in section 361 of the PHS Act, a statute enacted in 1944.¹¹ The first sentence of section 361(a) authorizes the Surgeon General¹² with the approval of the HHS Secretary “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 [of the United States], or from one State or possession into any other State or possession.”¹³ Section 361(a) further states:

⁸ 42 U.S.C. § 264.

⁹ *See id.*

¹⁰ 42 U.S.C. § 269.

¹¹ 42 U.S.C. § 264; H.R. REP. NO. 1364 (1944), reprinted in 1944 U.S.C.C.A.N. 1211, 1234.

¹² The Office of the Surgeon General was abolished by section 3 of the 1966 reorganization plan, and its statutory functions were assigned to the Secretary of HHS (then HEW). *See* 31 Fed. Reg. 8855 (June 25, 1966). In carrying out all responsibilities, the Surgeon General now reports to the Assistant Secretary for Health, who is the principal advisor to the HHS Secretary on public health and scientific issues. Accordingly, the duties and responsibilities accorded to the Surgeon General under section 361 of the PHS Act should be understood as subsumed by the HHS Secretary.

¹³ 42 U.S.C. § 264(a). Section 361(b)-(d) authorizes the apprehension, detention, examination,

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.¹⁴

As explained recently by the U.S. Supreme Court, “the second sentence [of section 361(a)] informs the grant of authority [in the first sentence] by illustrating the kinds of measures that could be necessary: inspection, fumigation, disinfection, sanitation, pest extermination, and destruction of contaminated animals and articles.¹⁵ These measures directly relate to preventing the interstate spread of disease by identifying, isolating, and destroying the disease itself.”¹⁶ Although the Court’s interpretation was made in the context of a preliminary ruling of a case challenging the CDC’s issuance of an eviction moratorium aimed at preventing the interstate spread of COVID-19,¹⁷ this interpretation would apply with equal force to measures aimed at preventing the introduction, transmission, or spread of communicable diseases from foreign countries into the United States, which is based on the same grant of authority in the first sentence of section 361(a).¹⁸ Although violations of quarantine rules and regulations are subject to criminal penalties under section 368 of the PHS Act,¹⁹ in practice the CDC relies primarily on the U.S. Coast Guard within the Department of Homeland Security to provide law enforcement and other maritime assistance as authorized by section 365 of the PHS Act.²⁰

Regulations implementing section 361 as they relate to maritime public health are found primarily in 42 CFR part 71, which contains

and conditional release of individuals for purposes of federal quarantine and isolation. Section 361(e) provides that neither section 361 nor regulations enacted under its authority shall preempt state or local public health laws or regulations, except in the event of a conflict with federal public health authority. *See* 42 U.S.C. § 264(b)-(e).

¹⁴ 42 U.S.C. § 264(a).

¹⁵ *Ala. Ass’n of Realtors v. Dep’t of Health & Hum. Servs.*, 141 S. Ct. 2485, 2488 (2021).

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ *See* 42 U.S.C. § 264(a).

¹⁹ *See* 42 U.S.C. § 271; 42 C.F.R. § 71.2.

²⁰ *See* 42 U.S.C. § 268 (stating that U.S. Customs and Coast Guard officers shall aid in the enforcement of quarantine rules and regulations).

measures to prevent the introduction, transmission, and spread of communicable diseases from foreign countries into the United States.²¹ Several provisions relate to the reporting of deaths and illnesses of public health concern among passengers or crew and facilitate contact tracing by public health authorities.²² These include: § 71.5 (transmission of vessel passenger, crew, and voyage information for public health purposes); § 71.21 (reporting of deaths and illnesses onboard ships destined for the United States, including gastrointestinal illnesses); and § 71.35 (reports of deaths and illnesses during stays in port).²³

Several other provisions relate to public health inspections and measures applied to either an arriving carrier or to cargo and things found onboard an arriving carrier. These include:

- § 71.31(a) states that arriving carriers will not undergo inspection unless there is a threat of communicable disease introduction, such as when illness or insanitary conditions occur onboard;
- § 71.31(b) authorizes the detention of an arriving carrier and the issuance of a “controlled free pratique” stipulating what public health measures are to be met as a condition of the carrier being permitted to enter a U.S. port, commence operations, and disembark passengers;
- § 71.32(b) authorizes the detention, disinfection, disinfestation, fumigation, or other related measures respecting an arriving carrier or articles or things found onboard if the CDC Director

²¹ See 42 C.F.R. § 71. The CDC does not oversee interstate passenger carrying conveyances as a routine matter. Rather, these types of vessels typically fall under the authority of the Food & Drug Administration’s Interstate Travel Program which operates under the authority of the PHS Act and regulations at 21 CFR parts 1240, 1250. See *Interstate Travel Program*, FDA, <https://www.fda.gov/food/food-inspection-programs/interstate-travel-program> (last visited Apr. 4, 2023). However, the CDC Director retains the authority to take measures the Director deems reasonably necessary to prevent the interstate spread of communicable disease, including inspection, fumigation, disinfection, sanitation, pest extermination, and destruction of animals or articles believed to be sources of infection. See 42 CFR § 70.2 (authoring measures in the event of inadequate local control).

²² See 42 C.F.R. § 71.21.

²³ See 42 C.F.R. §§ 71.5, 71.21, 71.35.

determines that doing so is necessary to prevent the introduction, transmission, or spread of communicable diseases;

- § 71.41 states that arriving carriers are subject to sanitary inspection to determine the presence of rodent, insect, or other vermin infestation, contaminated food or water, or other insanitary conditions requiring public health measures; and
- § 71.48 provides that carriers on an international voyage and in traffic between U.S. ports are subject to inspection based on the occurrence of deaths, illnesses, or insanitary conditions.

Finally, some provisions relate to document requirements or other administrative matters.²⁴ These include: § 71.11 (stating that carriers at foreign ports clearing or departing for the United States are not required to obtain or deliver a bill of health), § 71.34 (exempting carriers operated by the U.S. military services), and § 71.46 (relating to certificates declaring a vessel to be free of rodents).²⁵

Typically, maritime public health activities within the CDC are carried out by two distinct entities: the Quarantine and Border Health Services Branch (QBHSB) Maritime Activities, within the Division of Global Migration and Quarantine (DGMQ), and the CDC Vessel Sanitation Program (VSP) within 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.²⁶ Among other duties, Maritime Activities coordinates the collection and analysis of data related to illness and death onboard cruise or cargo ships destined for the United States, assists quarantine stations in outbreak investigations and in responding to maritime illness reports for certain communicable diseases (e.g., varicella, tuberculosis, rubella, measles, mumps, pertussis), and develops guidance for quarantine stations, the cruise travel industry, and other maritime partners.²⁷

²⁴ See 42 C.F.R. §§ 71.11, 71.34, 71.46.

²⁵ See *id.*

²⁶ See *Maritime Activity*, CDC (Jan. 2011), <https://www.cdc.gov/quarantine/pdfs/maritime-industry.pdf>; see also *Vessel Sanitation Program*, CDC, <https://www.cdc.gov/nceh/vsp/default.htm> (Mar. 30, 2023).

²⁷ See *Maritime Activity*, *supra* note 26.

The 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 onboard cruise ships in U.S. waters.²⁸ The VSP inspects cruise ships based on public health standards published in its VSP Operations Manual²⁹ and is currently funded through user fees paid by cruise lines and based on a fee schedule published in the Federal Register.³⁰ In response to the COVID-19 pandemic, these two entities were merged temporarily in April 2020 to form a Maritime Unit under the Global Migration Taskforce within the CDC's COVID-19 Incident Management structure.³¹

II. EVACUATIONS AND REPATRIATIONS IN RESPONSE TO COVID-19

During the early stages of the COVID-19 pandemic between January and March 2020, the federal government³² organized and managed the largest combined repatriation and federal quarantine operation in U.S. history.³³ Beginning in January 2020, the federal government repatriated and quarantined approximately 800 U.S. citizens from Hubei Province, People's Republic of China (PRC) and their immediate family members.³⁴ This required organizing specially chartered flights from the PRC and selecting and maintaining federal

²⁸ See *About the Vessel Sanitation Program*, CDC, <https://www.cdc.gov/nceh/vsp/desc/aboutvsp.htm> (last visited Sept. 19, 2022).

²⁹ See *Vessel Sanitation Program 2018 Operations Manual*, CDC, https://www.cdc.gov/nceh/vsp/docs/vsp_operations_manual_2018-508.pdf (last visited Sept. 19, 2022).

³⁰ See *Fees for Sanitation Inspection of Cruise Ships*, 87 Fed. Reg. 73767 (Dec. 01, 2022).

³¹ See NATIONAL ACADEMIES OF SCIENCES, *IMPROVING THE CDC QUARANTINE STATION NETWORK'S RESPONSE TO EMERGING THREATS 40* (2022) [hereinafter NATIONAL ACADEMIES REPORT].

³² In addition to HHS and its component agencies, this effort involved the U.S. Department of State, the U.S. Department of Homeland Security (DHS), the Department of Defense (DOD), and various State agencies. See *Control of Communicable Diseases; Foreign Quarantine*, 85 Fed. Reg. 56424, 56430 (Sept. 11, 2020).

³³ See *id.* ("HHS/CDC is unaware of a repatriation and quarantine operation in the modern history of the United States that matched the initiative in size and scope.")

³⁴ *Id.*

quarantine sites in the United States.³⁵ Later, in February 2020, the *Diamond Princess* Cruise Ship in Japan experienced what was then the largest cluster of COVID-19 cases outside of the PRC.³⁶ The federal government again organized specially chartered flights and repatriated approximately 329 U.S. passengers back to the United States.³⁷ These passengers required housing separate from those individuals from the previous PRC repatriation flights and were quarantined for a minimum of 14 days.³⁸ Then, in March 2020, following a large-scale outbreak of COVID-19 onboard the *Grand Princess* Cruise Ship, docked in Oakland, California, the federal government disembarked approximately 2,000 passengers who entered quarantine or isolation at federal sites.³⁹ The scale of the outbreaks onboard the *Diamond Princess* and *Grand Princess* cruise ships were significant; 800 total COVID-19 cases, including 10 deaths.⁴⁰

The scale and scope of these efforts had a profound impact on the CDC's subsequent decision to halt cruise ship operations in the United States.⁴¹ Because the federal government no longer operates or maintains Public Health Service hospitals capable of acting as dedicated sites for federal quarantine and isolation,⁴² alternate housing facilities needed to be arranged quickly.⁴³ In one case, local officials in Costa Mesa, California obtained a temporary restraining order blocking federal efforts to house *Diamond Princess* repatriates in a vacated, state-

³⁵ *Id.*

³⁶ *Id.*

³⁷ *Id.*

³⁸ See CDC Media Statement, *Diamond Princess Repatriation* (Feb. 15, 2020), <https://www.cdc.gov/media/releases/2020/s0215-diamond-princess-repatriation.html> (last visited September 20, 2022).

³⁹ See Control of Communicable Diseases; Foreign Quarantine, 85 Fed. Reg. at 56430.

⁴⁰ Leah F. Moriarty et al., *Public Health Responses to COVID-19 Outbreaks on Cruise Ships — Worldwide, February–March 2020*, 69 MORBIDITY & MORTALITY WKLY. REP. 347, 349 (2020).

⁴¹ Erika Edwards, *Cruises in U.S. Waters Halted Until at Least November, CDC Says*, NBC NEWS (Oct. 1, 2020, 7:40 AM), <https://www.nbcnews.com/health/health-news/cruises-u-s-waters-halted-until-least-november-cdc-says-n1241554>.

⁴² See 42 U.S.C. § 249 (authorizing treatment and care at hospital facilities maintained by the Public Health Service for persons detained in accordance with quarantine laws).

⁴³ Control of Communicable Diseases; Foreign Quarantine, 85 Fed. Reg. at 56430.

owned facility, causing the federal government to look for alternate arrangements.⁴⁴

The federal government relied on secured military facilities to act as quarantine sites for all exposed individuals, hotels for isolation of infected individuals who were not ill enough to require hospitalization, and hospital beds for those in need of such medical care.⁴⁵ In addition to identifying and securing such facilities, including transportation,⁴⁶ infection control and infection prevention measures needed to be implemented, individuals medically monitored and tested, and “wrap-around” services (e.g., food, laundry, housekeeping, pharmaceutical prescriptions, translation services, non-COVID-19 related healthcare services, mental health counseling, and “town hall” style conference calls) provided.⁴⁷ The size and unprecedented nature of these efforts led to significant challenges among federal agencies and HHS component agencies regarding critical aspects of the response, including responsibility for personal protective equipment for on-site staff.⁴⁸

Ensuring that individuals were afforded adequate due process also raised similar organizational and logistical challenges. In overseeing the quarantine and isolation aspects of the operation, the CDC relied on recently promulgated regulations found in 42 CFR parts 70 and 71.⁴⁹ In the case of the PRC and *Diamond Princess* repatriates, the CDC

⁴⁴ *Id.*; see also *Federal Government Abandons Plans To Use Fairview For Diamond Princess COVID-19 Positive Passengers*, CITY OF COSTA MESA NEWS (Feb. 28, 2020), <https://www.cityofcostamesanews.com/federal-government-abandons-plans-to-use-fairview-for-diamond-princess-covid-19-positive-passengers/>.

⁴⁵ Control of Communicable Diseases; Foreign Quarantine, 85 Fed. Reg. at 56430.

⁴⁶ Part of this effort involved coordinating with foreign governments that sought to repatriate their own citizens from the United States. See Moriarty, *supra* note 40, at 349, (“Repatriation flights for foreign nationals were organized by several governments in coordination with U.S. federal and California state government agencies.”).

⁴⁷ *Id.*

⁴⁸ Several agencies within HHS were involved in the response including CDC, the Office of the Assistant Secretary for Preparedness and Response (ASPR), the Office of the Assistant Secretary for Financial Resources (ASFR), the U.S. Public Health Service Commissioned Corps (PHSCC), and the Administration for Children and Families (ACF). See *id.*; GOV’T ACCOUNTABILITY OFF., GAO-21-334, COVID-19 HHS SHOULD CLARIFY AGENCY ROLES FOR EMERGENCY RETURN OF U.S. CITIZENS DURING A PANDEMIC (2021).

