

No. 21-12243

**IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT**

STATE OF FLORIDA,
Plaintiff-Appellee,

v.

XAVIER BECERRA, SECRETARY OF HEALTH AND HUMAN
SERVICES, *et al.,*
Defendants-Appellants.

On Appeal from the United States District Court
for the Middle District of Florida (Hon. Steven D. Merryday)

**TIME-SENSITIVE MOTION FOR STAY PENDING APPEAL
AND ADMINISTRATIVE STAY**

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INTRODUCTION

The federal government respectfully asks this Court to stay pending appeal the district court's preliminary injunction, which will lift—for all cruise ships arriving at, within, or departing from a Florida port on or after July 18—the COVID-19 health and safety protocols that were established by the Centers for Disease Control and Prevention (CDC) in close consultation with the cruise ship industry. We ask the Court to issue an administrative stay pending its consideration of this motion.

Working collaboratively with the cruise ship industry, the CDC developed COVID-19 protocols to allow passenger operations to resume safely this summer. *See* Addendum (Add.) 149-150 ¶¶ 22-23 (declaration). These protocols were set out in the CDC's Conditional Sailing Order (Order) and technical guidance, which rely on conventional communicable-disease control measures such as testing and reporting COVID-19 cases among passengers and crew, quarantine of exposed persons and their contacts, isolation of infectious persons to contain outbreaks, and collection and analysis of public health data. Add. 144-145 ¶¶ 10-11.

The cruise ship industry is far along in the implementation of these protocols. For example, of the 65 ships covered by the Conditional Sailing

Order, 59 ships have already acquired the onboard laboratory testing equipment needed to test samples for COVID-19. Add. 146 ¶ 15. The first passenger cruise from a U.S. port sailed on June 26, and many more have departure dates in July and August, meaning many ships are or will be close to completing the phased steps laid out in the Conditional Sailing Order. Add. 148-149 ¶ 21. That Order will expire on or before November 1, 2021.

The State of Florida, however, has taken a series of actions that undermined the cruise ships' own plans with regard to resumption of passenger cruises and impede the cruise ship industry's ability to operate safely. First, Florida enacted a law that prohibits cruise ship operators from requiring documentation that passengers are vaccinated, as many cruise ships have stated they intend to do. Then, in this action, Florida obtained a preliminary injunction that will lift the Conditional Sailing Order's health and safety protocols for cruise ships arriving at, within, or departing from a Florida port on or after July 18.

The preliminary injunction rests on errors of law and is a clear abuse of the district court's discretion. Florida did not even establish Article III standing, and certainly did not show that the injunction will prevent—rather than cause—irreparable harm. The premise of the injunction is that the

CDC’s health and safety protocols “burden the cruise industry’s capacity for profitable sailing,” Add. 131, and that Florida will profit indirectly by means such as increased tax revenue if these protocols are lifted, Add. 29-30. But Florida submitted no evidence to support that “counterintuitive theory of standing,” *California v. Texas*, 141 S. Ct. 2104, 2119 (2021), which implausibly assumes that prospective cruise ship passengers are indifferent to whether COVID-19 health and safety protocols are in place.

Contrary to the district court’s understanding, these CDC protocols are standard communicable-disease control measures that fall easily within the CDC’s authority. All of the cruise ships at issue here are foreign-flagged vessels that stop at foreign ports. Add. 143 ¶ 7. Longstanding regulations (unchallenged here) allow the CDC to issue a “controlled free pratique”—that is, “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)—to prevent the introduction or spread of a communicable disease, *id.* § 71.31(b). Moreover, in May 2021, Congress granted special privileges to certain cruise ships that obtain and operate in accordance with a “COVID-19 Conditional Sailing Certificate” of the CDC. Alaska Tourism Restoration Act, Pub. L.

No. 117-14, § 2(a), (b), 135 Stat. 273 (May 24, 2021). That legislation would be a nullity if the Conditional Sailing Order were invalid, which it plainly is not.¹

STATEMENT

I. The CDC’s COVID-19 Health And Safety Protocols For Cruise Ships

A. This case involves the CDC’s authority to prevent the further introduction, transmission, or spread of COVID-19 by cruise ships. All of the cruise ships at issue here are foreign-flagged vessels that stop at one or more foreign ports during each voyage. Add. 143 ¶ 7. Cruise ship voyages from the United States include itineraries to countries that have low vaccination rates for COVID-19 but are reopening to international tourism. Add. 155 ¶ 31. Cruise ship travel may risk introducing variants of concern into the United States from countries such as the Bahamas, Mexico, Honduras, Saint Maarten, Dominican Republic, Haiti, Aruba, and Saint Kitts and Nevis. *Id.*

The CDC has statutory authority to make and enforce such regulations as in its judgment are necessary to prevent the introduction, transmission, or spread of communicable disease from a foreign country into the United

¹ Pursuant to Rule 8 of the Federal Rules of Appellate Procedure, we moved in district court for a stay pending appeal, Dkt. No. 96, which the district court today denied, Add. 166. Florida opposes this motion.

States. 42 U.S.C. § 264(a); 42 C.F.R. § 70.2. With respect to carriers arriving at U.S. ports, longstanding regulations allow the CDC to issue a “controlled free pratique”—defined as “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)—in order to prevent the introduction, transmission, or spread of a communicable disease, *see id.* § 71.31(b).

B. Early in the pandemic, cruise ships experienced significant outbreaks of COVID-19. *See No Sail Order and Suspension of Further Embarkation*, 85 Fed. Reg. 16,628, 16,629-30 (Mar. 24, 2020) (No Sail Order). To prevent the spread of COVID-19, the CDC suspended cruise ship operations in March 2020. *Id.* at 16,631. That order, as extended, expired in October 2020.²

In October 2020, the CDC replaced the No Sail Order with the Conditional Sailing Order, which provided a framework for resuming cruise

² *See No Sail Order and Suspension of Further Embarkation: Notice of Modification and Extension and Other Measures Related to Operations*, 85 Fed. Reg. 21,004 (Apr. 15, 2020); *No Sail Order and Suspension of Further Embarkation; Second Modification and Extension of No Sail Order and Other Measures Related to Operations*, 85 Fed. Reg. 44,085 (July 21, 2020); *No Sail Order and Suspension of Further Embarkation; Third Modification and Extension of No Sail Order and Other Measures Related to Operations*, 85 Fed. Reg. 62,732 (Oct. 5, 2020).

ship passenger operations in U.S. waters. *See Framework for Conditional Sailing and Initial Phase COVID-19 Testing Requirements for Protection of Crew*, 85 Fed. Reg. 70,153 (Nov. 4, 2020). The Conditional Sailing Order will expire on or before November 1, 2021. *Id.* at 70,163.

In issuing the Conditional Sailing Order, the CDC found markedly higher transmission rates on board cruise ships than exist in other settings. 85 Fed. Reg. at 70,156. Thus, the Order required cruise ships to develop plans to prevent and contain outbreaks through measures such as testing, monitoring, quarantine, isolation, and a short test voyage (referred to as a simulated voyage), in order to receive a Conditional Sailing Certificate that allows controlled free pratique. *Id.* at 70,158-59; 85 Fed. Reg. at 21,007; Add. 144-145 ¶¶ 10-11.

The CDC has since issued technical guidance that reflects evolving public-health conditions and regular consultations with cruise industry representatives. The CDC solicited (among other things) the industry's plans for vaccinating crew and vaccination strategies to protect passengers and on-shore communities. Add. 165. In an April 26, 2021, statement describing the industry's vaccination goals, industry representatives explained that their intention was "for all of our crewmembers to be

vaccinated” and that they were “recommending all guests over the age of 18 be fully vaccinated before sailing.” *Id.* The industry anticipated that “the vast majority of our guest bookings will be fully vaccinated before sailing.” *Id.* The industry concluded that “this approach will significantly reduce risk of COVID-19 transmission, allow for easier modifications of requirements in the [Order] that are predicated on prevaccine conditions,” and “facilitate cruise resumption in the U.S. by Summer 2021.” *Id.*

Similarly, in a May 11, 2021 letter, Cruise Line International Association (CLIA)—which is the leading industry trade group—stated that “vaccines are a gamechanger and cruise line requirements will serve to incentivize passengers to become vaccinated.” Add. 155 ¶ 33; Add. 159. Consistent with CLIA’s proposal, Add. 163, the CDC does not require a test voyage for a cruise that requires 95% of passengers and 95% of crew to be vaccinated, Add. 144-145 ¶ 10. Other protocols such as testing, quarantine, masking, and social distancing are likewise relaxed for vaccinated passengers.³

³ <https://www.cdc.gov/quarantine/cruise/covid19-operations-manual-cso.html#testing-of-embarking-and-disembarking-passengers> (testing); <https://www.cdc.gov/quarantine/cruise/management/technical-instructions-for-cruise-ships.html> (quarantine);

II. Factual Background And District Court Proceedings

A. Plaintiff is the State of Florida, which, through a series of actions, has undermined the cruise industry's ability to resume safe passenger operations.