⁴⁹ See James J. Misrahi, *The CDC’s Communicable Disease Regulations: Striking the Balance between Public Health & Individual Rights*, 67 Emory L.J. 463, 472 (2018).

relied on regulations pertaining to quarantine and isolation of foreign arrivals to prevent the introduction, transmission, and spread of federally quarantinable diseases.⁵⁰ In the case of the *Grand Princess* passengers, the CDC relied on similar interstate authorities because these individuals were already in the United States when placed under quarantine.⁵¹ Although in both cases, the CDC issued group quarantine orders⁵² based on common attributes of exposure to COVID-19, the CDC also issued isolation orders on an individual basis because the attributes relating to infection (e.g., positive test results, display of symptoms) were unique to each individual.⁵³

CDC regulations relating to service of process also required the CDC to provide everyone with a copy of the quarantine or isolation order (in translation as needed) no later than 72 hours after the individuals were deemed to have been apprehended.⁵⁴ Once served, these orders had to be reassessed within 72 hours to ensure that the reasons for the quarantine or isolation remained valid, that the CDC was using the least restrictive means to protect the public's health, and to advise individuals of an opportunity for a medical review hearing.⁵⁵ Ultimately, two consolidated medical review hearings were conducted for a small group of *Grand Princess* passengers, which among other things, necessitated the appointment of a medical review officer, appointment of legal counsel for those proceeding as indigents, the preparation of an administrative record, and convening of transcribed, remote agency hearing.⁵⁶

⁵⁰ See 42 C.F.R. §§ 71.32(a), 71.33.

⁵¹ See 42 C.F.R. § 70.6.

⁵² See 42 C.F.R. §§ 70.14, 71.37.

⁵³ For similar reasons, CDC determined that any order extending an individual's time in quarantine based on exposure to someone who had tested positive for COVID-19, or any order authorizing transporting the individual to a different geographic location, required an individual order because these factors altered materially the circumstances of an individual's confinement. *Id.*

⁵⁴ Although these regulations permit CDC to publish or post group quarantine orders in a conspicuous location if individual service would be impracticable, CDC did not avail itself of this provision. *See id.*

⁵⁵ See 42 C.F.R. §§ 70.15, 71.38.

⁵⁶ See 42 C.F.R. §§ 70.16, 70.17, 71.29, 71.39.

III. CDC ISSUES AND EXTENDS NO SAIL ORDER (NSO)

A. CDC Issues Nationwide NSO — March 14, 2020

Ongoing federal quarantine and isolation of individuals was not a prospective solution because it did not address the continuing risk of COVID-19 transmission onboard cruise ships nor was it a scalable or sustainable solution considering the enormity of federal resources involved in these efforts.⁵⁷ Among other things, these large-scale quarantine and isolation operations diverted finite federal resources away from other response efforts needed for the escalating pandemic.⁵⁸ On March 14, 2020, the CDC took the unprecedented step of pausing all cruise ship operations in U.S. waters for 30 days.⁵⁹ Except as directed by U.S. Coast Guard or HHS/CDC personnel, cruise ships were not permitted to disembark passengers or crew, embark new passengers or crew, reembark crew, or commence or continue operations in U.S. waters.⁶⁰ This followed an announcement by the Cruise Lines International Association (“CLIA”) on March 13, 2020, that its associated member “cruise lines would voluntarily suspend cruise ship operations for...30 days.”⁶¹ Among other purposes, the initial NSO was intended to provide public health authorities and cruise lines “the necessary pause in operations to develop and implement an appropriate and robust plan to prevent and mitigate the spread of COVID-19.”⁶²

The CDC’s issuance of a nationwide pause in cruise ship operations was unprecedented because the agency’s practice prior to COVID-19 had been to issue such orders rarely and based on deficiencies observed through onboard inspections of specific cruise ships.⁶³

⁵⁷ See Control of Communicable Diseases; Foreign Quarantine, 85 Fed. Reg. at 56431 (concluding that federal quarantine was neither “a scalable nor sustainable” option based on finite resources and the pressing demands of the COVID-19 response).

⁵⁸ See *id.*

⁵⁹ No Sail Order and Suspension of Further Embarkation, 85 Fed. Reg. 16628 (Mar. 24, 2020).

⁶⁰ *Id.* at 16631.

⁶¹ *Id.*

⁶² *Id.*

⁶³ See *Vessel Sanitation Program, Inspections*, CDC, http://web.archive.org/web/20220929191823/https://www.cdc.gov/nceh/vsp/desc/about_inspections.htm (Feb. 26, 2020) (noting that no sail orders are rare and that prior to COVID-19, CDC had last issued such an order in 2001).

Typically, the CDC's vessel sanitation inspectors conduct operational sanitation inspections to determine whether cruise ships are maintaining sanitation standards in accordance with the current VSP Operations Manual.⁶⁴ Although an inspection failure does not by itself necessarily warrant a suspension in operations, VSP inspectors may recommend that a ship not sail if an imminent public health risk exists.⁶⁵ Such an imminent public health risk would be considered to exist, for instance, if the cruise ship was unable to properly maintain potable drinking water, keep food within safe temperatures, clean and sanitize equipment, properly dispose of waste, or if an infectious disease outbreak threatened the health of newly arriving passengers.⁶⁶ Because the VSP operates as a voluntary program, a cruise ship operator rarely chooses to not follow a voluntary "no sail" recommendation or take corrective action in response to an inspection failure.⁶⁷

It was the scope and nature of the COVID-19 pandemic at the time that militated against a "fail first" policy based on public health deficiencies observed through inspections of specific cruise ships followed by issuance of voluntary no sail recommendations.⁶⁸ Cruise ships have unique aspects and operational features that made them particularly conducive to COVID-19 spread in the early stages of the pandemic.⁶⁹ These included frequent interactions between large numbers of passengers and crew in confined spaces, close quartering among crew and cabinmates, an abundance of high touch surfaces, and, considering

⁶⁴ *Id.*

⁶⁵ *Id.*

⁶⁶ *Id.*

⁶⁷ *See id.* Based on the complexity of evacuation and quarantine and isolation procedures, the *Grand Princess* Cruise Ship was held under its own, separate NSO which was issued on March 9, 2020. Disinfection of the vessel was carried out under the supervision of the VSP, and the ship later released into the custody of its cruise ship operator. CDC also briefly detained three other ships because exposed crew from the *Grand Princess* Cruise Ship had been transferred to these ships. These ships were briefly held under an NSO pending a review of ships' medical logs and testing of crew for COVID-19. *See* U.S. DEPT. OF HEALTH & HUM. SERVS. CTRS. FOR DISEASE CONTROL & PREVENTION, NO SAIL ORDER (2020).

⁶⁸ *See, e.g.*, Press Release, CDC, CDC's Framework for Conditional Sailing Order Temporarily Extended Through January 15, 2022 (Oct. 25, 2021), <https://www.cdc.gov/media/releases/2021/p1025-Conditional-Sailing-Order.html>.

⁶⁹ *Id.* (stating that "[w]hile cruising will always pose some risk of disease spread, CDC remains committed to ensuring that cruising is conducted in way that protects crew members, passengers, port personnel, and communities.").

their itineraries, an ability to spread COVID-19 widely to ports of call and passengers' home communities.⁷⁰ The cruise ship passenger population also typically includes a higher proportion of older adults that, prior to the advent of vaccines, therapeutics, and greater widespread immunity, were at increased risk for death and illness.⁷¹ The intensive medical needs of this older population would have placed healthcare workers at increased risk of infection, further stressed an overburdened healthcare system that at the time was experiencing shortages of beds needed for influenza and other seasonal and critical healthcare conditions, and diverted healthcare and other resources away from other pandemic response activities.⁷²

Based on these factors, the CDC Director determined under section 361 of the PHS Act⁷³ and 42 C.F.R. § 71.32(b), that a reasonable belief existed that cruise ships were or could become infected or contaminated with COVID-19.⁷⁴ The scope of the pandemic was also "inherently and necessarily a problem that [was] international and interstate in nature, and [could not] be controlled sufficiently by the cruise ship industry or individual state or local health authorities."⁷⁵ Thus, relying on interstate authorities under 42 CFR 70.2, the Director also determined that "measures taken or likely to be taken by state and local health authorities regarding COVID-19 onboard cruise ships [were] inadequate to prevent the further interstate spread of the disease."⁷⁶ In addition, section 365 of the PHS Act⁷⁷ was cited as a basis for allowing U.S. Coast Guard to assist in enforcing the nationwide NSO.⁷⁸

⁷⁰ No Sail Order and Suspension of Further Embarkation, 85 Fed. Reg. 16628, 16629–30 (Mar. 24, 2020).

⁷¹ *Id.* at 16630.

⁷² *Id.*

⁷³ *See generally* 42 U.S.C. § 264 (outlining the types of communicable diseases for which the Secretary of Health and Human Services is authorized to promulgate "such regulations as . . . are necessary to prevent the introduction, transmission, or spread of communicable diseases").

⁷⁴ No Sail Order and Suspension of Further Embarkation, 85 Fed. Reg. at 16631.

⁷⁵ *Id.*

⁷⁶ *Id.*

⁷⁷ *See generally* 42 U.S.C. § 268 ("It shall be the duty of . . . Coast Guard officers to aid in the enforcement of quarantine rules and regulations[.]").

⁷⁸ No Sail Order and Suspension of Further Embarkation, 85 Fed. Reg. at 16631.

Although not specifically cited in the March 14th order, but included in subsequent extensions was 42 C.F.R. § 71.31(b), which authorizes the CDC Director to detain an arriving carrier and issue a “controlled free pratique”⁷⁹ stipulating what public health measures are to be met as a condition for the carrier to enter a U.S. port and carry out operations, including disembarking passengers.⁸⁰ Under this authority, the nationwide NSO and subsequent extensions, in effect, operated as denials of “free pratique” (or clearance) for cruise ships to enter U.S. ports which would have otherwise existed absent evidence that such ships constituted sources of contagion.⁸¹ As a matter of historical practice, a ship denied “free pratique” or “controlled free pratique” to enter a U.S. port was not considered detained but permitted to continue on its voyage to a foreign port of call.⁸²

B. CDC Modifies and Extends NSO — April 15, 2020

Effective April 15, 2020, the CDC modified and extended the nationwide NSO to address ongoing concerns relating to crew health and safety.⁸³ As explained in the order itself, the suspension of a global tourism industry, such as the cruise line industry, is a massive and complex undertaking.⁸⁴ Although over 250,000 passengers from more than 120 vessels had been disembarked during the initial suspension

⁷⁹ “Controlled free pratique” means “permission for a carrier to enter a U.S. port, disembark, and begin operation under certain stipulated conditions.” 42 C.F.R. § 71.1(b) (2017).

⁸⁰ 42 C.F.R. § 71.31(b) (2021). “The Director may require detention of a carrier until the completion of the measures outlined in this part that are necessary to prevent the introduction or spread of a communicable disease. The Director may issue a controlled free pratique to the carrier stipulating what measures are to be met, but such issuance does not prevent the periodic boarding of a carrier and the inspection of persons and records to verify that the conditions have been met for granting the pratique.” *Id.*

⁸¹ Historically, ships flew the yellow quarantine flag to signal that the ship was free from contagion and that the ship’s master requested permission to enter a port. *See* Rob Murray, *What Flag to Fly in Quarantine?*, SAIL WORLD (Mar. 24, 2021, 5:17 PM), <https://www.sail-world.com/news/236201/What-flag-to-fly-in-quarantine>.

⁸² *See* Int’l Health Regulations [IHR] (1969), Art. 32(1) (prohibiting the application of health measures to ships passing through a jurisdiction’s waters without calling upon a port) & Art. 35 (encouraging the granting of free pratique by radio if a ship’s arrival will not result in the arrival or spread of disease).

⁸³ *See* No Sail Order and Suspension of Further Embarkation; Notice of Modification and Extension, 85 Fed. Reg. 21004, 21004–05 (Apr. 15, 2020).

⁸⁴ *Id.* at 21005.

of operations, managing the tens of thousands of crew members remaining on the dozens of ships in U.S. waters required extensive further coordination of efforts.⁸⁵ These efforts were complicated by the cascading number of outbreaks occurring across multiple cruise lines that in many instances led to emergency medical evacuations of crews at sea who needed intensive care in shoreside hospital facilities.⁸⁶ Furthermore, although the initial suspension of operations had been intended to allow cruise lines the opportunity to develop and implement plans to prevent and mitigate the spread of COVID-19, two separate plans submitted by the cruise industry failed to adequately address the rapidly deteriorating public health situation.⁸⁷

Accordingly, as a condition of “controlled free pratique” to continue to engage in operations in U.S. waters, the April 15th extension and modification of the NSO required cruise ship operators to develop and submit for CDC review sufficiently detailed response plans to prevent, mitigate, and respond to the spread of COVID-19 onboard their ships.⁸⁸ Response plans had to include protocols for onboard monitoring of crew through temperature checks and screening; increased frequency of reporting to the CDC of case counts, methods of testing, and persons in need of hospitalization or evacuation; crew training in mitigation, prevention, and response activities; and standards for cleaning and disinfection.⁸⁹ Cruise ship operators also had to design their plans, to the greatest extent possible, to minimize impacts on U.S. or local

⁸⁵ At the time, CDC estimated that there remained 50 cruise ships off the East Coast of the United States and in the Bahamas with about 47,800 crew onboard and 45 cruise ships with about 32,000 crew onboard off the West Coast and Gulf Coast. *Id.* at 21005-06.

⁸⁶ CDC documented COVID-19 outbreaks on a number of cruise ships including the *Costa Magica*, *Costa Favolosa*, *Celebrity Eclipse*, *Disney Wonder*, *Holland America Zaandam*, and *Celebrity Coral Princess*. *Id.* at 21005. Some of these outbreaks were extensive with the *Costa Magica* and *Costa Favolosa* reporting illness in 88 crew members and the *Zaandam* reporting illness in 250 persons. *Id.*

⁸⁷ CLIA developed two separate response plans: “*On Course: Cruise Industry COVID-19 Response and Protocols*” and “*Framework: For Cruise Industry Care of Crew and other Persons on Board while Ships Remain Idle during the Global COVID-19 Pandemic*” that proposed industry management of cruise ship outbreaks without burdening the U.S. government. *Id.* at 21006. However, the transportation resources, contracts for predesignated facilities, and multiple redundancies in response capabilities promised in these plans remained notional. *See id.*

⁸⁸ *Id.* at 21007.

⁸⁹ *Id.*

government resources, including the healthcare system.⁹⁰ In contrast to the original 30-day NSO, the extension and modification remained in place until the earliest of three events: (1) the HHS Secretary's declaration that COVID-19 constituted a public health emergency expiring; (2) the CDC Director rescinding or modifying the order based on specific public health or other considerations; or (3) 100 days from the date of publication in the Federal Register (i.e., July 24, 2020).⁹¹

Following the April 15th extension and considering the global suspension of cruise ship travel,⁹² the CDC worked with cruise ship operators to safely disembark and repatriate crew members to their home countries.⁹³ Among other requirements, cruise ship operators had to rely on non-commercial transportation, screen disembarking crew members for illness, ensure that disembarking crew wore face masks, and instruct disembarking crew to self-quarantine and practice social distancing after reaching their home destinations.⁹⁴ Cruise ship operators had to further attest through a legal attestation subject to criminal penalties under 18 U.S.C. § 1001 that these conditions had been met.⁹⁵ During this period, the CDC also created its Maritime Unit to review NSO response plans and provide other guidance and assistance to the cruise ship industry.⁹⁶

By April 29, 2020, seven cruise ship operators representing approximately 110 cruise ships or about 95% of cruise ships subject to the April 15th extension had submitted NSO response plans.⁹⁷ A small number of cruise ship operators also chose to temporarily withdraw their ships from U.S. waters rather than complete the plan review

⁹⁰ *Id.* at 21007–08.