On April 2, 2021, Governor DeSantis issued an Executive Order that prohibits businesses in Florida from requiring patrons or customers to provide any documentation certifying COVID-19 vaccination. *See* Fl. Exec. Order No. 21-81, § 2. Despite the concerns raised by the cruise ship industry, Governor DeSantis confirmed that he would not make an exception for cruise ship operators. *See, e.g.,* Steven Lemongello & Gray Rohrer, *DeSantis' Ban of Vaccine Passports Could Lead to Showdown with Businesses in Florida*, Orlando Sentinel (Apr. 15, 2021) (Orlando Sentinel).⁴

On May 3, 2021, Governor DeSantis signed into law a bill that codified that prohibition, effective July 1, 2021. *See* Fla. SB 2006, § 18 (enacting Fla. Stat. § 381.00316(1)). The Governor's press release emphasized that the

<https://www.cdc.gov/quarantine/cruise/covid19-operations-manual-cso.html#mask-use> (mask use);
<https://www.cdc.gov/quarantine/cruise/covid19-operations-manual-cso.html#physical-distancing> (physical distancing).

⁴ <https://www.orlandosentinel.com/politics/os-ne-prem-ne-vaccination-passports-florida-20210415-p5ih3mwtjrervlnnufbe3mijgi-story.html>.

legislation codified the prohibition that he had imposed “through an executive order last month, blocking any business or government entity from requiring proof of COVID-19 vaccination.” Press Release, *Governor Ron DeSantis Signs Landmark Legislation to Ban Vaccine Passports and Stem Government Overreach* (May 3, 2021) (Press Release).⁵

In April 2021, Florida filed this action, challenging on various grounds the health and safety protocols that are required under the CDC’s Conditional Sailing Order and technical guidance. On May 5, 2021, Florida filed an amended motion for a preliminary injunction, arguing that the CDC’s restrictions should be lifted because “vaccines are available to any adults who want them, and businesses have learned how to mitigate the spread of the virus.” Dkt. No. 25, at 1. Florida’s motion did not acknowledge the Governor’s Executive Order or the state legislation that prohibits cruise ship operators from requiring documentation that prospective passengers are vaccinated.

B. The district court granted Florida’s motion and enjoined the CDC from “enforcing against a cruise ship arriving in, within, or departing from a

⁵ <https://www.flgov.com/2021/05/03/governor-ron-desantis-signs-landmark-legislation-to-ban-vaccine-passports-and-stem-government-overreach/>.

port in Florida the conditional sailing order and the later measures (technical guidelines, manuals, and the like).” Add. 138. The court stayed the injunction until July 18. *Id.*

Addressing Florida’s asserted basis for standing and irreparable injury, the district court declared that the COVID-19 health and safety protocols required under the Conditional Sailing Order and technical guidance “burden the cruise industry’s capacity for profitable sailing.” Add. 131. The court assumed that the cruise industry will become more profitable—and that Florida will indirectly benefit through increased tax and port revenue and lower unemployment spending—if the CDC’s health and safety protocols are enjoined. Add. 34, 129.

Addressing the dangers that the injunction will pose for the public health, the district court did not question the CDC’s determination that “cruise ships present a unique setting that is particularly conducive to transmission of the virus.” Add. 134 (quotation marks omitted). However, the court declared that this concern is diminished by “the proliferation of vaccines.” *Id.* The court recognized that Florida law prohibits cruise ship operators from requiring passengers to document their vaccination status

but stated that Florida law does not “necessarily” prevent passengers from “volunteering” that information. Add. 33 n.8.

Addressing the merits, the district court concluded that the Conditional Sailing Order likely exceeds the CDC’s authority. The court acknowledged that longstanding regulations (unchallenged here) allow the CDC to impose conditions on “free pratique”—that is, “permission for a carrier to enter a U.S. port, disembark, and begin operation under certain stipulated conditions” to prevent the transmission of communicable disease. Add. 57 (quoting 42 C.F.R. § 71.1(b)); *see also* Add. 74-75 (citing 42 C.F.R. § 71.31). The court also recognized that in May 2021 legislation, Congress granted privileges to certain cruise ships that obtain and operate in accordance with “a COVID-19 Conditional Sailing Certificate of the Centers for Disease Control and Prevention.” Add. 80 (quoting the Alaska Tourism Restoration Act § 2(a), 135 Stat. at 273). Nonetheless, the court ruled that the CDC has no authority to issue such a Certificate and suggested that such authority would be an unconstitutional delegation of power to the CDC. Add. 82-83.

The district court also declared that the Conditional Sailing Order was arbitrary and capricious because it reserved the CDC’s authority to issue

“additional technical instructions as needed,” Add. 111, and because the CDC ostensibly failed to consider whether state or local measures are sufficient to prevent cruise ships from introducing or spreading COVID-19, Add. 114. Finally, the court declared that notice-and-comment rulemaking was required before the CDC could provide the cruise industry with a framework for resuming passenger operations at U.S. ports. Add. 115-126.

ARGUMENT

The preliminary injunction rests on errors of law and is a clear abuse of the district court’s discretion. The “chief function of a preliminary injunction is to preserve the status quo until the merits of the controversy can be fully and fairly adjudicated.” *Northeastern Fla. Chapter of the Ass’n of Gen. Contractors of Am. v. City of Jacksonville*, 896 F.2d 1283, 1284 (11th Cir. 1990). Here, however, the district court’s order will lift the COVID-19 health and safety protocols that were developed with cruise industry input and that the cruise industry is currently implementing. That disruption to this orderly process comes at the behest of Florida—which has actively undermined the cruise ships’ planned resumption of passenger cruises by prohibiting operators from requiring documentation that passengers are vaccinated. The preliminary injunction should be stayed pending appeal.

Florida did not establish standing or irreparable harm, nor did the State demonstrate any of the other factors necessary to obtain the “extraordinary and drastic remedy” of a preliminary injunction. *Callahan v. U.S. Dep’t of Health & Human Servs.*, 939 F.3d 1251, 1257 (11th Cir. 2019).

I. Florida Failed To Establish Article III Standing Or Irreparable Harm

Florida is not an entity that is regulated by the Conditional Sailing Order or technical guidance, which apply to the cruise ship industry. Instead, Florida claims to be indirectly injured by the actions of third parties, a theory that makes standing “substantially more difficult to establish.” *California v. Texas*, 141 S. Ct. 2104, 2117 (2021) (quotation marks omitted).

Like the plaintiff States in *California v. Texas*, Florida submitted no evidence to support its “counterintuitive theory of standing.” 141 S. Ct. at 2119. The premise of this suit is that the COVID-19 safety protocols in the Conditional Sailing Order and technical guidance “burden the cruise industry’s capacity for profitable sailing,” Add. 131, and that profitable cruise operations will increase if such health and safety protocols are lifted, which in turn will benefit Florida indirectly through increased tax and port revenue and reduced unemployment spending, Add. 34, 129.

“[N]either logic nor intuition” supports that theory of standing, which assumes that prospective cruise ship passengers are indifferent to whether COVID-19 health and safety requirements are in effect. *California*, 141 S. Ct. at 2118. That assumption is both implausible and unsubstantiated. As one commentator observed: “Cruise ships are closed environments where you’re going to have hundreds or thousands of people all together for a week or two at a time.” Orlando Sentinel, *supra*. “There’s no question that the cruise ship operators are going to want to reassure their customers that this is a safe place to be, particularly when you consider that some of the earliest outbreaks that we had last spring were on cruise ships.” *Id.*

Furthermore, as the district court recognized, a plaintiff can “defeat standing” by contributing to its own injury. Add. 33 n.8. And here, Florida has actively impeded the cruise industry’s ability to conduct safe operations by prohibiting cruise ship operators from requiring documentation that passengers are vaccinated—with violators subject to a fine of up to \$5,000 per violation. *See* Fla. SB 2006, § 18 (enacting Fla. Stat. § 381.00316(1), (4)). Florida has thus undermined the vaccination strategy that industry representatives developed to “facilitate cruise resumption in the U.S. by Summer 2021.” Add. 165. The district court’s suggestion that SB 2006 does

not “necessarily” prevent passengers from “volunteering” to verify their vaccinated status, Add. 33 n.8, is little comfort to an industry seeking to reassure prospective customers of the safety of their voyages or to promote “fully vaccinated” cruises.⁶ If, as the district court speculated, cruise lines decide to curtail their Florida-based operations or “abandon Florida’s ports,” Add. 130, those consequences will be a product of the State’s own actions.

In short, Florida neither established Article III standing nor made the “showing of irreparable injury” that “is the sine qua non of injunctive relief.” *Siegel v. LePore*, 234 F.3d 1163, 1176 (11th Cir. 2000) (en banc) (quotation marks omitted). The preliminary injunction should be stayed pending appeal (and ultimately vacated) for those reasons alone.

II. Florida Has No Likelihood Of Success On The Merits

Florida also failed to demonstrate a likelihood of success on the merits. Its failure to establish standing precludes a finding that it is likely to succeed on the merits. *See Munaf v. Geren*, 553 U.S. 674, 690 (2008). Moreover, contrary to the district court’s ruling, the Conditional Sailing Order and

⁶ *See, e.g.,* Monica Humphries, *Everything You Need to Know About Fully Vaccinated Cruises*, Insider (June 22, 2021), <https://www.insider.com/what-to-know-about-vaccinated-cruises-requirement-2021-6>.

technical guidance fall within the CDC’s longstanding authority and were approved by Congress in recent legislation.

A. All of the cruise ships at issue here are foreign-flagged vessels that must stop at one or more foreign ports during each voyage. Add. 143 ¶ 7. Cruise travel has the potential to introduce COVID-19 variants of concern into the United States from countries such as the Bahamas, Mexico, Honduras, Saint Maarten, Dominican Republic, Haiti, Aruba, and Saint Kitts and Nevis. Add. 155 ¶ 31.

The CDC has authority to make and enforce such regulations as in its judgment are necessary to prevent the introduction, transmission, or spread of communicable disease from a foreign country into the United States. 42 U.S.C. § 264(a); 42 C.F.R. § 70.2. For carriers arriving at U.S. ports, longstanding regulations (unchallenged here) allow the CDC to issue a “controlled free pratique”—defined as “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)—to prevent the introduction or spread of a communicable disease, *see id.* § 71.31(b).

The Conditional Sailing Order and technical guidance are well within that longstanding authority. The protocols that cruise ships must follow

under the Order and technical guidance are conventional communicable-disease control measures, such as testing and reporting COVID-19 cases among passengers and crew, quarantine of exposed persons and their contacts, isolation of infectious persons to contain outbreaks, and collection and analysis of public health data. Add. 144-145 ¶¶ 10-11.

The district court did not identify any other measures that would be better suited to prevent and contain COVID-19 outbreaks onboard cruise ships. Moreover, the injunction rests on the court's misunderstanding of what the Conditional Sailing Order required. For example, the court stated that the Order prescribed an "excruciating" requirement "to build laboratories on board" cruise ships. Add. 76. There is no such requirement; operators were simply required to procure an onboard testing unit about the size of a desktop printer that easily fits within their existing medical centers. Add. 145 ¶ 12. Fifty-nine of the 65 ships covered by the Conditional Sailing Order have already acquired that equipment. Add. 146 ¶ 15.

The district court was equally mistaken in declaring that the Conditional Sailing Order imposed an "industry-wide detention of a fleet of vessels in American waters." Add. 53. Although the CDC has authority to detain carriers, *see* 42 C.F.R. §§ 71.31(b), 71.32(b), the Conditional Sailing

Order did not detain any cruise ships, which have been and remain free to sail, Add. 146 ¶ 14. The Order established conditions under which a cruise ship may obtain and retain controlled free pratique, *i.e.*, permission to enter a U.S. port, disembark, and begin operation. *See* 85 Fed. Reg. at 70,158; 42 C.F.R. §§ 71.2; 71.31(b).

For the same reasons, the district court was wrong to analogize the protocols at issue here to the eviction moratorium that the Supreme Court recently left in place. Add. 59. Even the unfavorable lower-court opinions involving the eviction moratorium recognized that the CDC's authority to prevent the spread of communicable disease included areas of traditional federal jurisdiction. *See, e.g., Tiger Lily, LLC v. U.S. Dep't of Hous. & Urban Dev.*, 992 F.3d 518, 522-23 (6th Cir. 2021). The protocols here are consistent with even the narrowest interpretation of CDC's authority in those rulings: the cruise ships travel in international waters—which is an area of traditional federal jurisdiction—and the Conditional Sailing Order and technical guidance rely on conventional communicable disease-control measures to prevent and contain outbreaks of COVID-19 onboard.

B. Furthermore, Congress enacted legislation in May 2021 that was explicitly premised on the CDC's authority under the Conditional Sailing

Order. Federal law generally requires that a foreign-flagged vessel stop at a foreign port whenever traveling between U.S. ports. 46 U.S.C. § 55103. To comply with that federal statute, Alaskan cruise itineraries typically include a stop at a Canadian port but, because of the pandemic, Canada has barred cruise ships from operating in Canadian waters through February 2022.

Dkt. No. 46-11.

In May 2021, Congress enacted the Alaska Tourism Restoration Act, which provided a temporary exemption from the requirement to stop at a foreign port for a covered cruise ship that “has been issued, operates in accordance with, and retains a COVID–19 Conditional Sailing Certificate of the [CDC].” Alaska Tourism Restoration Act § 2(a), (b), 135 Stat. at 273.

That statutory exemption would be a nullity—and Alaskan cruises would be unable to sail—if the CDC lacked authority to issue Conditional Sailing Certificates to cruise ships. The district court gave no sound reason for disregarding this recent legislation, which was explicitly premised on the validity of the Conditional Sailing Order. The Supreme Court has repeatedly emphasized that a court “cannot interpret federal statutes to negate their own stated purposes.” *King v. Burwell*, 576 U.S. 473, 493 (2015) (quoting *New York State Dep’t of Soc. Servs. v. Dublino*, 413 U.S. 405, 419-20 (1973)).

C. The other grounds offered by the district court for enjoining the Conditional Sailing Order and technical guidance are equally meritless.

Contrary to the district court's suggestion, the CDC's authority to issue the Conditional Sailing Order and related technical guidance presents no serious issue under the non-delegation doctrine. *See* Add. 83-104. The vessels at issue here are foreign-flagged, and the non-delegation doctrine applies with reduced force in the context of foreign affairs. *See United States v. Curtiss-Wright Export Corp.*, 299 U.S. 304, 314-330 (1936); *see also Gundy v. United States*, 139 S. Ct. 2116, 2137 (2019) (Gorsuch, J., dissenting). And even in the domestic context, the Supreme Court has rejected non-delegation challenges to statutes that empower agencies to regulate in the "public interest," *see National Broad. Co. v. United States*, 319 U.S. 190, 225-226 (1943); to set prices that are "fair and equitable," *see Yakus v. United States*, 321 U.S. 414, 420 (1944); and to establish air-quality standards to "protect the public health," *see Whitman v. American Trucking Ass'n*, 531 U.S. 457, 472-476 (2001). The standard set out in 42 U.S.C. § 264 is more specific than those standards. Moreover, Congress considered and approved the Conditional Sailing Order when it enacted the May 2021 legislation that is premised on that authority.

The district court was likewise wrong to deem the Conditional Sailing Order impermissibly “vague” because it reserved the CDC’s authority to issue “additional technical instructions as needed.” Add. 111. It was eminently reasonable for the CDC to refine its technical guidance in light of rapidly evolving public-health conditions, as Congress itself recognized. *See* Alaska Tourism Restoration Act, Pub. L. No. 117-14, § 2(a)(1)(B) (defining “covered cruise ship” as one that “operates in accordance with any restrictions or guidance of the [CDC] associated with such [Conditional Sailing] Certificate, *including any such . . . guidance issued after the date of enactment of this Act*” (emphasis added)).

Nor did the CDC fail to consider whether “measures by state and local governments” are adequate to prevent the spread of COVID-19 by cruise ships. Add. 112. The CDC explained that “[c]ruise ships by their very nature travel interstate and internationally and can move beyond the jurisdictional boundaries of any single state or local health authority.” 85 Fed. Reg. at 70,157. “Furthermore, local transmission of COVID-19 onboard a cruise ship can escalate quickly into additional interstate and international transmission when infected persons travel.” *Id.* Moreover, Florida’s local port authorities asked the CDC to develop technical guidance. Add. 144 ¶ 9;

see also, e.g., Dkt. No. 31-2, Page ID 1662 (Sept. 21, 2020, comment from Port Everglades urging the CDC “to develop standard protocols and guidelines that can be used by our cruise line partners”).

There is also no plausible contention that notice-and-comment rulemaking was required before the CDC could provide the cruise industry with a framework for resuming passenger operations at U.S. ports. Controlled free pratique is a license, which falls within the definition of an “order” rather than a “rule” under the Administrative Procedure Act. *See* 5 U.S.C. § 551(6), (8), (9). And in any event, before issuing the Conditional Sailing Order, the CDC solicited and considered comments on a detailed request for information that served the same purpose as notice-and-comment rulemaking. *See* CDC Regulations.gov, RFI Cruise Ship Planning, Comments (July 21, 2020), <https://www.regulations.gov/document/CDC-2020-0087-0001/comment> (approximately 13,000 comments received). Florida has never explained how an additional round of comment would have affected the Conditional Sailing Order or why it would have expedited, rather than delayed, the resumption of safe passenger cruise operations at U.S. ports.