⁹¹ *Id.* at 21004–05.

⁹² See Request for Information Related to Cruise Ship Planning, 85 Fed. Reg. 44083, 44087 (July 21, 2020) (describing actions taken to restrict cruise ship travel by other countries, including Canada, Australia, and various European and Caribbean countries).

⁹³ *Id.* (CDC estimated that through July 10, 2020, it had worked to disembark and safely return home about 8,825 crew members, including 314 U.S. citizens and residents).

⁹⁴ *Id.*

⁹⁵ See *Attestation for Non-Commercial Travel or Crew Transfers Pre-Approval of NSO Response Plan*, CDC (Apr. 23, 2020), https://www.cdc.gov/quarantine/pdf/attestation-for-non-commercial-travel-pre-approval-of-nso-response-plan_042320_final_fillable-p.pdf.

⁹⁶ Request for Information Related to Cruise Ship Planning, 85 Fed. Reg. at 44088.

⁹⁷ *Id.*

process.⁹⁸ Additionally, the CDC published detailed guidance to assist cruise ship operators in preventing, detecting, and medically managing COVID-19 cases among crew,⁹⁹ established a new surveillance system to track COVID-19 data onboard cruise ships,¹⁰⁰ and created a color-coded classification system to guide operators in dealing with crew management issues.¹⁰¹

C. CDC Modifies and Extends NSO for a Second Time — July 16, 2020

On July 16, 2020, the CDC extended the nationwide NSO for a second time.¹⁰² This followed a June 19, 2020, decision by CLIA and its member lines to voluntarily extend its suspension of cruise operations from U.S. ports through September 15, 2020.¹⁰³ In issuing the second extension, the CDC noted the difficulty cruise ship operators had in developing and adhering to NSO response plans, as well as complying with the CDC disease prevention guidelines even though ships were

⁹⁸ Carnival Corporation advised CDC on May 24 and again on June 3, 2020, that none of its operating companies had any ships in U.S. waters. *Id.* at 44088, n.15. Windstar cruises similarly withdrew its ships from U.S. waters and stated that they had no intention of returning while the NSO remained in effect. *Id.* at 44088, n.16. Cruise ship operators with ships that had not been in U.S. waters during the period of the NSO or that chose to voluntarily withdraw their ships could regain “controlled free pratique” by submitting surveillance data and completing the NSO response plan review process. *Id.* at 44093, n.33.

⁹⁹ *Id.* at 44087.

¹⁰⁰ CDC developed the “Enhanced Data Collection (EDC) During COVID-19 Pandemic Form” to conduct disease surveillance among crew who remained on board cruise ships based on clinical indicators of COVID-19 such as acute respiratory illness, influenza-like illness, and pneumonia. *Id.*

¹⁰¹ CDC assessed the status of a ship by reviewing surveillance data from the weekly EDC form. “Green” ship status meant that a ship has no confirmed cases of COVID-19 or COVID-like illness and could lessen onboard restrictions for crew. “Yellow” status meant that one or more COVID-like illness cases had been reported onboard and testing was pending. “Red” status meant that COVID-19 had been confirmed onboard and the ship had to 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 changed to “Green.” *Id.* at 44087-88.

¹⁰² Like the previous order, the second extension remained in place until the earliest of three events: (1) expiration of the HHS Secretary’s declaration that COVID-19 constituted a public health emergency; (2) rescission or modification of the order by the CDC Director based on specific public health or other considerations; or (3) September 30, 2020. *Id.* at 44093-94.

¹⁰³ See Press Release, CLIA, CLIA Announces Voluntary Suspension of Cruise Operations from U.S. Ports (USA), (June 19, 2020), <https://cruising.org/en/news-and-research/press-room/2020/june/clia-announces-voluntary-suspension-of-cruise-operations-from-us-ports>.

operating with limited crew and no passengers.¹⁰⁴ Because the CDC required cruise lines to submit comprehensive response plans that completely and adequately addressed the elements of an appropriate plan described in the April 15th NSO extension, submission and review of these documents was burdensome for both cruise lines and the CDC.¹⁰⁵ Most plans required multiple reviews and revisions.¹⁰⁶ Plan elements that cruise lines typically failed to address adequately included lack of details concerning crew monitoring; not specifying quantities of onboard medical and testing equipment, including personal protective equipment; failing to close congregate crew settings such as self-service buffets, gyms, and other facilities; and not implementing social distancing protocols.¹⁰⁷

The CDC also noted alleged instances of cruise lines failing to comply with the April 15th NSO extension.¹⁰⁸ These allegations included failing to enforce social distancing, engaging in unauthorized crew transfers, failing to submit required surveillance data, hosting of social gatherings for crew, and not closing crew bars, gyms, and other group settings.¹⁰⁹ The CDC documented these alleged instances of non-compliance through a “*Notice of Potential Non-Compliance with the No Sail Order*” sent to cruise line officials requesting that they respond to allegations and propose corrective action.¹¹⁰ In extending the NSO through September 30, 2020, the CDC also noted the occurrence of continued outbreaks of COVID-19 onboard cruise ships,¹¹¹ as well as the evolving scientific evidence that cruise ships at the time posed a higher

¹⁰⁴ 85 Fed. Reg. at 44,091.

¹⁰⁵ See generally *id.*

¹⁰⁶ *Id.* at 44,088.

¹⁰⁷ *Id.*

¹⁰⁸ See generally, *id.* at 44,088-90.

¹⁰⁹ *Id.* at 44,088-89.

¹¹⁰ Such notices were sent to Holland America, Norwegian Cruise Line Holdings, and Disney Cruise Line. *Id.* In response to a “Dear Colleague” letter, Royal Caribbean and Virgin Voyages noted areas of non-conformity with the April 15th NSO and proposed their own corrective actions. *Id.*

¹¹¹ Cruise ships with significant outbreaks in passengers and crew occurring in foreign ports included the *Celebrity Eclipse* and *Coral Princess*. *Id.* at 44,090.

risk of COVID-19 transmission than other settings and “amplified an already highly transmissible disease.”¹¹²

D. CDC Modifies and Extends NSO for a Third Time — October 1, 2020

Contemporaneous with the CDC’s issuance of its second NSO extension in July 2020, Royal Caribbean Group and Norwegian Cruise Line Holdings established an expert panel known as the “Healthy Sail Panel” (HSP) to develop “practical and effective recommendations” related to COVID-19 mitigation that could be executed on cruise ships.¹¹³ On July 21, 2020, the CDC had also published a “*Request for Information Related to Cruise Ship Planning and Infrastructure, Resumption of Passenger Operations, and Summary Questions*” (RFI) soliciting public input and information to inform future public health guidance and measures related to cruise ship travel.¹¹⁴ The HSP’s methods included creating work groups to discuss and propose recommendations to the cruise ship industry in four topic areas: (1) health, screening and exposure reduction; (2) environmental, operations, and engineering controls; (3) response, contingency planning, and (4) execution; destination and itinerary planning.¹¹⁵ Crew safety issues were also considered.¹¹⁶ These work groups met at least every other week to discuss questions related to their topic area, including those questions raised in the CDC’s RFI.¹¹⁷ In biweekly meetings, the full HSP expert panel discussed the four work groups’ recommendations, modified them as needed, and reached a consensus as to whether the work groups’ recommendations should be incorporated into a final set of

¹¹² CDC cited an article published in the *Journal of Travel Medicine* demonstrating that prior to the implementation of control measures, such as ship-wide quarantine, the *Diamond Princess* cruise ship experienced an onboard R-naught (R0) for COVID-19 of 14.8, meaning that each case transmitted infection to approximately 15 other people. *Id.*

¹¹³ See *Healthy Sail Panel FAQs*, ROYAL CARIBBEAN, https://creative.rcl.com/Sales/Royal/Misc/HSP_FAQs_7.5.pdf (last visited Sept. 9, 2022).

¹¹⁴ 85 Fed. Reg. 44083 (July 21, 2020)

¹¹⁵ See *generally Advice from the Healthy Sail Panel*, at 4. (September 21, 2020), <https://safety4sea.com/wp-content/uploads/2020/09/healthy-sail-panel-full-recommendations.pdf> (hereinafter, “Healthy Sail Panel”).

¹¹⁶ *Id.* at 1, 4-5.

¹¹⁷ *Id.*

recommendations.¹¹⁸ The HSP's final set of recommendations were completed on September 21, 2020, and made available to the CDC.¹¹⁹

Although the CDC did not participate in the HSP's proceedings, it did send two observers who dialogued and exchanged information with other subject-matter experts.¹²⁰ The CDC's Maritime Unit also reviewed documents from the HSP's proceedings, as well as its final recommendations.¹²¹ The Maritime Unit agreed with the HSP's recommendations that certain public health measures, such as contact tracing, enhanced sanitation, in-cabin medical visits, and better COVID-19 education of passengers and crew, could help improve traveler comfort and public health outcomes.¹²² However, in the Maritime Unit's view more action was needed to prevent potentially infected travelers from boarding ships so that fewer government resources would be needed to manage cases and outbreaks.¹²³ Nevertheless, when the CDC later drafted the CSO, it adopted certain key proposals recommended by the HSP such as a "phased approach" to resuming passenger operations and simulated voyages to test new health and safety protocols.¹²⁴

On October 1, 2020, the CDC extended the nationwide NSO for a third and final time.¹²⁵ This was the shortest extension of the NSO, expiring 30 days later on October 31, 2020.¹²⁶ This action was again preceded by a decision made by CLIA and its member lines on August 5,

¹¹⁸ *Id.* at 5.

¹¹⁹ See Donald Wood, *Healthy Sail Panel Sends CDC Recommendations to Restart Cruises*, TRAVEL PULSE (Sept. 21, 2020, 9:18 AM), <https://www.travelpulse.com/news/cruise/healthy-sail-panel-sends-cdc-recommendations-to-restart-cruises.html>.

¹²⁰ See Declaration of Captain Aimee Treffiletti, Florida v. Becerra, 544 F. Supp. 3d 1241 (M.D. Fla. 2021) (No. 8:21-cv-00839)- (hereinafter, "Treffiletti Declaration").

¹²¹ *Id.* at 18-19.

¹²² *Id.* at 19.

¹²³ *Id.*

¹²⁴ *Id.* at 8-9.

¹²⁵ The third extension would remain in place until the earliest of: (1) expiration of the Secretary of Health and Human Services' declaration that COVID-19 constituted a public health emergency; (2) rescission or modification of the order by the CDC Director based on specific public health or other considerations; or (3) October 31, 2020. Third Modification and Extension of No Sail Order, 85 Fed. Reg. at 62,732 (U.S. Dept. Health & Hum. Servs. Ctrs. Disease Control & Prevention Oct. 5, 2020).

¹²⁶ *Id.*

2020, to voluntarily suspend operations through October 31, 2020.¹²⁷ Although the CDC and cruise lines had worked to slow transmission on cruise ships, from March 1 through September 28, 2020, there were 3,689 confirmed cases of COVID-19 on cruise ships and 41 deaths.¹²⁸

Among the reasons cited by the CDC for the difficulty in controlling transmission were the limitations of polymerase chain reaction (“PCR”) testing for COVID-19 that existed at that time.¹²⁹ Testing is a “snapshot in time” and some tests would either result in incorrect negative results (“false negatives”) or, not accurately reveal the presence of illness if conducted while the individual was still incubating the disease.¹³⁰ Thus, the CDC stressed the importance of accompanying crew testing with quarantine upon boarding a ship.¹³¹ The CDC also noted that some ships in foreign countries that had been permitted to resume operations had experienced outbreaks of COVID-19 among passengers and crew.¹³² The CDC surmised that even in circumstances where new health and safety protocols had been implemented to mitigate transmission of COVID-19, operators still needed additional time to appropriately educate and train crew on these new procedures.¹³³ Lastly, the CDC needed more time to consider the nearly 13,000 comments submitted in response to its RFI that could be used to inform future cruise ship operations.¹³⁴

¹²⁷ See Press Release, CLIA and Its Ocean-Going Cruise Line Members Announce Third Voluntary Suspension of U.S. Operations (USA), CLIA (Aug. 5, 2020), <https://cruising.org/en/news-and-research/press-room/2020/august/clia-announces-third-voluntary-suspension-of-us-cruise-operations>.

¹²⁸ CDC also estimated that during this timeframe more than 82% of ships within U.S. jurisdiction had been affected by COVID-19. Third Modification and Extension of No Sail Order, 85 Fed. Reg. at 62,732.

¹²⁹ *Id.* at 62,734-35.

¹³⁰ *Id.* at 62,735.

¹³¹ *Id.*

¹³² *Id.*

¹³³ See *id.* at 62,737-38.

¹³⁴ *Id.* at 62,736.

IV. CDC TRANSITIONS TO CONDITIONAL SAIL ORDER (CSO)

On October 30, 2020, the CDC transitioned from the NSO to the CSO, which outlined a plan to gradually return to cruise ship passenger operations in phases.¹³⁵ The CDC noted that no U.S. Food and Drug Administration (“FDA”) authorized vaccine against COVID-19 existed at that time.¹³⁶ Scientific evidence also supported a phased approach because unrestricted cruise ship travel would have likely “exacerbate[d] and amplif[ied]” the spread of COVID-19.¹³⁷ Without mitigation measures, cruise ships further posed a greater risk of transmitting COVID-19 than other settings.¹³⁸

In adopting the new framework, the CDC considered steps taken by cruise ship operators to improve their public health response to COVID-19, including through the HSP, as well as comments received to its RFI.¹³⁹ In response to its RFI, the CDC received comments from the public, as well as from the cruise industry, seaport authorities, and the travel and hospitality industries.¹⁴⁰ Approximately 75% of respondents, including many cruise travelers, supported resuming passenger cruising, although about 25% favored delaying cruise travel based on the state of the pandemic or until vaccines were widely available.¹⁴¹ However, even among those who supported a return to cruising, most commenters expressed the need for increased public health measures, such as health screening, testing, mask use, social distancing, travel insurance, refunds for those cancelling cruises due to illness, and limits on shipboard capacity.¹⁴² The CDC stated that although it

¹³⁵ Framework for Conditional Sailing and Initial Phase COVID-19 Testing Requirements for Protection of Crew, 85 Fed. Reg. 70,153 (U.S. Dept. Health & Hum. Servs. Ctrs. Disease Control & Prevention Nov. 4, 2020) [hereinafter *Framework for Conditional Sailing*].