III. The Preliminary Injunction Will Exacerbate The Spread Of COVID-19

Finally, there is no doubt that the preliminary injunction will exacerbate the spread of COVID-19. In June 2021 alone, the CDC was repeatedly notified of positive COVID-19 test results among crew members onboard cruise ships. Add. 153-154 ¶ 29. And as the CDC has explained, conditions onboard cruise ships make them unique environments that facilitate the spread of COVID-19. Add. 141-142 ¶ 4. For example, cruise ships bring together travelers from different countries, may include more than 6,000 passengers, and bring crew and passengers together for extended periods in close quarters. *Id.*

Moreover, cruise ship voyages from the United States will include itineraries to countries that have low vaccination rates but are reopening to international tourism. Add. 155 ¶ 31. Cruise ship travel to these countries may risk introducing variants of concern into the United States from countries such as the Bahamas, Mexico, Honduras, Saint Maarten, Dominican Republic, Haiti, Aruba, and Saint Kitts and Nevis. *Id.*⁷

⁷ The district court mistakenly suggested that the incidence of outbreaks on foreign cruises is trivial. Add. 135. There have been significant outbreaks on foreign cruises, Dkt. No. 31-1 ¶ 80, and, as explained above, some countries such as Canada continue to bar all cruise operations.

The district court had no basis to substitute its view (or Florida's view) that the CDC's protocols can safely be lifted for the contrary determination made by the expert public health agency in consultation with the cruise ship industry and squarely within its traditional authority. These protocols appropriately balance public health concerns with the shared desire to resume passenger cruises—as is amply demonstrated by the fact that the cruise lines (which have not appeared in this litigation) are well underway in implementing the Conditional Sailing Order and already are, or soon will be, resuming passenger cruises.

CONCLUSION

This Court should stay the district court's preliminary injunction pending appeal and issue an administrative stay pending the Court's consideration of this motion.

Respectfully submitted,

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*Deputy Assistant Attorney General*⁸

/s/ Alisa B. Klein

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JULY 2021

⁸ The Acting Assistant Attorney General is recused.

CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing motion complies with the word limit of Federal Rule of Appellate Procedure 27(d)(2)(A) because the motion contains 4,715 words. The motion complies with the typeface and type-style requirements of Federal Rules of Appellate Procedure 27(d)(1)(E) and 32(a)(5) and (6) because it has been prepared using Microsoft Word 2016 in proportionally spaced 14-point Century Expd BT typeface.

/s/ Alisa B. Klein
ALISA B. KLEIN

CERTIFICATE OF SERVICE

I hereby certify that on July 7, 2021, I electronically filed the foregoing motion with the Clerk of the Court for the United States Court of Appeals for the Eleventh Circuit by using the appellate CM/ECF system.

Participants in the case are registered CM/ECF users, and service will be accomplished by the appellate CM/ECF system.

/s/ Alisa B. Klein

ALISA B. KLEIN

ADDENDUM

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District Court Docket.....	Add. 1
Notice of Appeal (July 6, 2021).....	Add. 14
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Cruise Industry Proposed Vaccination Goals (April 26, 2021)	Add. 165
District Court Order Denying Stay Pending Appeal (July 7, 2021)	Add. 166

APPEAL, MEDIATION, STAYED

**U.S. District Court
Middle District of Florida (Tampa)
CIVIL DOCKET FOR CASE #: 8:21-cv-00839-SDM-AAS**

State of Florida v. Becerra et al
Assigned to: Judge Steven D. Merryday
Referred to: Magistrate Judge Amanda Arnold Sansone
Cause: 05:0702 Administrative Procedure Act

Date Filed: 04/08/2021
Jury Demand: None
Nature of Suit: 899 Other Statutes:
Administrative Procedures Act/Review or
Appeal of Agency Decision
Jurisdiction: U.S. Government Defendant

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LEAD ATTORNEY

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Date Filed	#	Docket Text
04/08/2021	1	COMPLAINT against All Defendants (Filing fee \$ 402 receipt number AFLMDC-18108694) filed by State of Florida. (Attachments: # 1 Civil Cover Sheet, # 2 Proposed Summons, # 3 Exhibit 1, October 30 Order, # 4 Exhibit 2, March 14 Order, # 5 Exhibit 3, April 9 Order, # 6 Exhibit 4, July 16 Order, # 7 Exhibit 5, September 30 Order, # 8 Exhibit 6, Congressional Testimony)(Percival, James) (Entered: 04/08/2021)
04/08/2021	2	NEW CASE ASSIGNED to Judge Steven D. Merryday and Magistrate Judge Amanda Arnold Sansone. New case number: 8:21-cv-0839-SDM-AAS. (SJB) (Entered: 04/08/2021)
04/08/2021	3	SUMMONS issued as to Xavier Becerra, Centers for Disease Control and Prevention, Health and Human Services, United States of America, and Rochelle Walensky. (JLD) (Entered: 04/08/2021)
04/09/2021	4	NOTICE of Local Rule 1.07(c) and Local Rule 3.02(a)(2): -Local Rule 1.07(c) requires lead counsel to <i>promptly</i> file a Notice of a Related Action that identifies and describes any related action pending in the Middle District. -Local Rule 3.02(a)(2) requires the parties in every civil proceeding, except those described in subsection (d), to file a case management report (CMR) using the uniform form at www.flmd.uscourts.gov . The CMR must be filed (1) within forty days after any defendant appears in an action originating in this court, (2) within forty days after the docketing of an action removed or transferred to this court, or (3) within seventy days after service on the United States attorney in an action against the United States, its agencies or employees. Judges may have a special CMR form for certain types of cases. These forms can be found at www.flmd.uscourts.gov under the Forms tab for each judge. (Signed by Deputy Clerk). (KR) (Entered: 04/09/2021)
04/09/2021	5	NOTICE: COMPLIANCE WITH LOCAL RULE 1.08. Signed by Judge Steven D. Merryday on 2/5/2021. (KR) (Entered: 04/09/2021)
04/09/2021	6	CORPORATE Disclosure Statement by State of Florida. (Patel, Anita) (Entered: 04/09/2021)
04/14/2021		REFUND for duplicate payment. Receipt number AFLMDC-18108083 refunded in the amount of \$ \$402.00 paid to Jenna Hodges.. (NLC) (Entered: 04/14/2021)
04/15/2021	7	NOTICE by State of Florida re 1 Complaint, 3 Summons issued as to USA <i>Proof of Service</i> (Attachments: # 1 Exhibit A. Proof of Service, # 2 Exhibit B. Additional Proof of Service)(Percival, James) (Entered: 04/15/2021)
04/20/2021	8	MOTION to Intervene by State of Alaska. (Attachments: # 1 Exhibit 1- Federal Maritime

		Commission Report, # 2 Exhibit 2 Impacts to Alaska Report, # 3 Exhibit 3 State of Alaska's Complaint)(Wenger, Edward) (Entered: 04/20/2021)
04/22/2021	9	MOTION for Preliminary Injunction by State of Florida. (Attachments: # 1 Exhibit CLIA Study, # 2 Exhibit Federal Maritime Commission Report, # 3 Exhibit Cruises are Still Stuck, # 4 Exhibit CDC on Hotels, # 5 Exhibit CDC on Casinos, # 6 Exhibit CDC on Sporting Events, # 7 Exhibit Cruise Hive, # 8 Exhibit CDC on Cruise Ship Travel Abroad, # 9 Exhibit CLIA Press Release, # 10 Exhibit Carnival Interview, # 11 Exhibit CDC on Airlines, # 12 Exhibit CDC April 2021 Guidance, # 13 Exhibit CDC Technical Instructions_Local, # 14 Exhibit CDC Technical Instructions_Crew, # 15 Exhibit CDC on Fully Vaccinated, # 16 Exhibit CDC on How COVID Spreads, # 17 Exhibit Cruises in CDC Dock, # 18 Exhibit WH Memo, # 19 Exhibit Heckman Declaration, # 20 Exhibit Port Everglades Report, # 21 Exhibit PortMiami Report, # 22 Exhibit JAXPORT Report, # 23 Exhibit Port Tampa Bay Report, # 24 Exhibit Port Canaveral Report, # 25 Exhibit Johnston Declaration, # 26 Exhibit Fitz-Patrick Declaration, # 27 Exhibit Economic Impact of COVID, # 28 Exhibit Cruise Industry Spars with CDC, # 29 Exhibit Cruises Leaving United States, # 30 Text of Proposed Order)(Hilborn, Jason) (Entered: 04/22/2021)
04/22/2021	10	SUPPLEMENT re 8 MOTION to Intervene by State of Alaska (Wenger, Edward) (Entered: 04/22/2021)
04/22/2021	11	REQUEST for oral argument re 9 MOTION for Preliminary Injunction by State of Florida. (Hilborn, Jason) (Entered: 04/22/2021)
04/23/2021	12	ORDER and NOTICE of hearing re 9 --motion for preliminary injunction scheduled for <u>5/12/2021 at 09 00 AM</u> in Tampa Courtroom 15A before Judge Steven D Merryday (BK) Modified on 5/4/2021 (BK) (Entered: 04/23/2021)
04/26/2021	13	MOTION for Lael A. Harrison to appear pro hac vice, Special Admission fee paid, Receipt No. AFLMDC-18175932 for \$150 by State of Alaska. (Attachments: # 1 Harrison Certificate of Good Standing)(Wenger, Edward) Motions referred to Magistrate Judge Amanda Arnold Sansone. (Entered: 04/26/2021)
04/26/2021	14	MOTION for Jessica M. Alloway to appear pro hac vice, Special Admission fee paid, Receipt No AFLMDC 18175984 for \$150 by State of Alaska (Attachments # 1 Alloway Certificate of Good Standing)(Wenger, Edward) Motions referred to Magistrate Judge Amanda Arnold Sansone (Entered 04/26/2021)
04/26/2021	15	ENDORSED ORDER granting 13 Motion to Appear Pro Hac Vice; granting 14 Motion to Appear Pro Hac Vice. Attorneys Lael A. Harrison and Jessica M. Alloway may appear pro hac vice, subject to the requirement that counsel complete the E- Filer Registration for access to CM/ECF (https://www.flmd.uscourts.gov/webforms/e-filer-registration-form) within seven days of this order. Signed by Magistrate Judge Amanda Arnold Sansone on 4/26/2021. (BEE) (Entered: 04/26/2021)
04/26/2021	16	Unopposed MOTION for Extension of Time to File Response/Reply as to 8 MOTION to Intervene by All Defendants. (Powell, Amy) (Entered: 04/26/2021)
04/26/2021	17	NOTICE of compliance re 12 Notice of hearing on motion by State of Florida (Attachments: # 1 Exhibit)(Percival, James) (Entered: 04/26/2021)
04/26/2021	18	ORDER granting 16 Motion for Extension of Time to File Response; not later than May 7, 2021, the defendants must respond to Alaska's motion to intervene. Directing Alaska to submit an amicus brief no later than May 5, 2021. Signed by Judge Steven D. Merryday on 4/26/2021. (KR) (Entered 04/26/2021)
04/26/2021	19	MOTION for Leave to File Amicus Brief by State of Alaska. (Attachments: # 1 Amicus