¹³⁶ *Id.* at 70,154.

¹³⁷ *Id.* at 70,154-55.

¹³⁸ *Id.* at 70,156.

¹³⁹ *Id.* CDC did not consider the CSO to qualify as a rule under the Administrative Procedure Act (APA). *Id.* at 70,157. However, CDC noted that if it qualified as such, CDC had already obtained public comment through its RFI and, considering the public health emergency caused by COVID-19, good cause existed to forego a delay in effective date and further public comment. *Id.* at 70,158.

¹⁴⁰ *Id.* at 70,156.

¹⁴¹ *Id.*

¹⁴² *Id.*

bases its public health determinations on the best available science and not on public opinion, the willingness of the public to accept COVID-19 mitigation measures that affected the cruise experience was a significant factor in its approach.¹⁴³

The CDC also considered alternatives in adopting the new framework.¹⁴⁴ A return to unrestricted cruising, was rejected because it would have increased morbidity and mortality and burdened federal, state, and local medical and public health infrastructures.¹⁴⁵ In economic terms, public health oversight of the cruise ship industry was needed “to correct a market failure stemming from information asymmetry.”¹⁴⁶ The CSO was needed to overcome the “market failure” of travelers not being fully informed of which public health measures adopted by cruise ship operators would most likely mitigate their personal health risk of contracting COVID-19.¹⁴⁷ Another alternative, continuing to suspend cruise ship passenger operations, was also considered and rejected because it did not allow the CDC to distinguish between cruise ship operators that adopted COVID-19 mitigation measures from those that did not.¹⁴⁸ As originally conceived, the framework would have allowed individual cruise lines to progress through its phases at variable paces.¹⁴⁹ Cruise lines that successfully implemented public health measures would have been able to return to passenger operations more quickly than other cruise lines that, by necessity, moved more slowly.¹⁵⁰

¹⁴³ *Id.*

¹⁴⁴ *Id.*

¹⁴⁵ *Id.*

¹⁴⁶ *Id.* at 70,157. Asymmetric information occurs in a contractual agreement or economic transaction when two parties have disproportionate information. See Jason Gordon, *Asymmetric Information-Explained, What is Asymmetric Information*, THE BUS. PROFESSOR (Mar. 10, 2022), https://thebusinessprofessor.com/en_US/communications-negotiations/asymmetric-information-definition. Asymmetric information can lead the party with greater information to abuse or unfairly disadvantage the party with less information. *Id.*

¹⁴⁷ *Framework for Conditional Sailing*, *supra* note 135.

¹⁴⁸ *Id.*

¹⁴⁹ *Id.*

¹⁵⁰ *Id.*

The CSO announced a four-phase approach to resuming cruise ship passenger operations.¹⁵¹ These phases required cruise ship operators to: (1) establish a capacity to test crew (and future passengers) onboard ships in U.S. waters; (2) conduct a simulated voyage that would test their ability to mitigate onboard COVID-19; (3) complete a certification process; and (4) conduct passenger operations in a way that mitigated COVID-19 risk to passengers, crew, and shoreside communities.¹⁵² Although the CDC stated it would provide more information to cruise ship operators through forthcoming technical instructions and guidance, the CSO included many details regarding what steps operators would need to take to complete these phases.¹⁵³

The initial crew testing phases of the CSO required cruise ship operators to complete several steps.¹⁵⁴ First, cruise ship operators, under the CDC's supervision, had to collect clinical specimens from crew and arrange to have these samples transported to and tested by shoreside laboratory facilities.¹⁵⁵ Second, cruise ship operators in coordination with the CDC were to develop onboard testing capabilities to test all symptomatic travelers (crew and future passengers) and their close contacts for COVID-19.¹⁵⁶ This required cruise ship operators to obtain a specialized testing instrument (rapid RT-PCR point-of-care equipment) and ensure that medical staff were properly trained in specimen handling, storage, and testing.¹⁵⁷ The CDC did not require cruise ships to build onboard facilities comparable to shoreside laboratories.¹⁵⁸ Rather, the testing instrument was about the size of desktop printer, required only rudimentary training, and fitted easily within a cruise ship's pre-existing medical center that typically carries different types of testing equipment for diagnosing shipboard illness.¹⁵⁹ Finally, the

¹⁵¹ *Id.*

¹⁵² *Id.* at 70, 153.

¹⁵³ *Id.* at 70, 153.

¹⁵⁴ *Id.* at 70, 153.

¹⁵⁵ *Id.*

¹⁵⁶ *Id.*

¹⁵⁷ *Id.* at 70, 162.

¹⁵⁸ Temporary Extension and Modification of Framework for Conditional Sailing Order (CSO) for Cruise Ships Operating or Intending to Operate in U.S. Waters, 86 Fed. Reg. 59,720, 59723 n.11 (U.S. Dept. Health & Hum. Servs. Ctrs. Disease Control & Prevention Oct. 22, 2021).

¹⁵⁹ *Id.*

CDC required newly embarking land-based crew to have specimens collected and tested shoreside for COVID-19.¹⁶⁰ These newly-embarking crew members would then be quarantined (or isolated if they tested positive) upon boarding the ship.¹⁶¹ The CDC expected cruise ship operators to complete the mass crew testing component of these initial phases within 60 days (i.e., December 29, 2020).¹⁶²

The subsequent phases of the CSO also required cruise ship operators to take multiple steps.¹⁶³ First, in preparation for obtaining permission to conduct a simulated voyage and apply for the necessary sailing certificate, cruise ship operators had to document the existence of various agreements.¹⁶⁴ These included: (1) a medical care agreement addressing the evacuation and onshore hospital needs of passengers and crew; (2) a housing agreement identifying shoreside facilities for isolation and quarantine of COVID-19 cases and their close contacts; and (3) a port agreement to determine the number of ships that could dock at a single port without overwhelming the public health response resources of any single jurisdiction.¹⁶⁵ Second, in conducting the simulated voyage, cruise ship operators had to follow certain minimum health and safety standards.¹⁶⁶ These included standards for documenting the informed consent of participants, undertaking a simulated voyage in such a way as to replicate certain cruise-related activities (e.g., embarking and disembarking, transferring of sick patients from cabins to isolation rooms, and evacuation procedures), and addressing any observed deficiencies through an “after-action” report.¹⁶⁷ Third, the cruise ship operator in applying for a “COVID-19 Conditional Sailing Certificate” had to complete an application and submit a signed certification under 18 U.S.C. § 1001 attesting to its ability to manage severe COVID-19 cases and outbreaks as required by the

¹⁶⁰ *Framework for Conditional Sailing*, *supra* note 135, at 70,163.

¹⁶¹ *Id.* at 70,159.

¹⁶² *Id.* at 70,162.

¹⁶³ *Id.* at 70,159.

¹⁶⁴ *Id.*

¹⁶⁵ *Id.*

¹⁶⁶ *Id.*

¹⁶⁷ *Id.* at 70,159-60.

CDC.¹⁶⁸ Finally, assuming its application for a sailing certificate had been approved, the cruise ship operator was permitted to conduct passenger revenue voyages in accordance with certain minimum standards, such as agreeing to cancel the voyage once a predetermined threshold of COVID-19 cases had been detected onboard.¹⁶⁹ The CDC would also need to issue additional technical instructions and guidance documents to allow cruise ship operators to complete these phases.

V. CDC ISSUES TECHNICAL INSTRUCTIONS AND GUIDANCE UNDER THE CSO

The CDC released technical instructions and guidance for the next phase of the CSO in two phases.¹⁷⁰ The technical instructions for Phase 2A were released on April 2, 2022, and included more frequent illness reporting and routine testing, an updated color-coding system for ships, and planning materials for the medical, housing, and port agreements needed to ensure that cruise lines had the necessary infrastructure in place in the event of outbreaks.¹⁷¹ Importantly, in the interim months between the issuance of the CSO and the Phase 2A guidance, the FDA had issued Emergency Use Authorizations (EUAs) for two different COVID-19 vaccines, Pfizer-BioNTech and Moderna.¹⁷² Thus, cruise ship operators, as required through the CDC's technical instructions relating to port agreements, were also required to establish a plan and timeline for vaccination of crew and port personnel.¹⁷³

The approximately three-month delay between December 29, 2020 (the date by which most cruise ship operators were expected to

¹⁶⁸ *Id.* at 70,160.

¹⁶⁹ *Id.* at 70,161.

¹⁷⁰ See Media Statement, U.S. Dept. Health & Hum. Servs. Ctrs. for Disease Control & Prevention, CDC Issues Next Phase of the Conditional Sail Ord. for Cruise Ship Operators (Friday, Apr. 2, 2021), <https://www.cdc.gov/media/releases/2021/s0402-conditional-sail-orders.html> [hereinafter *CDC Media Statement Next Phase*].

¹⁷¹ *Id.*

¹⁷² See *CDC Museum COVID-19 Timeline*, U.S. DEPT. HEALTH & HUM. SERVS. CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/museum/timeline/covid19.html> (Aug. 16, 2022) (“December 11, 2020[:] FDA issues an EUA for the Pfizer-BioNTech COVID-19 vaccine”; “December 18, 2020[:] FDA issues an EUA for the Moderna COVID-19 vaccine.”).

¹⁷³ See *CDC Media Statement Next Phase*, *supra* note 170.

complete mass crew testing) and April 2, 2021 (the date the CDC issued its Phase 2A technical instructions and guidance), was attributed to several factors.¹⁷⁴ Among other things, cruise ship operators needed more time to conduct mass crew testing and procure testing instruments and supplies some of which were in short supply.¹⁷⁵ The CDC also attributed the delay to the change in administration that occurred on January 20, 2021, which involved changes in the CDC and other federal leadership and necessitated briefing new individuals concerning the CDC's cruise ship response activities.¹⁷⁶ Drafting new guidance was also a time-consuming process that required consultation with federal and local partners.¹⁷⁷

On April 5, 2021, three days after the issuance of the CDC's Phase 2A guidance, CLIA issued a statement criticizing the guidance as burdensome, largely unworkable, and purportedly reflecting a "zero-risk objective" rather than a mitigation approach.¹⁷⁸ Three days later, on April 8, 2021, the State of Florida filed suit against the CDC in federal district court challenging the CSO on the basis that it economically harmed Florida and its citizens.¹⁷⁹ Then, beginning on April 12, 2021, the CDC began a series of twice-weekly meetings with senior leadership from other federal agencies and representatives from various cruise lines.¹⁸⁰ These meetings allowed participants to engage in more

¹⁷⁴ Treffiletti Declaration, *supra* note 120, at 21.

¹⁷⁵ *Id.*

¹⁷⁶ *Id.*

¹⁷⁷ *Id.*

¹⁷⁸ See Press Release, Cruise Lines Int'l Ass'n, Cruise Lines International Association (CLIA) Issues Statement Reiterating Its Call for the Lifting of the CDC's Conditional Sailing Order (Apr. 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>.

¹⁷⁹ See News Release, Governor Ron DeSantis, Governor Ron DeSantis and Attorney General Ashley Moody Announce Lawsuit Against Biden Administration Shutdown of Cruise Industry (Apr. 8, 2021), <https://www.flgov.com/2021/04/08/governor-ron-desantis-attorney-general-ashley-moody-announce-lawsuit-against-biden-administration-shutdown-of-cruise-industry/>.

¹⁸⁰ See Media Statement, U.S. Dept. Health & Hum. Servs. Ctrs. for Disease Control & 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> [hereinafter CDC Media Statement Phases 2B and 3]. Although these high-level senior leadership calls began in April, CDC had frequent interactions with cruise lines beginning in November 2020 to gather information about their restart plans. See Third Declaration of Captain Aimee

dialogue and exchange information relating to the impact of vaccines and other scientific developments relating to the ongoing COVID pandemic and its effects on cruising.¹⁸¹ Participants also had the opportunity to raise operational questions relating to the CSO and the CDC's published technical instructions relating to mass crew testing and Phase 2A.¹⁸²

On April 28, 2021, the CDC released a "Dear Colleague" letter that provided important clarifications relating to the CDC's previously issued Phase 2A guidance, acknowledged that cruising would never be a "zero-risk" activity, and committed to resuming passenger operations under the CSO by mid-summer.¹⁸³ Among other things, in the "Dear Colleague" letter, the CDC: (1) committed to responding to applications for Conditional Sailing Certificates within 5 business days; (2) allowed cruise ship operators to embark up to 50% of non-essential crew needed for their first revenue sailings before finalizing their port agreements; (3) authorized the use of multi-port agreements (as opposed to separate agreements with individual port authorities); (4) acknowledged that a hospital (as a party to a cruise ship operator's medical agreement) could not guarantee specific bed capacity for sick passengers and crew; and (5) clarified that cruise operators when negotiating housing agreements could consider the ability of travelers to drive to and quarantine in their own private residences.¹⁸⁴ Importantly, the CDC also allowed cruise ship operators, at their discretion, to forego conducting a simulated voyage if 98% of crew (later lowered to 95%) were fully vaccinated and the operator limited sailings to 95% of passengers who had been verified by the cruise line as fully vaccinated prior to sailing.¹⁸⁵ These percentages were based on CDC modeling data indicating that in addition to other preventative measures such as quarantine of newly embarking crew and testing, cruise ship operators

Treffiletti at 10, *Florida v. Becerra*, 544 F. Supp. 3d 1241 (M.D. Fla. 2021) (No. 8:21-cv-00839), (hereinafter Third Treffiletti Declaration).

¹⁸¹ CDC Media Statement Phases 2B and 3, *supra* note 180.

¹⁸² *Id.*

¹⁸³ See Letter from Captain Aimee Treffiletti, USPHS, Mar. Unit, Glob. Migration Task Force, CDC, to Cruise Industry Colleagues (Apr. 28, 2021), https://s.wsj.net/public/resources/documents/Cruise%20Line%20Meetings%20Dear%20Colleague%20Letter_4%2028%202021_FINAL.pdf. [hereinafter *Letter from Captain Aimee Treffiletti*]

¹⁸⁴ *Id.*

¹⁸⁵ *Id.*

needed to conduct voyages with a high percentage of vaccinated passengers and crew to avoid significant outbreaks of COVID-19.¹⁸⁶

On May 5, 2021, the CDC released the technical instructions for Phase 2b and 3 of the CSO.¹⁸⁷ Based on these additional instructions, cruise ship operators now had all the planning materials they needed to conduct a simulated voyage and apply for a COVID-19 Conditional Sailing Certificate.¹⁸⁸ These technical instructions included eligibility and requirements for conducting a simulated voyage, guidance for cruise ship inspections conducted during simulated and restricted passenger voyages, and operational procedures to mitigate COVID-19 risk (e.g., surveillance, laboratory testing, infection prevention and control, use of face masks, social distancing, and protocols for embarking and disembarking passengers).¹⁸⁹ The CDC did not anticipate releasing any additional documents for Phase 4 because, in the final phase of the CSO, cruise ships operators could conduct passenger revenue voyages in accordance with the CSO's requirements.¹⁹⁰ However, as needed, the CDC would update online documents to incorporate changes to quarantine, testing, and cruise ship color status based on lessons learned and the evolving state of the pandemic.¹⁹¹

The CDC subsequently made a series of updates to various online guidance documents, including its operations manual, technical instructions, and cruise ship color status, on May 14, May 18, May 26, and June 4, 2021.¹⁹² The CDC updated or revised these documents to better align with changes in other CDC guidance or based on information gathered from individual cruise lines during twice weekly industry and U.S. government interagency calls.¹⁹³ These changes reflected the improving public health outlook at the time, including increasing U.S. vaccination rates and decreasing U.S. deaths and case

¹⁸⁶ See Treffeletti Declaration, *supra* note 120, at 28.

¹⁸⁷ CDC Media Statement Phases 2B and 3, *supra* note 180.

¹⁸⁸ *Id.*

¹⁸⁹ *Id.*

¹⁹⁰ *Id.*

¹⁹¹ *Id.*

¹⁹² See Supplemental Declaration of Captain Aimee Treffeletti at 3-4, Florida v. Becerra 544 F. Supp. 3d 1241 (M.D. Fla. 2021) (No. 8:21-cv-00839) (hereinafter, "Supplemental Treffeletti Declaration").

¹⁹³ *Id.* at 4.

counts, and benefited the cruise industry by reducing burdens and alleviating restrictions.¹⁹⁴ On May 11, 2021, CLIA had also sent the CDC a letter stating, among other things, “vaccines are a gamechanger and cruise line requirements will serve to incentivize passengers to become vaccinated.”¹⁹⁵

The CDC, in coordination with the cruise industry, also moved quickly to approve port agreements and requests to conduct simulated voyages.¹⁹⁶ As of June 4, 2021, the CDC’s Maritime Unit had approved port agreements for 22 ships with 6 additional ships pending review.¹⁹⁷ The Maritime Unit had also received 11 requests to conduct simulated voyages and approved 9, with most voyages scheduled to occur in mid-to-late summer.¹⁹⁸ As of June 4, 2021, the CDC had also provisionally approved (approved subject to submission of certain documents) two applications for COVID-19 Conditional Sailing Certificates.¹⁹⁹

On June 20–22, 2021, the first simulated voyage occurred with five CDC personnel present to inspect the vessel and three inspectors sailing onboard the cruise ship during the simulated voyage.²⁰⁰ During and at the close of the inspection, CDC inspectors shared and discussed their observations with cruise ship personnel, including observations relating to areas of needed improvement, such as staff training, documentation procedures, clearer signage, and better separation of vaccinated and unvaccinated travelers.²⁰¹ On June 26, 2021, the Royal Caribbean Group became the first cruise ship operator to conduct a revenue passenger voyage in U.S. waters since the start of the pandemic.²⁰²

¹⁹⁴ *Id.*

¹⁹⁵ See Time Sensitive Motion for a Stay Pending Appeal and Admin. Stay, *Florida v. Becerra*, 544 F.Supp.3d 1241 (M.D. Fla. 2021) (No. 21-12243).

¹⁹⁶ See *id.* at 1-2; Supplemental Treffiletti Declaration, *supra* note 192 at 1-2.

¹⁹⁷ Time Sensitive Motion for a Stay Pending Appeal and Admin. Stay, *Florida v. Becerra*, 544 F.Supp.3d 1241 (M.D. Fla. 2021) (No. 21-12243) at A25.

¹⁹⁸ *Id.* at A25, A131.

¹⁹⁹ *Id.* at A18-A19.

²⁰⁰ See Third Treffiletti Declaration, *supra* note 180, at 12.

²⁰¹ *Id.* at 12-13.

²⁰² *Id.* at 13; see also Andrea Sachs, *Aboard the First Cruise Ship to Set Sail from the States Since the Pandemic Began*, WASH. POST (Jul. 16, 2021, 8:00 AM), <https://www.washingtonpost.com/lifestyle/travel/first-cruise-celebrity-edge-coronavirus->

VI. FEDERAL DISTRICT COURT ENJOINS CDC FROM ENFORCING CSO IN FLORIDA

On June 18, 2021, the U.S. District Court for the Middle District of Florida issued a preliminary injunction, effective July 18, 2021, enjoining the CDC from enforcing the CSO, and related technical instructions and guidance, against cruise ships arriving in, within, or departing from a port in Florida.²⁰³ Florida had filed this action on April 8, 2021, asserting five claims: (1) the CSO exceeded the CDC's statutory and regulatory authority; (2) the CDC acted arbitrarily and capriciously in issuing the CSO; (3) the CDC unreasonably delayed agency action necessary to allow cruise ships to resume passenger operations; (4) the CDC failed to conduct notice and comment rulemaking and improperly relied on the "good cause" exception to the notice requirement under 5 U.S.C. § 553(b)(B); and (5) if interpreted according to the CDC, section 361 of the PHS Act²⁰⁴ would constitute an unconstitutional delegation of legislative authority.²⁰⁵ Florida then moved for a preliminary injunction claiming that the CSO's phased return to cruise ship passenger operations caused it irreparable economic injury.²⁰⁶ Notably, Florida's claims were premised entirely upon economic considerations; at no point did Florida submit evidence by any public health experts, not even by its own state health department or Florida Surgeon General.²⁰⁷

As an initial matter, the court found that Florida had standing because it had established an economic injury attributable to increased unemployment spending for former cruise industry employees and an ongoing injury to Florida ports based on lost tax revenue.²⁰⁸ Florida's alleged injury was also "fairly traceable" to the CSO because it inhibited full resumption of, and the expected state revenue from, cruise

[safety/2021/07/15/e5494e5e-de7b-11eb-ae31-6b7c5c34f0d6_story.html](https://www.fda.gov/safety/2021/07/15/e5494e5e-de7b-11eb-ae31-6b7c5c34f0d6_story.html).

²⁰³ Florida v. Becerra, 544 F. Supp. 3d 1241, 1305 (M.D. Fla. 2021) (based on appellate proceedings in this case, the preliminary injunction became effective on July 23, 2021); see Order Vacating July 17, 2021 Order and Denying Appellant's Time Sensitive Motion for Stay Pending Appeal and Administrative Stay, Florida v. Becerra, 544 F. Supp.3d 1241 (2021) (No. 21-12243-D).

²⁰⁴ 42 U.S.C. § 264.

²⁰⁵ *Becerra*, 544 F. Supp. 3d at 1246-47.

²⁰⁶ *Id.* at 1250-51.

²⁰⁷ See Complaint, Florida v. Becerra, 544 F. Supp. 3d 1241 (M.S. Fla. 2021) (No. 8:21-cv-00839).

²⁰⁸ *Becerra*, 544 F. Supp. 3d at 1253-54.

ships' sailing.²⁰⁹ Furthermore, Florida's alleged injury was "redressable" because enjoining all or part of the CSO would allow cruise ships to "sail more quickly" and "mitigate . . . the plausible and imminent prospect of the cruise industry's leaving" the state.²¹⁰ Additionally, the court found that Florida had standing under the Administrative Procedure Act (APA) because it asserted an interest within the zone of interests protected by that statute.²¹¹ Further, the court found statutory standing existed under the APA because the PHS Act (the statutory basis for the CDC's actions) anticipated an effect on states and the CSO constrained Florida's economy.²¹²

The court also found that Florida had shown a likelihood of success on the merits of its claim that the CDC had exceeded its statutory and regulatory authority.²¹³ Relying mostly on a recent line of cases critical of the CDC's issuance of an eviction moratorium in response to the COVID-19 pandemic,²¹⁴ the court interpreted the broad grant of statutory authority in the first sentence of section 361(a) of the PHS Act²¹⁵ referencing the HHS Secretary's authority to make and enforce regulations as "necessary" and "in his judgment" to be limited by the specific measures (i.e., "inspection, fumigation, disinfection . . .") enumerated in the second sentence of the statute.²¹⁶ The court also employed various canons of statutory interpretation to reach a similar conclusion: *ejusdem generis* (confining general words to the meaning of specific and particular words); *noscitur a sociis* (defining ambiguous words by neighboring words); canon against surplusage (giving effect to every word in a statute); constitutional avoidance canon (construing a statute to avoid its unconstitutionality); and the major questions

²⁰⁹ *Id.* at 1254-55.

²¹⁰ *Id.* at 1256.

²¹¹ *Id.* at 1256-57.

²¹² *Id.*

²¹³ *Id.* at 1276.

²¹⁴ *E.g.*, *Tiger Lily, LLC v. HUD*, 992 F.3d 518, 523 (6th Cir. 2021); *Skyworks, Ltd. v. CDC*, 524 F. Supp. 3d 745, 759-60, (N.D. Ohio 2021); *Alabama Ass'n of Realtors v. HHS*, 539 F. Supp. 3d 29, 39 (D.D.C. 2021).

²¹⁵ 42 U.S.C. § 264(a).

²¹⁶ *Becerra*, 544 F. Supp. 3d at 1268-70.

doctrine (assuming that Congress speaks clearly when assigning agencies expansive powers of political or economic significance)..²¹⁷

In the court's view, although the CSO contained a few requirements resembling the CDC's statutory authority under section 361(a), such as reporting of "ill" passengers and sanitizing certain areas of a ship, it also included unauthorized measures.²¹⁸ These measures included requiring cruise ship operators to: "(1) build an onboard laboratory, (2) revamp a ship's ventilation system, (3) remain detained until complying with long-delayed and ever-shifting requirements, and (4) ensure the vaccination of 98% of crew and 95% of the passengers to bypass a costly and burdensome simulated voyage requirement."²¹⁹ The court also rejected the view that the CSO merely placed conditions on the issuance of free pratique for a ship to operate at a U.S. port finding that the CSO imposed "an indiscriminate and burdensome conditioning of free pratique that amounts to an unprecedented detention of an entire fleet of recreational cruising vessels."²²⁰

Additionally, the court construed the CDC's regulations as authorizing only a relatively narrow set of public health measures related to ships arriving from foreign ports.²²¹ For instance, detention and conditioned free pratique under 42 CFR 71.31(a) were only "temporary tools directed to a specific vessel to accomplish the other measures appearing in Part 71"²²² whereas, the CSO was a "long-term detention" prescribing "excruciating and extra-regulatory" measures.²²³ Further, the broad authority under 42 CFR 70.2 to take measures in the event of inadequate local control also could not be used to fill gaps in

²¹⁷ *Id.*

²¹⁸ *Id.* at 1272.

²¹⁹ *Id.*

²²⁰ *Id.*

²²¹ *See id.* at 1272-76.

²²² *Id.* at 1274; Other measures specifically enumerated under Part 71 include disinfection of cargo under § 71.42 or disinfestation of vermin under § 71.41. *Id.*

²²³ *Id.* ("The conditional sailing order prescribes excruciating and extra-regulatory 'measures,' such as the requirement to build laboratories on board; the requirement to contract with customers as well as several public and private entities at ports-of-call; the requirement for pervasive daily testing and reporting; the requirement to conduct self-funded, expensive simulated voyages (or to vaccinate 95% of passengers, including children too young to qualify for vaccination at this time); and the requirement to limit operations after obtaining a conditional sailing certificate.").

regulations under Part 71 because section 70.2 “fails to suggest any broader authority” and Part 70 “says nothing meaningful about the regulation of a vessel.”²²⁴ Regardless, in the court’s view these regulations could not confer more authority than permitted by the statute, which if read consistent with the CDC’s interpretation would constitute an unconstitutional delegation of legislative authority based on a lack of sufficient “intelligible principles” limiting agency action.²²⁵ Lastly, the court found that Florida was likely to succeed on the merits of its claim that the CSO was arbitrary and capricious under the APA based on lack of sufficient good cause and notice,²²⁶ and because it imposed “exhaustive, indeterminate, inconsistent, and unclear requirements” on the cruise ship industry.²²⁷

The court also dismissed the CDC’s argument that the passage of the Alaska Tourism Restoration Act (ATRA), Pub. L. No. 117-14, 117th Cong. (May 24, 2021), acted as Congressional ratification of the CSO.²²⁸ Under the Passenger Vessel Services Act (PVSA), foreign-flagged cruise ships are prohibited from sailing from a U.S. port to another U.S. port unless the cruise ship stops in transit at a foreign port.²²⁹ The ATRA created an exemption under the PVSA for cruise ships sailing to and from Alaska if these ships had a “COVID-19 Conditional Sailing Certificate” issued by the CDC.²³⁰ In the court’s view, the ATRA did not act as Congressional ratification of the CSO because Congress had merely used the CSO as a means of identifying the category or class of ships temporarily exempted from the PVSA.²³¹ This interpretation

²²⁴ *Id.* at 1273.

²²⁵ *See id.* at 1278-88.

²²⁶ Although the court recognized that CDC solicited comments through its RFI, the court did not consider this as satisfying the notice and comment requirements under the APA because CDC purportedly did not evaluate and respond to specific comments. *Id.* at 1294-95, 1298. (“At every turn, CDC’s informal, quasi-notice-and-comment ‘interaction’ amounts to an extended monologue, supported by the unconvincing veneer of a ‘request for information,’ after which the agency failed to account to the cruise industry, to the states, and to the public”).

²²⁷ *Id.* at 1290-99.

²²⁸ *Id.* at 1276-78

²²⁹ *See* 46 U.S.C. § 55103.

²³⁰ *Becerra*, 544 F. Supp. 3d at 1276-77.

²³¹ *Id.* at 1277.

ignored the fact that Congress had also named the specific ships eligible for this exemption in the statute.²³²

VII. CDC MOVES FOR AN EMERGENCY STAY PENDING APPEAL

The district court's June 18, 2021, order preliminarily enjoined the CDC from enforcing the CSO (including technical instructions, manuals, and similar guidance) against any cruise ship arriving in, within, or departing from a port in Florida.²³³ However, the district court stayed its order until July 18, 2021, at which time the CSO and its guidance could only continue to exist as non-binding recommendations, "the same tools used by [the] CDC when addressing the practices in other similarly situated industries, such as airlines, railroads, hotels, casinos, sports venues, buses, subways, and others."²³⁴ The court also allowed the CDC to propose a narrower injunction "permitting cruise ships to sail timely and remaining within the CDC's authority as interpreted in this order" until July 2, 2021.²³⁵ On July 6, 2021, the CDC submitted a notice of appeal to the U.S. Court of Appeals for the Eleventh Circuit and moved for an emergency stay pending appeal.²³⁶

In its time-sensitive motion for a stay pending appeal and an administrative stay of the district court's preliminary injunction, the CDC made several arguments.²³⁷ First, it stressed that the CDC had closely

²³² The district court's statutory interpretation of the ATRA is puzzling because the ATRA listed specific ships eligible for its exemption by name. *See* Alaska Tourism Restoration Act, Pub. L. No. 117-14, May 24, 2021, 135 Stat. 273. Thus, there would have been no need for Congress to identify these ships as a category or class by also referencing the CSO unless Congress intended to ratify CDC's actions. The court seems not to have considered the statutory canon against surplusage in its analysis.