		Curiae Brief of the State of Alaska in Support of Florida's Motion for Preliminary Injunction, # 2 Certificate of Service)(Alloway, Jessica) Modified text on 5/3/2021 (AG). (Entered: 04/26/2021)
05/03/2021	20	MOTION to File Excess Pages <i>In Opposition to Plaintiff's Motion for a Preliminary Injunction</i> by All Defendants. (Powell, Amy) (Entered: 05/03/2021)
05/03/2021	21	MOTION for Leave to File Amicus Brief by Marc S. Young. (Attachments: # 1 Amicus Brief, # 2 Exhibits to Amicus Brief)(AG) (Entered: 05/03/2021)
05/04/2021	22	ORDER granting 20--motion re excess pages; enlarging to forty-five pages the permitted length of defendants' response to the plaintiff's motion for a preliminary injunction; permitting the plaintiff to reply by <u>5/19/2021</u> in a paper not exceeding twenty pages. Signed by Judge Steven D. Merryday on 5/4/2021. (BK) (Entered: 05/04/2021)
05/04/2021	23	Unopposed MOTION for Miscellaneous Relief, specifically LEAVE TO AMEND FLORIDA'S MOTION FOR A PRELIMINARY INJUNCTION by State of Florida. (Patel, Anita) (Entered: 05/04/2021)
05/05/2021	24	ORDER granting 23---motion to amend; permitting the plaintiff to submit by <u>5/6/2021</u> an amended motion for preliminary injunction "for the sole purpose of filing the corrected declaration." Signed by Judge Steven D. Merryday on 5/5/2021. (BK) (Entered: 05/05/2021)
05/05/2021	25	Amended MOTION for Preliminary Injunction by State of Florida. (Attachments: # 1 Exhibit CLIA Study, # 2 Exhibit Federal Maritime Commission Report, # 3 Exhibit Cruises are Still Stuck, # 4 Exhibit CDC on Hotels, # 5 Exhibit CDC on Casinos, # 6 Exhibit CDC on Sporting Events, # 7 Exhibit Cruise Hive, # 8 Exhibit CDC on Cruise Ship Travel Abroad, # 9 Exhibit CLIA Press Release, # 10 Exhibit Carnival Interview, # 11 Exhibit CDC on Airlines, # 12 Exhibit CDC April 2021 Guidance, # 13 Exhibit CDC Technical Instructions_Local, # 14 Exhibit CDC Technical Instructions_Crew, # 15 Exhibit CDC on Fully Vaccinated, # 16 Exhibit CDC on How COVID Spreads, # 17 Exhibit Cruises in CDC Dock, # 18 Exhibit WH Memo, # 19 Exhibit Heckman Declaration, # 20 Exhibit Port Everglades Report, # 21 Exhibit PortMiami Report, # 22 Exhibit JAXPORT Report, # 23 Exhibit Port Tampa Bay Report, # 24 Exhibit Port Canaveral Report, # 25 Exhibit Johnston Declaration, # 26 Exhibit Fitz-Patrick Declaration, # 27 Exhibit Economic Impact of COVID, # 28 Exhibit Cruise Industry Spars with CDC, # 29 Exhibit Cruises Leaving United States, # 30 Text of Proposed Order) (Patel, Anita) (Entered: 05/05/2021)
05/05/2021	26	MOTION to Intervene by State of Texas. (Attachments: # 1 Exhibit "A" - Complaint in Intervention for Preliminary and Permanent Injunctive Relief)(Harvey, David) (Entered: 05/05/2021)
05/05/2021	27	MOTION for Ryan G. Kercher to appear pro hac vice, Special Admission fee paid, Receipt No. AFLMDC-18219709 for \$150 by State of Texas. (Attachments: # 1 Exhibit "A" - Certificate of Good Standing - Ryan G. Kercher)(Harvey, David) Motions referred to Magistrate Judge Amanda Arnold Sansone. (Entered: 05/05/2021)
05/05/2021	28	MOTION for Kimberly Fuchs to appear pro hac vice, Special Admission fee paid, Receipt No. AFLMDC-18219726 for \$150 by State of Texas. (Attachments: # 1 Affidavit "A" - Certificate of Good Standing - Kimberly Fuchs)(Harvey, David) Motions referred to Magistrate Judge Amanda Arnold Sansone. (Entered: 05/05/2021)
05/05/2021	29	Witness List by State of Florida. (Patel, Anita) (Entered: 05/05/2021)
05/05/2021	30	Exhibit List <i>for Preliminary Injunction Hearing</i> by State of Florida. (Patel, Anita)

05/05/2021	31	MEMORANDUM in opposition re 25 Motion for Preliminary Injunction, 9 Motion for Preliminary Injunction filed by Xavier Becerra, Centers for Disease Control and Prevention, Health and Human Services, United States of America, Rochelle Walensky. (Attachments: # 1 Declaration of Capt. A. Treffiletti, # 2 Exhibit A - Selected Public Comments, # 3 Exhibit B - April 28 Letter, # 4 Exhibit C - Technical Instructions & Operations Manual, # 5 Exhibit D - Application for a Conditional Sailing Certificate, # 6 Exhibit E - Vaccination Statement)(Powell, Amy) (Entered: 05/05/2021)
05/05/2021	32	Exhibit List for <i>Preliminary Injunction Hearing</i> by Xavier Becerra, Centers for Disease Control and Prevention, Health and Human Services, United States of America, Rochelle Walensky. (Powell, Amy) (Entered: 05/05/2021)
05/06/2021	33	ENDORSED ORDER granting 27 Motion to Appear Pro Hac Vice; granting 28 Motion to Appear Pro Hac Vice. Attorneys Ryan G. Kercher and Kimberly Fuchsmay may appear pro hac vice, subject to the requirement that counsel complete the E-Filer Registration for access to CM/ECF (https://www.flmd.uscourts.gov/webforms/e-filer-registration-form) within seven days of this order. Signed by Magistrate Judge Amanda Arnold Sansone on 5/6/2021. (BEE) (Entered: 05/06/2021)
05/06/2021	34	NOTICE by State of Florida <i>OF AGREEMENT BETWEEN THE PARTIES</i> (Patel, Anita) (Entered: 05/06/2021)
05/07/2021	35	MOTION to Stay <i>Motion to Stay</i> by State of Alaska. (Alloway, Jessica) (Entered: 05/07/2021)
05/07/2021	36	ENDORSED ORDER: Alaska moves 35 for a stay. The motion is construed as a motion for leave to amend Alaska's motion to intervene. The motion is GRANTED. Alaska may amend the motion to intervene no later than May 21, 2021. Notwithstanding any earlier order, the defendants may respond to Alaska's motion within seven days after Alaska amends (or elects not to amend). Signed by Judge Steven D. Merryday on 5/7/2021. (Entered: 05/07/2021)
05/10/2021	37	MOTION for Lael A. Harrison to appear telephonically by State of Alaska. (Harrison, Lael) Motions referred to Magistrate Judge Amanda Arnold Sansone. Modified text on 5/10/2021 (MCB). (Entered: 05/10/2021)
05/10/2021	38	MOTION for Kimberly Fuchs, Ryan Kercher, Grant Dorfman to appear telephonically at <i>May 12, 2021 preliminary injunction hearing</i> by State of Texas. (Fuchs, Kimberly) Motions referred to Magistrate Judge Amanda Arnold Sansone. (Entered: 05/10/2021)
05/11/2021	39	ENDORSED ORDER denying 38 Motion to Appear Telephonically. Signed by Judge Steven D. Merryday on 5/11/2021. (Entered: 05/11/2021)
05/11/2021	40	ENDORSED ORDER denying 37 Motion to Appear Telephonically. Signed by Judge Steven D. Merryday on 5/11/2021. (Entered: 05/11/2021)
05/12/2021	41	Unopposed MOTION for Peter N. Lobasso to appear pro hac vice, Special Admission fee paid, Receipt No. AFLMDC-18241887 for \$150 by American Society of Travel Advisors. (Stockel, Eric) Motions referred to Magistrate Judge Amanda Arnold Sansone. (Entered: 05/12/2021)
05/12/2021	42	MOTION for Leave to File Amicus Brief by American Society of Travel Advisors. (Attachments: # 1 Exhibit Proposed Amicus Curiae Brief)(Stockel, Eric) (Entered: 05/12/2021)
05/12/2021	43	ENDORSED ORDER granting 41 Motion to Appear Pro Hac Vice. Attorney Peter N.