²³³ *Becerra*, 544 F. Supp. 3d at 1305.

²³⁴ *Id.*

²³⁵ *Id.*

²³⁶ *See* Notice of Appeal, *Florida v. Becerra*, 544 F.Supp.3d 1241 (M.D. Fla. 2021) (No. 8:21-cv-00839); Defendants' Time-Sensitive Motion For a Stay Pending Appeal, *Florida v. Becerra*, 544 F.Supp.3d 1241 (M.D. Fla. 2021) (No. 8:21-cv-00839). For reasons related to litigation practice, this time sensitive motion for a stay pending appeal was submitted before both the district court and the U.S. Court of Appeals for the Eleventh Circuit. *Id.* On July 7, 2022, the district court denied the motion for a stay pending appeal for substantially the same reasons outlined in its preliminary injunction order. *See* Order Denying Motion to Stay, *Florida v. Becerra*, 544 F.Supp.3d 1241 (M.D. Fla. 2021) (No. 8:21-cv-00839).

²³⁷ *See* Time Sensitive Motion for a Stay Pending Appeal and Administrative Stay, *Florida v.*

consulted with cruise lines in developing the CSO's health and safety protocols which relied on traditional public health tools such as testing and reporting of cases, quarantining exposed persons and isolating the infected, and collecting and analyzing public health data.²³⁸ In contrast, Florida had impeded cruise ship operators by enacting a law (signed May 3, 2021) prohibiting cruise lines from documenting proof of vaccination from passengers.²³⁹ Second, Florida could not establish standing or irreparable injury because it was not an entity regulated by the CSO and had contributed to its own injury by interfering with cruise ship operators' plans to require vaccination of passengers.²⁴⁰ Third, Florida was unlikely to succeed on the merits because the CSO and its guidance was well within the CDC's longstanding authority, had been ratified by Congress when it passed ATRA,²⁴¹ was not in violation of the non-delegation doctrine,²⁴² and did not require notice and

Sec'y, Dep't of Health and Hum. Servs., No. 21-12243 (11th Cir. July 7, 2021) (hereinafter, "Time Sensitive Motion").

²³⁸ *Id.*

²³⁹ *Id.* at 2; *see also* Fla. Stat. § 381.00316 (2021); *Norwegian Cruise Line Holdings, Ltd. v. State Surgeon Gen., Fla. Dept. of Health*, 50 F. 4th 1126, 1134-1155 (11th Cir. 2022) (holding that Florida's statute prohibiting businesses from requiring documentary proof of vaccination was a regulation of economic conduct that did not implicate the First Amendment nor violate the dormant Commerce Clause). Although not a party to the proceedings, NCLH submitted an amicus brief before the Eleventh Circuit stating that it supported and fully intended to comply with the CSO. *See* USCA11, Docket # 21-12243 (filed 7/13/2021). In NCLH's view, the chief impediment to it resuming operations ironically was Florida, not CDC, because Florida's vaccine passport law interfered with its plans to resume operations with 100% vaccinated passengers and crew. *Id.*

²⁴⁰ Time Sensitive Motion at 13-15, *supra* note 237.

²⁴¹ The CDC noted that the ATRA, applied to cruise ships that specifically operated in accordance with and retained a COVID-19 Conditional Sailing Certificate. *Id.* at 18-19. It argued that the district court had offered no sound explanation for ignoring this statute. *Id.*

²⁴² *Id.* at 20. The CDC noted that the non-delegation applied with reduced force in the context of foreign affairs. *Id.* Specifically, the CSO related to foreign affairs because cruise ships operating out of Florida's ports were all foreign-flagged and traveled to foreign countries. *Id.* Regardless, it argued that the standard set out in 42 U.S.C. § 264 was sufficiently detailed to defeat a non-delegation challenge. *Id.*

comment.²⁴³ Finally, the public interest favored the CDC because enjoining the CSO would exacerbate the spread of COVID-19.²⁴⁴

In support of its appeal motion, the CDC submitted a declaration from Captain Aimee Treffiletti who was the lead in charge of the CDC's Maritime Unit.²⁴⁵ Among other things, the declaration sought to correct the significant factual errors and mischaracterizations of the CSO made by the district court in its preliminary injunction order.²⁴⁶ For instance, the CSO did not require cruise ships to build expensive onboard laboratories.²⁴⁷ Instead, operators had to purchase an onboard testing unit about the size of a desktop printer that fit easily within their existing medical centers.²⁴⁸ Similarly, the CSO did not require operators to revamp a ship's ventilation system, but rather ensure that existing ventilation systems (e.g., toilet room exhaust fans) operated properly and medical centers and cabins designated for isolation and quarantine had sufficient negative air pressure (i.e., air blows in, not out).²⁴⁹ Importantly, at no time had any cruise ship been "detained" under the CSO.²⁵⁰ Cruise ships that chose not to follow the CSO's health and safety standards were free to depart U.S. waters.²⁵¹ Those ships continuing to operate in U.S. waters under the CSO were also not "detained" but free to move about.²⁵² Finally, although cruise ships shared similarities with other forms of travel (e.g., airlines, railroads, buses, subways) and recreational activities (e.g., hotels, casinos, sports venues, and theme parks), scientific studies had confirmed that

²⁴³ The CDC argued that "controlled free pratique" operated as a "license" which qualified as an "order" under the APA and not as a "rule." *Id.* at 22. In any event, it argued that the purposes of notice and comment rulemaking under the APA had been served by the CDC soliciting and fully considering comments submitted under the RFI. *Id.*

²⁴⁴ *Id.* at 23.

²⁴⁵ See Third Treffiletti Declaration, *supra* note 180, at 2.

²⁴⁶ *Id.* at 5-7.

²⁴⁷ *Id.* at 6.

²⁴⁸ *Id.*

²⁴⁹ *Id.* at 6-7.

²⁵⁰ *Id.* at 7; see also 42 C.F.R. § 71.1 (defining detention as "the temporary holding of a person, ship, aircraft, or other carrier, animal, or thing in such place and for such period of time as may be determined by the Director.").

²⁵¹ See Third Treffiletti Declaration, *supra* note 180, at 7.

²⁵² *Id.*

transmission rates at the time for COVID-19 were higher onboard cruise ships than in other settings.²⁵³

The Treffiletti Declaration also highlighted the important progress made by the cruise ship industry in collaboration with the CDC to resume passenger operations.²⁵⁴ Despite this progress, and the CDC's acknowledgement that cruising would never be a "zero-risk" activity, the public health situation still required federal supervision to allow operators to resume passenger operations in a way that mitigated public health risk.²⁵⁵ Because nearly all cruise ships are foreign flagged, operate on roundtrip itineraries, and, per the PVSA, may not travel between U.S. ports without making a stop at a foreign port, the CDC was the only jurisdictional entity capable of overseeing public health onboard cruise ships.²⁵⁶ Moreover, public health departments at the state and local level did not traditionally regulate cruise ship operations and typically lacked the legal authority, staffing, training, and public health resources to conduct disease surveillance and manage communicable disease risk on board cruise ships.²⁵⁷ Florida, in particular, appeared to have no health and safety protocols specific to mitigating COVID-19 risk onboard cruise ships.²⁵⁸ Lastly, the CDC had recently classified the Delta variant as a virus variant of concern that spread more easily than earlier variants and for which public health measures (particularly with regard to the unvaccinated) such as mask use and physical distancing were especially important.²⁵⁹

VIII. COURT DENIES EMERGENCY STAY AND PRELIMINARY

²⁵³ *Id.* at 2-3.

²⁵⁴ As of July 5, 2021: (1) 53 out of the 65 cruise ships covered by the CSO had completed mass crew testing and 59 had acquired the necessary onboard laboratory testing equipment; (2) the Maritime Unit had approved port agreements that collectively covered 47 vessels at 11 ports of call; (3) the Maritime Unit had granted 13 requests from cruise ship operators to conduct simulated voyages; and (4) the Maritime Unit had issued COVID-19 Conditional Sailing Certificates to 12 ships to conduct revenue passenger voyages. *Id.* at 7-10.

²⁵⁵ *Id.* at 4.

²⁵⁶ *Id.*; Sherri Eisenberg, *What is the Jones Act and how does it impact cruise ships?*, THE POINTS GUY (Dec. 27, 2021), <https://thepointsguy.com/guide/what-is-the-jones-act-for-cruise-ships/>.

²⁵⁷ Third Treffiletti Declaration, *supra* note 180, at 4-5.

²⁵⁸ *Id.* at 5.

²⁵⁹ *Id.* at 15.

INJUNCTION ENTERS INTO EFFECT

On July 17, 2021, the U.S. Court of Appeals for the Eleventh Circuit issued an order granting the CDC's emergency motion for a stay pending appeal of the district court's preliminary injunction.²⁶⁰ The order noted that one of the judges on the three-judge panel had dissented and that opinions would follow.²⁶¹ However, six days later, on July 23, 2021, the Eleventh Circuit issued an order *sua sponte* vacating its July 17th order on the basis that the CDC had failed to demonstrate that it was entitled to a stay pending appeal.²⁶² The July 23rd order vacating the court's earlier order was unaccompanied by any opinions and offered no additional explanation.²⁶³

On July 23, 2021, understanding the district court's preliminary injunction order to now have immediate effect, the CDC sent a "Dear Colleague" letter to cruise industry representatives informing them that the CSO and its accompanying measures, such as technical instructions, would be nonbinding recommendations for cruise ships arriving in, located within, or departing from Florida's ports.²⁶⁴ However, the CDC would continue to operate the CSO as a voluntary program for such ships and requested that cruise ship operators inform the CDC's Maritime Unit by close of business on July 26, 2021, whether they intended to follow all the CSO's provisions on a voluntary basis.²⁶⁵ Pursuant to the CDC's color-coding system, ships choosing to not follow the CSO's provisions on a voluntary basis would be

²⁶⁰ See Order of USCA Granting Appellants Time-Sensitive Motion for Stay Pending Appeal and Administrative Stay, *Florida v. Becerra*, 544 F. Supp. 3d 1241 (M.D. Fla. 2021) (No. 8:21-cv-00839).

²⁶¹ *Id.*

²⁶² See Order of USCA Vacating Order of July 17, *Florida v. Becerra*, 544 F. Supp. 3d 1241 (M.D. Fla. 2021)(No. 8:21-cv-00839).

²⁶³ See *id.* Some leading public health legal experts criticized the Eleventh Circuit for failing to offer any explanation for its sudden reversal. See Taylor Dolven, *Appeals court reverses course, lifts CDC cruise COVID-19 safety rules*, TAMPA BAY TIMES (July 23, 2021), <https://www.tampabay.com/news/florida-politics/2021/07/23/appeals-court-reverses-course-lifts-cdc-cruise-covid-19-safety-rules/> ("Larry Gostin, professor of global health law at Georgetown University and director of the World Health Organization's center on global health law, said the reversal lacks transparency.").

²⁶⁴ See Florida Politics, *supra* note 6.

²⁶⁵ *Id.*, Fran Golden, *What Does the Legal Wrangling Between Florida and the CDC Mean For Cruisers?*, CRUISE CRITIC (Jul. 27, 2021, 3:30 PM), <https://www.cruisecritic.com/news/6331/>.

designated as “gray” on the CDC’s website.²⁶⁶ This designation meant that the CDC was unable to confirm whether the cruise ship operator’s health and safety protocols aligned with the CDC’s standards for mitigating COVID-19 onboard cruise ships.²⁶⁷ The “Dear Colleague” letter also reminded cruise ship operators of existing legal authorities that were unrelated to the operation of the CSO and not affected by the court’s preliminary injunction, including those relating to reporting of shipboard illnesses, sanitary inspections, and related measures.²⁶⁸

The next day, Florida filed an emergency motion before the district court to hold the CDC in contempt of court alleging that the CDC had violated the preliminary injunction by engaging in coercive conduct and threatening new enforcement action against the cruise industry.²⁶⁹ The CDC responded that nothing in the preliminary injunction prohibited cruise lines from continuing to follow the CSO on a voluntary basis.²⁷⁰ The district court deferred ruling on Florida’s emergency motion noting that Florida seemed to “anticipate a violation that has not occurred and that might not occur.”²⁷¹ However, Florida could in the future provide additional information to the court if the CDC acted in bad faith, for instance, by punishing, harassing, or retaliating against a cruise ship operator for not voluntarily complying with the CSO.²⁷² By July 26, 2021, the deadline requested by the CDC, all cruise ship operators with ships operating out of Florida’s ports informed the CDC that they would continue to follow the CSO and its accompanying guidance on a voluntary basis.²⁷³

²⁶⁶ Florida Politics, *supra* note 6.

²⁶⁷ *Id.*

²⁶⁸ *Id.*

²⁶⁹ *Id.*

²⁷⁰ *Id.*

²⁷¹ *Id.*

²⁷² *Id.*

²⁷³ Coincidentally, these actions coincided with another surge of COVID-19 cases beginning in July 2021 based on the highly contagious Delta variant circulating and for a time becoming the dominant virus strain. See Lisa Maragakis, *Coronavirus Second Wave, Third Wave and Beyond: What Causes a COVID Surge*, JOHNS HOPKINS MED., <https://www.hopkinsmedicine.org/health/conditions-and-diseases/coronavirus/first-and-second-waves-of-coronavirus> (Oct. 21, 2021); Golden, *supra* note 265.

IX. CDC TEMPORARILY EXTENDS AND MODIFIES CSO AND TRANSITIONS TO A VOLUNTARY PROGRAM

On October 25, 2021, the CDC issued an order temporarily extending and modifying the CSO, which entered into effect on November 1, 2021, and would remain in place through January 15, 2022.²⁷⁴ Based on the district court's preliminary injunction order, the temporary extension did not apply to cruise ships operating out of Florida's ports.²⁷⁵ However, the CDC would continue to operate the CSO as a voluntary program for those ships in Florida that chose to follow the CSO's measures on a voluntary basis.²⁷⁶ The CDC further stated that it would transition to a fully voluntary program at the end of the temporary extension to assist the cruise ship industry to detect, mitigate, and control the spread of COVID-19 onboard cruise ships.²⁷⁷

The CDC noted that since the issuance of the CSO in October 2020, it had worked with cruise lines collaboratively to ensure a safer restart of passenger operations.²⁷⁸ This included ensuring that all 83 ships covered by the CSO had acquired necessary onboard laboratory equipment and entered into port agreements.²⁷⁹ As of October 21, 2021, the CDC had also approved 18 requests for cruise ship operators to conduct simulated voyages and approved 53 applications for ships to conduct revenue voyages.²⁸⁰ However, based on concerns relating to the Delta variant, other variants of concern, and breakthrough cases among the fully vaccinated, the CDC had determined that a temporary extension of the CSO was necessary.²⁸¹ The CDC further stated that the extension was needed despite the best efforts of cruise ship operators

²⁷⁴ Temporary Extension and Modification of Framework for Conditional Sailing Order (CSO) for Cruise Ships Operating or Intending To Operate in U.S. Waters, 86 Fed. Reg. 59,720 (Oct. 28, 2021). Like previous orders, CDC stated that the extension would expire upon the earliest of three events: (1) the expiration of the COVID-19 public health emergency as declared by the HHS Secretary; (2) the CDC Director rescinding or modifying the order based on public health or other considerations; or (3) January 15, 2022. *Id.*

²⁷⁵ *Id.*

²⁷⁶ *Id.*

²⁷⁷ *Id.*

²⁷⁸ *Id.* at 59,723

²⁷⁹ *Id.*

²⁸⁰ *Id.* at 59,724.