		Lobasso may appear pro hac vice, subject to the requirement that counsel complete the E-Filer Registration for access to CM/ECF (https://www.flmd.uscourts.gov/webforms/e-filer-registration-form) within seven days of this order. Signed by Magistrate Judge Amanda Arnold Sansone on 5/12/2021. (BEE) (Entered: 05/12/2021)
05/13/2021	44	MINUTE ENTRY for <u>5/12/2021</u> in-person hearing re <u>9</u> --Plaintiff's Motion For Preliminary Injunction, before Judge Steven D. Merryday. Court Reporter: Shayna Montgomery (KR) (Entered: 05/13/2021)
05/13/2021	45	Plaintiff's Exhibit List and Exhibits admitted during <u>5/12/2021</u> in-person hearing. (Attachments: # 1 Exhibit 1, # 2 Exhibit 2, # 3 Exhibit 3, # 4 Exhibit 4, # 5 Exhibit 5, # 6 Exhibit 6, # 7 Exhibit 7, # 8 Exhibit 8, # 9 Exhibit 9, # 10 Exhibit 10, # 11 Exhibit 11, # 12 Exhibit 12, # 13 Exhibit 13, # 14 Exhibit 14, # 15 Exhibit 15, # 16 Exhibit 16, # 17 Exhibit 17, # 18 Exhibit 18, # 19 Exhibit 19, # 20 Exhibit 20, # 21 Exhibit 21, # 22 Exhibit 22, # 23 Exhibit 23, # 24 Exhibit 24, # 25 Exhibit 25, # 26 Exhibit 26, # 27 Exhibit 27, # 28 Exhibit 28, # 29 Exhibit 29)(KR) (Entered: 05/13/2021)
05/13/2021	46	Defendants' Exhibit List and Exhibits admitted during <u>5/12/2021</u> in-person hearing. (Attachments: # 1 Exhibit 1, # 2 Exhibit 2, # 3 Exhibit 3, # 4 Exhibit 4, # 5 Exhibit 5, # 6 Exhibit 6, # 7 Exhibit 7, # 8 Exhibit 8, # 9 Exhibit 9, # 10 Exhibit 10, # 11 Exhibit 11)(KR) (Entered: 05/13/2021)
05/13/2021	47	TRANSCRIPT of Hearing Re Plaintiff's Motion for Preliminary Injunction held on 05/12/2021 before Judge Steven D. Merryday. Court Reporter: Shayna Montgomery (813) 301-5024 - shayna_montgomery@flmd.uscourts.gov. Transcript may be viewed at the court public terminal or purchased through the Court Reporter before the deadline for Release of Transcript Restriction. After that date it may be obtained through PACER or purchased through the Court Reporter. Redaction Request due 6/3/2021 Redacted Transcript Deadline set for 6/14/2021 Release of Transcript Restriction set for 8/11/2021. (SRM) (Entered: 05/13/2021)
05/13/2021	48	NOTICE to counsel of filing of OFFICIAL TRANSCRIPT. The parties have seven (7) calendar days to file with the court a Notice of Intent to Request Redaction of this transcript. If no such Notice is filed, the transcript may be made remotely electronically available to the public without redaction after 90 calendar days. Any party needing a copy of the transcript to review for redaction purposes may purchase a copy from the court reporter or view the document at the clerk's office public terminal. Court Reporter: Shayna Montgomery. (SRM) (Entered: 05/13/2021)
05/14/2021	49	MEMORANDUM in opposition re 42 Motion for Leave to File Amicus Brief / Document filed by Xavier Becerra, Centers for Disease Control and Prevention, Health and Human Services, United States of America, Rochelle Walensky. (Powell, Amy) (Entered: 05/14/2021)
05/17/2021	50	Unopposed MOTION for Miscellaneous Relief, specifically Leave to File Reply in Support of Motion for Leave to File Amicus Curiae Brief by American Society of Travel Advisors. (Stockel, Eric) (Entered: 05/17/2021)
05/18/2021	51	ORDER appointing Joseph H. Varner III as mediator; designating James H. Percival as lead counsel; setting JUNE 1, 2021 as the mediation deadline; directing counsel to file a notice within two days giving the date and time of mediation. The notice of mediation is due May 20, 2021. Signed by Judge Steven D. Merryday on 5/18/2021. (KR) (Entered: 05/18/2021)
05/18/2021	52	ORDER re mediation; see order for details concerning appearance at mediation. Signed by Judge Steven D. Merryday on 5/18/2021. (KR) (Entered: 05/18/2021)

05/18/2021	42	ORDER granting 42--motion by ASTA to submit an amicus brief; permitting ASTA to submit an amicus brief by <u>5/21/2021</u>; denying as moot 50--motion for leave to reply. Signed by Judge Steven D. Merryday on 5/18/2021. (BK) (Entered: 05/18/2021)
05/19/2021	54	NOTICE by American Society of Travel Advisors <i>of Filing Amicus Curiae Brief</i> (Stockel, Eric) (Entered: 05/19/2021)
05/19/2021	55	Joint MOTION for Miscellaneous Relief, specifically to be excused from requirement that parties with full settlement authority attend mediation by All Defendants. (Powell, Amy) Modified text on 5/21/2021 (AG). (Entered: 05/19/2021)
05/19/2021	56	REPLY to Response to Motion re 25 Amended MOTION for Preliminary Injunction filed by State of Florida. (Hilborn, Jason) (Entered: 05/19/2021)
05/19/2021	57	MEMORANDUM in opposition re 26 Motion to Intervene <i>by the State of Texas</i> filed by Xavier Becerra, Centers for Disease Control and Prevention, Health and Human Services, United States of America, Rochelle Walensky. (Attachments: # 1 Exhibit Public Comment, Rodger Rees, Port Director/CEO, Galveston Wharves, CDC-2020-0087 (Sept. 22, 2020)) (Holland, Liam) (Entered: 05/19/2021)
05/20/2021	58	NOTICE of mediation conference/hearing to be held on May 27, 9:30 a.m. before Joseph H. Varner III. (Percival, James) (Entered: 05/20/2021)
05/20/2021	59	MOTION for Extension of Time to Amend <i>State of Alaska's Unopposed Motion for Extension of Time to Amend Complaint and Motion to Intervene</i> by State of Alaska. (Harrison, Lael) (Entered: 05/20/2021)
05/21/2021	60	ORDER granting 55--motion to excuse from mediation representatives with full settlement authority; substituting Magistrate Judge Anthony Porcelli as mediator; mediation scheduled for <u>5/27/2021 at 9:00 a.m.</u> in Courtroom 10A of the courthouse. Signed by Judge Steven D. Merryday on 5/21/2021. (BK) (Entered: 05/21/2021)
05/21/2021	61	ORDER granting 59--motion for an extension of time; extending through <u>6/2/2021</u> the time within which Alaska may amend 8--motion to intervene; permitting the defendants to respond to the amended motion to intervene within seven days after the amendment. Signed by Judge Steven D. Merryday on 5/21/2021. (BK) (Entered: 05/21/2021)
05/24/2021	62	MOTION for authorization to file electronically by Marc S. Young. (AG) (Entered: 05/24/2021)
05/24/2021	63	MOTION for Leave to File Supplement Amicus Brief by Marc S. Young. (Attachments: # 1 Supplemental Amicus Curiae brief, # 2 Amicus Curiae Exhibits)(AG) (Entered: 05/24/2021)
05/25/2021	64	MEMORANDUM in opposition re 63 Motion for Leave to File Amicus Brief / Document filed by Xavier Becerra, Centers for Disease Control and Prevention, Health and Human Services, United States of America, Rochelle Walensky. (Powell, Amy) (Entered: 05/25/2021)
05/26/2021	65	MOTION for Leave to File a Reply in Support of re 63 Motion for Leave by Marc S. Young. (MCB) (Entered: 05/26/2021)
05/27/2021	66	Minute Entry. In Person Proceedings held before Magistrate Judge Anthony E. Porcelli: SETTLEMENT CONFERENCE held on 5/27/2021. Settlement conference is continued to Tuesday, June 1, 2021. (LV) (Entered: 05/28/2021)
05/29/2021	86	Minute Entry. Telephonic Proceedings held before Magistrate Judge Anthony E. Porcelli: SETTLEMENT CONFERENCE held on 5/29/2021. (LV) (Entered: 06/11/2021)