²⁸¹ *Id.* at 59,720.

to improve their health and safety protocols and conduct their operations in a way that did not overwhelm shipboard medical facilities or burden shoreside hospitals.²⁸²

The CDC's temporary extension left major provisions of the CSO unchanged with only minor modifications to incorporate changes previously made through technical instructions and announced in cruise industry "Dear Colleague" letters.²⁸³ The most significant change was to narrow the CSO to only foreign-flagged cruise ships operating in certain U.S. jurisdictions.²⁸⁴ These jurisdictions were those that did not routinely exercise public health jurisdiction nor maintain maritime public health programs that conducted surveillance, inspections, investigations, and management of shipboard communicable disease outbreaks.²⁸⁵ The CDC further explained that unlike ocean-going foreign-flagged vessels, ships operating only interstate could more quickly make port and bring passengers and crew by ambulance to local hospitals without requiring U.S. Coast Guard to airlift or evacuate passengers and crew at sea.²⁸⁶ Smaller interstate vessels were also less likely to potentially overwhelm local public health resources and, in any event, were subject to FDA jurisdiction under its Interstate Travel Program (21 CFR 1240, 1250).²⁸⁷

On January 15, 2022, the CDC began operating a fully voluntary program for cruise ships to detect, mitigate, and control the spread of COVID-19.²⁸⁸ On February 15, 2022, the district court dismissed the complaint against the CDC after Florida submitted a notice of voluntary dismissal.²⁸⁹ The CDC had also previously agreed to voluntarily

²⁸² *Id.* at 59,724.

²⁸³ *Id.* at 59,721.

²⁸⁴ *Id.*

²⁸⁵ *Id.*

²⁸⁶ *Id.*

²⁸⁷ *Id.*

²⁸⁸ See Press Release, Cruise Lines International Association, CLIA Statement on the Transition of the Conditional Sailing Order (CSO) to a Voluntary Program (January 13, 2022), <https://cruising.org/en/news-and-research/press-room/2022/january/clia-statement-on-the-transition-of-the-conditional-sailing-order-to-a-voluntary-program>.

²⁸⁹ See Notice of Dismissal, *Florida v. Becerra*, 544 F. Supp. 3d 1241 (M.D. Fla. 2021) (No. 8:21-cv-00839); Order Dismissing Action, *Florida v. Becerra*, 544 F. Supp. 3d 1241 (M.D. Fla. 2021) (No. 8:21-cv-00839).

dismiss its appeal to the Eleventh Circuit on January 18, 2022.²⁹⁰ Accordingly, the district court's preliminary injunction order remained a preliminary ruling that did not reflect a final decision on the merits and was under appeal at the time the parties agreed to voluntarily dismiss the case.²⁹¹

The voluntary program consisted of the same elements as under the CSO, including a color-coding system that among other things designated ships opting out of the program as "gray" (meaning that the CDC could not verify the ship's health and safety protocols).²⁹² The voluntary program also classified ships according to three COVID-19 vaccination status levels: (1) "not highly vaccinated" (less than 95% of passengers and crew fully vaccinated); (2) "highly vaccinated" (95% of passengers and crew fully vaccinated but less than 95% with "up-to-date" (i.e., booster) vaccines; and (3) "vaccination standard of excellence" (95% of passengers and crew fully vaccinated and up to date).²⁹³ By February 18, 2022, the date set by the CDC as the deadline for joining the program, all major cruise lines (representing 110 ships across 18 cruise lines) had opted into the new voluntary program.²⁹⁴

On March 18, 2022, the CDC issued modified guidance reducing many burdens and restrictions on cruise lines.²⁹⁵ This included allowing cruise operators to resume interactive experiences (e.g., cooking classes), allowing certain close contacts to quarantine in their cabins instead of in specially designated quarantine cabins, and modifying

²⁹⁰ See Order Granting Motion to Voluntarily Dismiss Appeal, *Florida v. Sec'y, Dep't Health and Human Servs.*, 2022 WL 2445185 (11th Cir. 2022) (No. 21-12243-DD).

²⁹¹ See *id.*

²⁹² See Susan J. Young, *CLIA Not Happy with New CDC Voluntary Program for Cruise Lines*, TRAVEL AGENT CENT. (Feb. 10, 2022, 11:12 AM), <https://www.travelagentcentral.com/cruises/clia-not-happy-new-cdc-voluntary-program-cruise-lines>.

²⁹³ See Carolyn Crist, *CDC Announces Voluntary COVID Rules for Cruises*, WEBMD (De. 26, 2022), <https://www.webmd.com/lung/news/20220211/cdc-voluntary-rules-for-cruises>.

²⁹⁴ See Johanna Jainchill, *Major lines opt in to CDC's voluntary Covid program for cruising*, TRAVEL WEEKLY (February 19, 2022), <https://www.travelweekly.com/Cruise-Travel/cruise-lines-opt-CDC-voluntary-Covid-program>.

²⁹⁵ See Press Release, Cruise Lines Int'l, The Centers for Disease Control and Prevention (CDC) Issues Modified Guidance to the Technical Instructions for CDC's COVID-19 Program for Cruise Ships Operating in U.S. Waters (March 18, 2022), <https://cruising.org/en/news-and-research/press-room/2022/march/cdc-issues-modified-guidance-to-the-technical-instructions-for-cdcs-covid19-program>).

port agreements to remove references to ship and capacity limits.²⁹⁶ On March 30, 2022, in consideration of the improving public health situation, the CDC removed its Travel Health Notice warning against cruising which had been in place since March 2020.²⁹⁷

On July 18, 2022, the CDC formally ended its COVID-19 Voluntary Program for Cruise Ships.²⁹⁸ As part of its decision, the CDC noted that cruise ship operators now had access to guidance and tools to manage their own COVID-19 mitigation programs.²⁹⁹ Cruise passengers also had access to recommendations that allowed them to make their own informed decisions about cruise ship travel.³⁰⁰ The CDC's decision included retiring the color-coding system for cruise ships because the system relied on each cruise line adopting the same testing standards, which would now be permitted to vary among cruise lines.³⁰¹

X. LEGAL ANALYSIS AND CONSIDERATIONS FOR FUTURE ACTION

Although section 361(a) of the PHS Act in its first sentence grants the CDC broad authority to prevent the introduction, transmission, and spread of communicable diseases, recent court decisions have interpreted the statute more narrowly to limit the CDC to actions similar in kind to those measures enumerated specifically in the second sentence of the statute, i.e., "inspection, fumigation, disinfection, sanitation, pest extermination, and destruction of contaminated animals and articles."³⁰² Courts, however, have differed as to whether certain public

²⁹⁶ *Id.*

²⁹⁷ See Press Release, Cruise Lines Int'l, CLIA Applauds CDC's Removal of Travel Health Notice, (March 30, 2022), <https://cruising.org/en/news-and-research/press-room/2022/march/clia-applauds-cdcs-removal-of-travel-health-notice>.

²⁹⁸ Andrea Zelinski, *CDC eliminates Covid-19 Program for Cruise Ships*, TRAVEL WEEKLY (July 18, 2022), <https://www.travelweekly.com/Cruise-Travel/CDC-eliminates-Covid-19-Program-for-Cruise-Ships>.

²⁹⁹ *Id.*

³⁰⁰ *Id.*; see also *Cruise Ship Travel During COVID-19*, CDC, <https://www.cdc.gov/coronavirus/2019-ncov/travelers/cruise-travel-during-covid19.html> (last visited September 16, 2022).

³⁰¹ Zelinski, *supra* note 298.

³⁰² See *Tiger Lily, LLC v. Dep't of Housing and Urban Dev.*, 5 F.4th 666, 671 (6th Cir. 2021) ("Therefore, we conclude that the first sentence of § 264(a) authorizes the Secretary to take action and the second dictates what actions he may take.").

health measures specifically targeted at mitigating COVID-19 transmission, such as requiring people to wear face masks, can be construed as falling under the enumerated list of measures.³⁰³ In a report published recently by the National Academies of Sciences, Engineering, and Medicine, the National Academies recognized that uncertainty about the scope and limits of the CDC's authority could hinder future pandemic prevention and response efforts.³⁰⁴ To address these concerns, the National Academies recommends that Congress modernize the CDC's pandemic prevention and response powers, and, regardless of whether Congress chooses to act, that the CDC initiate rulemaking to clarify its authority.³⁰⁵

The National Academies has made several specific recommendations regarding how to modernize the CDC's statutory and regulatory authority.³⁰⁶ First, it recommends that Congress specify that the measures enumerated in section 361(a) include "regulation of international and interstate travel, requirements to wear face covering or other PPE, restrictions on mass gatherings, occupancy limits or sanitation requirements for gathering places, protections to support compliance with public health guidance, as well as other necessary powers."³⁰⁷ Second, as a guardrail to ensure that the CDC does not overreach or exceed its regulatory authority, it recommends that a new subsection (f) be written to clarify that, in the absence of an individualized risk assessment, the CDC could only exercise such extraordinary authority (e.g., restrictions on mass gatherings and housing and employment protections aimed at supporting public health guidance) based upon specific determinations made by the HHS Secretary.³⁰⁸

³⁰³ Compare *Health Freedom Defense Fund v. Biden*, 599 F. Supp. 3d 1144, 1157-1161 (M.D. Fla. 2022) (finding that CDC exceeded its statutory authority by imposing a mask mandate because "sanitation" is limited to active cleaning measures and not measures to preserve cleanliness), *vacated as moot on appeal*, *Health Freedom Defense Fund v. United States*, 71 F.4th 888 (11th Cir. 2023), with *Wall v. CDC*, No. 21-cv-975, 2022 WL 1619516, slip op. at *6 (M.D. Fla. Apr. 29, 2022) (finding that masks fit within the definition of "sanitation" because masks promote the public health by checking the transmission of airborne viruses, such as the virus that causes COVID-19).

³⁰⁴ See National Academies Report, *supra* note 31, at 172.

³⁰⁵ *Id.*

³⁰⁶ See *id.*

³⁰⁷ *Id.*

³⁰⁸ *Id.* at 196.

These specific determinations include: (1) that a public health emergency exists; (2) use of other measures, such as isolation and quarantine, and inspection, fumigation, disinfection, sanitation, pest extermination, and destruction of infected animals or articles, would not be effective in preventing communicable disease spread; and (3) state, local, and tribal regulations are insufficient to prevent foreign introductions of communicable disease or interstate disease spread.³⁰⁹ Lastly, it recommends that, regardless of whether Congress chooses to amend section 361, the CDC adopt definitions, procedural requirements, and substantive standards governing agency orders of broad applicability not based on individualized risk assessments.³¹⁰

Models other than those recommended by the National Academies also exist.³¹¹ Another potential model for revising the CDC's statutory authority would be to amend the PHS Act in a way analogous to how Congress created and charged the Transportation Security Administration (TSA) with overall responsibility for ensuring transportation security in the aftermath of the terrorist attacks of September 11, 2001.³¹² The TSA has broad authority to issue regulations and security directives necessary to protect all modes of transportation security.³¹³ For example, the TSA can issue a regulation or security directive "without providing notice or an opportunity for comment and without prior approval of the Secretary [of Homeland Security]" if the TSA determines that a regulation or security directive "must be issued immediately in order to protect transportation security."³¹⁴ Regulations and security directives issued under this authority are subject to review by a Transportation Security Oversight Board—a board consisting of the heads of various interested Cabinet agencies, or their designees, and a representative of the National Security Council³¹⁵—and "remain

³⁰⁹ *Id.*

³¹⁰ *Id.* at 197.

³¹¹ See Aviation and Transportation Security Act, Pub. L. No. 107-71, § 101(a), 115 Stat. 597, 597 (2001); 49 U.S.C. § 114.

³¹² See *id.*

³¹³ 49 U.S.C. § 114.

³¹⁴ 49 U.S.C. § 114(1)(2).

³¹⁵ 49 U.S.C. § 115(b).

effective for a period not to exceed 90 days” unless submitted to and ratified by the Board.³¹⁶

The TSA also requires regulated aircraft and airport operators to adopt security programs that provide for “the safety and security of persons and property” traveling on air transportation “against an act of criminal violence, aircraft piracy, and the introduction of an unauthorized weapon, explosive, or incendiary into an aircraft.”³¹⁷ These programs are subject to change, including when the TSA determines that “safety and the public interest require an amendment.”³¹⁸ Typically, if the TSA determines that an amendment to a particular operator’s security program is required, it will send the operator a notice, in writing, of the proposed amendment and allow the operator to submit a written response.³¹⁹ If, however, the TSA determines that there is an “emergency requiring immediate action with respect to safety and security in air transportation or in air commerce,” it may issue an amendment that is “effective without stay” on the date the operator receives notice.³²⁰

Finally, the TSA may issue “security directives” that apply to all regulated entities when “additional security measures are necessary to respond to a threat assessment or to a specific threat against civil aviation.”³²¹ Each airport and aircraft operator is required to have an approved security program and “must comply with each Security Directive issued.”³²² If an operator is unable to implement the measures in the security directive, the operator must inform the TSA and propose alternative measures for approval by the TSA.³²³ Pursuant to these various authorities, to promote transportation safety and security, the TSA issued security directives and emergency amendments

³¹⁶ 49 U.S.C. § 114(l)(2)(B).

³¹⁷ See 49 C.F.R. §§ 1542.101(a)(1) (concerning airports), 1544.103 (mandating similar requirements for domestic airports), 1546.105 (concerning foreign airlines).

³¹⁸ See 49 C.F.R. §§ 1542.105(c) (airport operators), 1544.103(c) (domestic airlines), 1546.105(c) (foreign airlines).

³¹⁹ 49 C.F.R. §§ 1542.105(c), 1544.105(c), 1546.105(c).

³²⁰ 49 C.F.R. §§ 1542.105(d), 1544.105(d), 1546.105(d).