06/01/2021	87	Minute Entry Telephonic Proceedings held before Magistrate Judge Anthony E Porcelli SETTLEMENT CONFERENCE held on 6/1/2021. (LV) (Entered: 06/11/2021)
06/02/2021	67	MOTION for Miscellaneous Relief, specifically Leave to File Short Supplemental Brief and Declaration <i>in opposition to PI motion</i> by All Defendants. (Powell, Amy) (Entered: 06/02/2021)
06/02/2021	68	MOTION to Intervene <i>State of Alaska's Amended Motion to Intervene</i> by State of Alaska (Attachments: # 1 Complaint for Declaratory Judgment)(Harrison, Lael) (Entered: 06/02/2021)
06/02/2021	69	RESPONSE to Motion re 67 MOTION for Miscellaneous Relief, specifically Leave to File Short Supplemental Brief and Declaration <i>in opposition to PI motion</i> filed by State of Florida. (Percival, James) (Entered: 06/02/2021)
06/04/2021	70	ORDER granting 67--defendants' motion to submit a supplemental memorandum; permitting the defendants to submit by <u>noon on 6/7/2021</u> a supplemental memorandum of five or fewer pages addressing only those issues specified in the motion; permitting the plaintiff to respond by <u>6/9/2021</u> in five or fewer pages; scheduling a hearing for <u>10:00 a.m. on 6/10/2021</u> in Courtroom 15A; requiring the attendance of at least lawyers Percival, Hilborn and Powell. Signed by Judge Steven D. Merryday on 6/4/2021. (BK) (Entered: 06/04/2021)
06/04/2021	71	NOTICE of hearing scheduled for 6/10/2021 at 10:00 AM in Tampa Courtroom 15A before Judge Steven D. Merryday. (BK) (Entered: 06/04/2021)
06/07/2021	72	MEMORANDUM in opposition re 25 Motion for Preliminary Injunction (<i>supplemental memorandum, per Dkt 70</i>) filed by Xavier Becerra, Centers for Disease Control and Prevention, Health and Human Services, United States of America, Rochelle Walensky. (Attachments # 1 Suppl Decl of Capt A Treffiletti)(Powell, Amy) (Entered 06/07/2021)
06/08/2021	73	Unopposed MOTION for Extension of Time to File Answer re 1 Complaint by All Defendants. (Powell, Amy) (Entered: 06/08/2021)
06/08/2021	74	ENDORSED ORDER denying as moot 8 Alaska's motion to intervene, which is superseded by a later motion to intervene (Doc. 68). Signed by Judge Steven D. Merryday on 6/8/2021. (Entered: 06/08/2021)
06/08/2021	75	ENDORSED ORDER denying as moot 25 Florida's motion for preliminary injunction, which is superseded by an amended motion for preliminary injunction (Doc. 25).Signed by Judge Steven D. Merryday on 6/8/2021. (Entered: 06/08/2021)
06/08/2021	76	ENDORSED ORDER granting 19 Alaska's motion for leave to file an amicus brief. The brief attached to the motion is received. Signed by Judge Steven D. Merryday on 6/8/2021. (Entered 06/08/2021)
06/08/2021	77	ENDORSED ORDER granting 21 Marc Young's motion for leave to file an amicus brief. The brief attached to the motion is received. Signed by Judge Steven D. Merryday on 6/8/2021. (Entered: 06/08/2021)
06/08/2021	78	ENDORSED ORDER denying 62 the motion by Marc Young for leave to file electronically. Signed by Judge Steven D. Merryday on 6/8/2021. (Entered 06/08/2021)
06/08/2021	79	ENDORSED ORDER denying 63 the motion by Marc Young for leave to file a supplemental amicus brief. Signed by Judge Steven D. Merryday on 6/8/2021. (Entered: 06/08/2021)

06/08/2021	80	ENDORSED ORDER denying 63 the motion by Marc Young for leave to file a reply. Signed by Judge Steven D. Merryday on 6/8/2021. (Entered: 06/08/2021)
06/08/2021	81	ENDORSED ORDER granting 73 the defendants motion to extend through July 1, 2021, the time within which to respond to the complaint. Signed by Judge Steven D. Merryday on 6/8/2021. (Entered: 06/08/2021)
06/09/2021	82	RESPONSE re 72 Memorandum in opposition filed by State of Florida. (Percival, James) (Entered: 06/09/2021)
06/09/2021	83	RESPONSE in Opposition re 68 MOTION to Intervene <i>State of Alaska's Amended Motion to Intervene</i> filed by Xavier Becerra, Centers for Disease Control and Prevention, Health and Human Services, United States of America, Rochelle Walensky. (Holland, Liam) (Entered: 06/09/2021)
06/10/2021	84	MINUTE ENTRY for 6/10/2021 in-person hearing re 9 Florida's Motion for a Preliminary Injunction. Court Reporter: Paul Spangler (GSO) (Additional attachment(s) added on 6/14/2021: # 1 Main Document) (GSO). (Entered: 06/10/2021)
06/10/2021	88	Minute Entry. In Person Proceedings held before Magistrate Judge Anthony E. Porcelli: SETTLEMENT CONFERENCE held on 6/10/2021. (LV) (Entered: 06/11/2021)
06/11/2021	85	Minute Entry. Telephonic Proceedings held before Magistrate Judge Anthony E. Porcelli: SETTLEMENT CONFERENCE held on 6/11/2021. Despite the party's good faith and concerted efforts, the settlement discussions have concluded and the parties have reached an impasse. (LV) (Entered: 06/11/2021)
06/15/2021	89	TRANSCRIPT of Hearing on Motion for a Preliminary Injunction held on 6/10/21 before Judge Steven D. Merryday. Court Reporter/Transcriber: Paul Spangler, Telephone number: 813-240-9127. Transcript may be viewed at the court public terminal or purchased through the Court Reporter/Transcriber before the deadline for Release of Transcript Restriction. After that date it may be obtained through PACER or purchased through the Court Reporter. Redaction Request due 7/6/2021; Redacted Transcript Deadline set for 7/16/2021; Release of Transcript Restriction set for 9/13/2021. (JNB) (Entered: 06/15/2021)
06/15/2021	90	NOTICE to counsel of filing of OFFICIAL TRANSCRIPT. The parties have seven (7) calendar days to file with the court a Notice of Intent to Request Redaction of this transcript. If no such Notice is filed, the transcript may be made remotely electronically available to the public without redaction after 90 calendar days. Any party needing a copy of the transcript to review for redaction purposes may purchase a copy from the court reporter or view the document at the clerk's office public terminal. Court Reporter: Paul Spangler. (JNB) (Entered: 06/15/2021)
06/18/2021	91	ORDER resolving 25 --Florida's motion for preliminary injunction. Signed by Judge Steven D. Merryday on 6/18/2021. (BK) (Entered: 06/18/2021)
06/21/2021	92	NOTICE by State of Florida <i>Regarding Case Management Report</i> (Patel, Anita) (Entered: 06/21/2021)
06/24/2021	93	MOTION for Extension of Time to File Answer re 1 Complaint by All Defendants. (Powell, Amy) (Entered: 06/24/2021)
06/24/2021	94	ENDORSED ORDER granting in part 93 --motion for an extension of time; extending through <u>7/22/2021</u> the time within which the defendants must respond to 1 --complaint. Signed by Judge Steven D. Merryday on 6/24/2021. (BK) (Entered: 06/24/2021)
07/06/2021	95	NOTICE OF APPEAL as to 91 Order on Motion for Preliminary Injunction by Xavier

		Becerra, Centers for Disease Control and Prevention, Health and Human Services, United States of America, Rochelle Walensky. Filing fee not paid. (Powell, Amy) (Entered: 07/06/2021)
07/06/2021	96	MOTION to Stay re 91 Order on Motion for Preliminary Injunction (<i>Time-Sensitive</i>) by All Defendants. (Attachments: # 1 3d Decl. of Capt. A. Treffiletti)(Powell, Amy) (Entered: 07/06/2021)
07/06/2021	97	TRANSMITTAL of initial appeal package to USCA consisting of copies of notice of appeal, docket sheet, order/judgment being appealed, and motion, if applicable to USCA re 95 Notice of Appeal. (CTR) (Entered: 07/06/2021)

PACER Service Center			
Transaction Receipt			
07/06/2021 12:35:38			
PACER Login:	bjspringer	Client Code:	
Description:	Docket Report	Search Criteria:	8:21-cv-00839-SDM-AAS
Billable Pages:	11	Cost:	1.10

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

STATE OF FLORIDA,

Plaintiff,

v.