³²¹ 49 C.F.R. §§ 1542.303(a) (airport operators), 1544.305(a) (aircraft operators).

³²² 49 C.F.R. §§ 1542.303(b), 1544.305(b).

³²³ 49 C.F.R. §§ 1542.303(d), 1544.305(d).

requiring people to wear masks in airports, on commercial aircraft, and on surface transportation.³²⁴

A similar statutory model allowing the CDC to issue public health directives to cruise ship operators in the event of a declared public health emergency would have provided a clearer legal basis for the CDC's actions under the NSO and CSO. Similar to the requirement for an airport and aircraft operator to have a security plan in place, under the April 15, 2020, NSO, cruise ship operators were required to operate under an NSO response plan designed to mitigate the risk of COVID-19 to crew.³²⁵ Under the CSO, cruise ship operators also had to adopt uniform standards across their fleets for public health surveillance, testing, reporting of cases, social distancing, mask wearing, and quarantine and isolation protocols.³²⁶

Additionally, the ability to issue public health directives on an emergency basis, without the administrative process imposed by notice-and-comment rulemaking, would have reduced legal uncertainty regarding the CDC's maritime public health response. During the period of the CSO in particular, the CDC frequently updated guidance documents, such as technical instructions and its operations manual, and issued "Dear Colleague" letters to reflect the constantly evolving state of the pandemic.³²⁷ These updates primarily reduced burdens or ameliorated restrictions on cruise ship operators to reflect improving public health conditions, such as increasing vaccination rates and reduced case counts.³²⁸ Submission of the NSO and CSO to an advisory body charged with reviewing these directives (similar in kind to the Transportation Security Oversight Board) would have also served as an important administrative guardrail.

In the absence of Congressional action to amend the PHS Act, there are important steps that the CDC can take through rulemaking to clarify its legal authority as they relate to maritime public health.

³²⁴ See *Corbett v. Transp. Sec. Admin.*, 19 F.4th 478, 490 (D.C. Cir. 2021) (holding that TSA's mask directives were reasonable and permissible to promote safety and security in the transportation system against threats posed by COVID-19), *cert. denied*, (2022).

³²⁵ Third Modification and Extension of No Sail Order, 85 Fed. Reg. 62,732, 62,734 (Oct. 5, 2020)

³²⁶ See *Framework for Conditional Sailing*, *supra* note 135; *Letter from Captain Aimee Treffiletti*, *supra* note 183.

³²⁷ See *supra* pp. 31-36.

³²⁸ *Id.*

For instance, in issuing the NSO and CSO, the CDC relied particularly on regulatory authority at 42 CFR 71.31(b) authorizing the CDC to detain an arriving carrier and issue a “controlled free pratique,” i.e., a set of stipulated public health conditions for a ship (or other carrier) to enter a U.S. port, disembark passengers, and commence port operations.³²⁹ However, the district court in *Becerra* interpreted “controlled free pratique” narrowly as only a temporary tool that could be directed at specific vessels in aid of other public health measures appearing in part 71, such as disinfection of cargo or extermination of rodents.³³⁰ The district court also appears to have wrongly equated the issuance of a controlled free pratique with detention, even though ships were free to—and in fact did—leave U.S. waters if unwilling or unable to abide by the terms stipulated by the CDC.³³¹

First, to address these misconceptions, the CDC could amend section 71.31(b) to clarify its authority to deny “free pratique” for ships to operate in U.S. waters provided that such ships are otherwise free to leave U.S. waters and voyage to a foreign port.³³² Second, consistent with how some courts have interpreted section 361, the CDC could, through regulation, clarify how many of the measures outlined in the CSO (e.g., requiring certain laboratory testing equipment or that cabins designated for isolation and quarantine have sufficient negative air pressure) fall within the rubric of “inspection” or “sanitation” as outlined in the enumerated list of measures found in the second sentence of section 361(a).³³³ Although these clarifications would be helpful, considering how some courts have chosen to interpret section 361 narrowly, the CDC may also wish to avail itself of other statutory authority found in the PHS Act.³³⁴

³²⁹ See 42 C.F.R. § 71.31(b) (2022).

³³⁰ *Florida v. Becerra*, 544 F. Supp. 3d 1241, 1274.

³³¹ *Id.*; see Third Treffiletti Declaration, *supra* note 180, at 7.

³³² The IHR (2005) prohibit State Parties from denying free pratique for public health reasons, unless the State Party is not equipped to apply health measures or is acting pursuant to Article 43 (authorizing additional public health measures based on scientific principles that are not more restrictive to international travel and trade than reasonably available alternatives). See IHR (2005), Art. 28.

³³³ See 42 U.S.C. § 264(a).

³³⁴ See *id.*

The CDC requires a robust set of regulations relating to maritime public health because it is the only jurisdictional entity capable of overseeing public health onboard cruise ships by virtue of cruise ships being foreign flagged, operating on roundtrip itineraries, and, per the PVSA, prohibited from traveling between U.S. ports without stopping at a foreign port.³³⁵ Considering that cruise ships travel internationally and between U.S. ports, local entities typically lack the legal authority, expertise, and resources to maintain maritime public health programs relating to cruise ship travel, one option for the CDC could be to rely on its legal authority found in section 366 of the PHS Act relating to vessels obtaining and delivering a bill of health.³³⁶

Section 366 is divided into five subsections (a) through (e).³³⁷ Section 366(a) provides that except as otherwise prescribed in regulations, vessels clearing or departing foreign ports shall be required to obtain a bill of health from a U.S. consular officer or a Public Health Service officer or other designated medical officer.³³⁸ The bill of health shall set forth the sanitary history and condition of the vessel and state that it has fully complied with regulations as promulgated under subsection (c).³³⁹ Section 366(b) provides, among other things, that when properly certified, bills of health are acceptable as evidence of the statements contained therein in any U.S. court.³⁴⁰ Section 366(c) authorizes the Surgeon General to prescribe regulations to prevent the introduction of communicable disease into the United States "by securing the best sanitary condition of such vessels, their cargoes, passengers, and crew."³⁴¹ Additionally, section 366(c) provides that "[s]uch regulations shall be observed by such vessels prior to departure, during the course of the voyage, and also during inspection, disinfection, or other quarantine procedure upon arrival at any United States quarantine station."³⁴² Section 366(d) exempts certain vessels from the requirements

³³⁵ See 46 U.S.C. § 55103.

³³⁶ 42 U.S.C. § 269.

³³⁷ § 269(a)-(e).

³³⁸ § 269(a).

³³⁹ *Id.*

³⁴⁰ § 269(b).

³⁴¹ § 269(c).

³⁴² *Id.*

in subsections (a) and (b), but not (c), if voyaging near the frontiers of the United States and as designated by treaty.³⁴³ Finally, section 366(e), among other things, provides that it shall be unlawful for any ship to enter a U.S. port, discharge its cargo, or land its passengers, except upon a certification by the quarantine officer that the ship has complied with the regulations promulgated under subsection (c).³⁴⁴ A related provision under section 367 of the PHS Act authorizes the application of the bills of health to air navigation and aircraft as the HHS Secretary deems necessary.³⁴⁵

Enacting new regulations under the authority of section 366 (and 367 as needed) would contain many apparent benefits but also some limitations that policymakers would need to carefully consider. First, requiring that ships in international traffic obtain and deliver a bill of health setting forth the sanitary history of the vessel and conditions observed during the voyage to prevent communicable disease transmission has a clear historical precedent.³⁴⁶ Second, the mandate to enact regulations under section 366 with regard to vessels appears arguably broader in some respects than in section 361.³⁴⁷ Not only may the HHS Secretary promulgate regulations relating to “sanitation” as in section 361, but is authorized to promulgate regulations “securing the *best* sanitary condition of such vessels, their cargoes, passengers, and crews.”³⁴⁸ The American Heritage Dictionary defines “best” in its first entry as “surpassing all others in excellence, achievement, or quality.”³⁴⁹ The authority in section 366(d) is also not limited to ships

³⁴³ § 269(d).

³⁴⁴ § 269(e).

³⁴⁵ § 270.

³⁴⁶ *E.g.*, Foreign Quarantine Bills of Health and Quarantine Inspection for Vessels, 9 Fed. Reg. 3978-79 (Apr. 14, 1944) (exempting certain vessels from the requirement to obtain a bill of health on a routine basis except when certain quarantinable diseases are prevalent at foreign ports of departure or call and upon condition that such vessels remain subject to inspection).

³⁴⁷ *See* 46 U.S.C. § 55103; *but see* 46 U.S.C. § 55103.

³⁴⁸ 42 U.S.C. § 269(c).

³⁴⁹ *See Am. Heritage Dictionary Entry: best*, THE AM. HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE, <https://ahdictionary.com/word/search.html?q=best> (last visited Sept. 18, 2022). The 1913 Webster’s Dictionary similarly defines “best” in its first entry as “having good qualities in the highest degree; most good, kind, desirable, suitable, etc.” *See WEBSTER’S DICTIONARY 1913*, <https://www.websters1913.com/> (last visited Nov. 8, 2022). Thus, usage of “best” to denote a particularly high degree of excellence does not appear to have changed

arriving into the United States but explicitly authorizes measures prior to departing a foreign port as well as during the course of the voyage.³⁵⁰

The enumeration of “passengers” and “crews” in addition to “vessels” and “cargoes” in section 366 also implies that sanitation could be used in a broader context than in section 361.³⁵¹ Specifically, securing “the best sanitary condition” of persons more strongly implies measures aimed at preventing the transmission of communicable disease among persons, such as through the wearing of masks, than measures aimed at simply maintaining ships in a sanitary state, such as through ensuring adequate potable water and waste disposal.³⁵² Lastly, section 366 grants the HHS Secretary broad flexibility as to the form, content, and methods for obtaining and delivering the bill of health because subsection (a) clearly states, “except as otherwise prescribed in regulations.”³⁵³

During the NSO and CSO, the CDC required cruise ship operators to complete attestations under 18 U.S.C. § 1001, attesting to the adequacy of their cruise ship response plans and compliance with the CDC’s requirements for preventing COVID-19 transmission onboard and to shoreside communities.³⁵⁴ Section 366(a) could similarly authorize the HHS Secretary to adopt these practices, or other alternatives, instead of relying on the outdated method of obtaining a bill of health in paper form from a U.S. consular officer and then delivering the document to the quarantine station upon arriving at a U.S. port.³⁵⁵ Although not specifically tied to the HHS Secretary’s declaration of a public health emergency under section 319 of the PHS Act,³⁵⁶ or other similar declarations,³⁵⁷ the Secretary, through regulations, could also

over time.

³⁵⁰ 42 U.S.C. § 269(c).

³⁵¹ See 42 U.S.C. § 269(c).

³⁵² See *id.*

³⁵³ See § 269(a).

³⁵⁴ See 18 U.S.C. § 1001.

³⁵⁵ See 42 U.S.C. § 269(a).

³⁵⁶ § 247(d).

³⁵⁷ CDC’s interstate regulations contain a definition of “public health emergency” that recognizes the Secretary’s ability to declare a public health emergency under section 319 of the PHS Act, but also recognizes other types of emergency declarations, including a Declaration of

choose to limit the CDC's ability to require a bill of health to circumstances involving declared public health emergencies.

However, the broad authority contained in section 366 relating to bills of health is not without its limitations. First, bills of health are not applicable to vessels operating exclusively interstate because the authority is explicitly limited to ships clearing or departing from foreign ports for the United States.³⁵⁸ Second, because the current CDC regulation states that carriers are not required to obtain or deliver bills of health, the agency would need to explicitly amend its regulations to impose such a requirement.³⁵⁹ This is also a particularly long standing regulation that appears to have been in place since at least 1956.³⁶⁰ Third, the International Health Regulations (IHR) prohibits State Parties from requiring health documents in international traffic other than those explicitly set forth in those regulations (e.g., maritime declaration of health) or in recommendations issued by the WHO.³⁶¹ Although the IHR do not create judicially enforceable private rights in U.S. courts,³⁶² the international regulations are considered legally binding among all of WHO's member states.³⁶³ Notably, there are several efforts underway to strengthen WHO by addressing gaps and shortcomings in global pandemic preparedness and response activities revealed by the COVID-19 pandemic, including a need for more rapid and timely sharing of data and information related to outbreaks.³⁶⁴ As part of these larger efforts, policymakers may also wish to consider

Public Health Emergency of International Concern by WHO under the IHR. *See* General Definitions, 42 C.F.R. § 70.1 (2017).

³⁵⁸ 42 U.S.C. § 269(a).

³⁵⁹ *See* 42 C.F.R. § 71.1 (2017).

³⁶⁰ 21 Fed. Reg. 9872 (Dec. 12, 1956).

³⁶¹ *See* WHO, *International Health Regulations*, 3d ed., PART VI – HEALTH DOCUMENTS Article 35 General rule (2005).

³⁶² *See* WHO, *International Health Regulations*, 3d ed. Appendix 2 (2005) (setting forth the reservations and understandings of the United States and other WHO member countries in adopting the IHR).

³⁶³ *See* *Emergencies: Ten things you need to do to implement the International Health Regulations*, WHO (May 26, 2014), <https://www.who.int/news-room/questions-and-answers/item/emergencies-ten-things-you-need-to-do-to-implement-the-international-health-regulations>.

³⁶⁴ *E.g.*, The Independent Panel for Pandemic Preparedness and Response, *COVID-19 Make it the Last Pandemic*, May 2021, https://theindependentpanel.org/wp-content/uploads/2021/05/COVID-19-Make-it-the-Last-Pandemic_final.pdf.

potential gaps in maritime public health response activities in the context of the IHR.

CONCLUSION

Beginning in February 2020, the CDC, in coordination with other federal agencies, took unprecedented actions affecting the cruise ship industry. This included repatriating and quarantining U.S. citizens from the *Diamond Princess* Cruise Ship, detaining the *Grand Princess* Cruise Ship and arranging for the quarantine and isolation of its passengers and crew, suspending cruise ships operations in the United States under the NSO, and finally permitting a gradual return to cruise ship operations in phases under the CSO before transitioning fully to a voluntary program. Some of these actions, as well as other CDC pandemic response activities, led to litigation and court decisions questioning the CDC's authority to take measures (when faced with a pandemic) to control the introduction, transmission, and spread of communicable disease.

Unfortunately, uncertainty created by these court decisions regarding the CDC's legal authority have the potential to hamper future outbreak response activities. Moreover, clarity regarding the CDC's roles and responsibilities in the area of maritime public health is particularly important because the CDC is the only jurisdictional entity fully capable of regulating public health onboard cruise ships that travel internationally and, per the PVSA, must stop at a foreign port as part of their U.S. itineraries. To address these concerns, policymakers may wish to review and, where necessary, amend the CDC's statutory and regulatory authority to clarify its authority to respond to outbreaks and other public health emergencies using traditional public health powers, including through bills of health.