XAVIER BECERRA, Secretary of the
Dep't of Health and Human Services,
et al.,

Defendants.

Case No. 8:21-cv-839-SDM-AAS

NOTICE OF APPEAL

PLEASE TAKE NOTICE that all Defendants (Xavier Becerra, Secretary of Health and Human Services; Rochelle Walensky, director of the Centers for Disease Control and Prevention ("CDC"); the CDC; and the United States of America) hereby appeal to the United States Court of Appeals for the Eleventh Circuit from this Court's Order dated June 18, 2021, ECF No. 91.

Dated: July 6, 2021

Respectfully submitted,

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UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

STATE OF FLORIDA,

Plaintiff,

v.

CASE NO. 8:21-cv-839-SDM-AAS

XAVIER BECERRA, et al.,

Defendants.

ORDER

In response to incidents of COVID-19 infection aboard cruise and naval vessels in early 2020, the Centers for Disease Control and Prevention (CDC) issued a series of “no-sail orders” that halted the cruise industry’s operation from March 2020 through October 2020. Effective October 30, 2020, CDC issued a “conditional sailing order,” the stated purpose of which is to safely re-open the cruise industry under a four-phased “framework.”

In this action Florida asserts five claims. In Count I, Florida alleges that the conditional sailing order exceeds CDC’s statutory and regulatory authority. (Doc. 1 at 13–15) In Count II, Florida alleges that CDC acted arbitrarily and capriciously in issuing the conditional sailing order. Specifically, Florida argues in Count II that CDC failed to recognize the prevalence of vaccines, the success of foreign sailing, the effectiveness of COVID-19 mitigation measures, and the opportunities revealed by evolving public health research — all of which would

counsel against the restrictions imposed by the conditional sailing order.

Also, Florida argues in Count II that CDC arbitrarily failed to consider “lesser alternatives,” treated the cruise industry differently from other industries, and ignored local health measures. (Doc. 1 at 15–18) In Count III, Florida alleges that CDC unreasonably delayed agency action necessary “to allow the cruise industry to safely re-open.” (Doc. 1 at 18) In Count IV, Florida alleges that CDC failed to conduct proper notice and comment rulemaking and improperly relied on the “good cause” exception to the notice requirement under 5 U.S.C. § 553(b)(B). Finally, in Count V, Florida alleges that if interpreted according to CDC the enabling statute, 42 U.S.C. § 264, on which CDC relies, effects an unconstitutional delegation of legislative authority. (Doc. 1 at 20) Facing an allegedly irreparable injury, Florida moves (Doc. 25) for a preliminary injunction.

Citing four broad arguments, CDC opposes a preliminary injunction. First, CDC argues that Florida lacks standing because the conditional sailing order regulates cruises, not states. Second, CDC argues that Florida cannot establish irreparable harm because Florida began this action months after CDC issued the sailing order and that, because cruises can sail by mid-summer, Florida cannot establish an imminent and irreparable injury. Third, CDC contends the conditional sailing order falls within CDC’s statutory and regulatory authority. Fourth, CDC contends that the conditional sailing order evinces “reasoned decision-making” and reasonable conclusions, “especially given the extraordinary deference due to [CDC] during the ongoing public health emergency.” Finally, CDC claims that the threat of

future COVID-19 infections aboard cruises decisively outweighs any economic injury to Florida. (Doc. 31 at 3–4)

BACKGROUND

Since early in 2020 COVID-19 reportedly has killed more than half a million Americans and has caused millions to become unemployed. In response to the discovery of COVID-19 aboard several cruise ships and naval vessels in early 2020, the Cruise Line International Association, a trade group including 95% of the cruise industry, on March 13, 2020, voluntarily ceased cruise ship operation. (Doc. 1-3 at 9; Doc. 31 at 2) On March 14, 2020, CDC issued a no-sail order that halted the cruise industry “for all cruise ships not voluntarily suspending operations.” (Doc. 1-4 at 7) CDC extended the no-sail order on April 15, 2020; July 16, 2020; and September 30, 2020. The last extension of the no-sail order expired October 31, 2020. (Docs. 1-5, 1-6, and 1-7)

On July 20, 2020, during the second extension of the no-sail order, CDC published in the Federal Register a “Request for Information” about the safe resumption of cruise ship operation. 85 Fed. Reg. 44083 (2020); (Doc. 1-3 at 14). The request prompted about thirteen thousand responses in the allowed sixty-days, which ended about six weeks before CDC issued the conditional sailing order. Although CDC claims to have “carefully considered” the comments, CDC never responded to the comments, chose to issue the conditional sailing order under the “good cause” exception to the “notice and comment” requirement of the APA, and

announced that “it would be impracticable and contrary . . . to the public’s interest” to delay the effective date of the order.¹ (Doc. 1-3 at 15, 19); 5 U.S.C. §§ 553(b)–(d).

A. The Conditional Sailing Order

On October 30, 2020, CDC issued the conditional sailing order. *Framework for Conditional Sailing and Initial Phase COVID-19 Testing Requirements for Protection of Crew*. (Doc. 1-3); 85 Fed. Reg. 70153 (2021). The conditional sailing order opens by explaining that COVID-19 “continues to spread rapidly around the world with no U.S. Food and Drug Administration authorized vaccine.” (Doc. 1-3 at 8) Therefore, “[b]ased on the evidence gathered and explained in the No Sail Order,” as well as “[c]urrent scientific evidence,” (Doc. 1-3 at 12–13), the conditional sailing order continued to restrict cruise ship² travel despite the measures, such as a “Healthy Sail Panel,” assembled by prominent cruise companies and top health experts³ employed by cruise companies to address COVID-19. (Doc. 1-3 at 13–14)

¹ The conditional sailing order states that “[i]n the event that this Order qualifies as a rule under the APA, notice and comment and a delay in effective date are not required because CDC has already obtained public comment and good cause exists.” (Doc. 1-3 at 19) And the conditional sailing order further states that, if the order qualifies as a rule, “the Office of Information and Regulatory Affairs has determined that it would be a major rule.” (Doc. 1-3 at 19)

² Defining a “cruise ship” as a “passenger-carrying vessel operating in U.S. waters with the capacity to carry 250 or more individuals . . . with an itinerary anticipating an overnight stay onboard.” The conditional sailing order regulates vessels intending to travel in “international, interstate or intrastate waterways” (Doc. 1-3 at 10)

³ The Healthy Sail Panel developed recommendations for safely resuming sailing. Also, the conditional sailing order cites a “global science summit” convened by the World Travel & Tourism Council and Carnival Corporation to address COVID-19 protocols and safety measures. (Doc. 1-3 at 14)

Disclaiming that the conditional sailing order constitutes a rule under the APA (Doc. 1-3 at 19) and incorporating by reference the earlier no-sail orders, the conditional sailing order explains that “[a]fter expiration of CDC’s No Sail Order (NSO) on October 31, 2020, CDC will take a phased approach to resuming cruise ship passenger operations in U.S. waters.” (Doc. 3-1 at 2) The conditional sailing order requires the completion of four phases before a vessel again qualifies to sail but explains that “[t]hese phases are subject to change based on public health considerations[.]” (Doc. 3-1 at 3) And the conditional sailing order explains (in several places) that “CDC will issue additional orders as needed that will be published in the Federal Register and technical instructions that will be subsequently posted on CDC’s website.” (Doc. 3-1 at 3, 21, 28, 34)

1. The Four Phases

Phase one obligates a cruise ship operator to build a laboratory aboard each vessel for testing crew members. In phase two, a cruise ship operator must undertake for each cruise ship a simulated voyage designed to evaluate the cruise ship operator’s on-board COVID-19 mitigation measures. (Doc. 1-3 at 26–7) However, before beginning a cruise ship’s first simulated voyage, the cruise ship operator must obtain, and CDC must approve, a “medical care agreement” and a “housing agreement” with health care providers and the port authority in each port-

of-call to ensure adequate logistics and care if COVID-19 appears aboard a ship in transit.⁴ (Doc. 1-3 at 23–4)

Phase three requires a “conditional sailing certificate” from CDC before a cruise ship operator undertakes a restricted passenger voyage. During this phase, a cruise ship operator must apply for a conditional sailing certificate “at least 60 calendar days prior to the date on which the cruise ship operator proposes to commence restricted passenger operations.” (Doc. 1-3 at 29, n.18) Under the threat of a criminal penalty imposed by 18 U.S.C. § 1001, the application must include the cruise ship operator’s attestation to, among other things, the operator’s compliance with CDC’s (mandatory) technical instructions and orders. (Doc. 1-3 at 29–30) After CDC review, even if CDC awards the operator a conditional sailing certificate, “CDC may limit the terms or conditions of a . . . Conditional Sailing Certificate” or revoke the certificate altogether. (Doc. 1-3 at 30, 35) A cruise ship operator can appeal the denial of a certificate or can attempt to modify the conditions of a certificate by submitting the proposed modification to CDC. (Doc. 1-3 at 32, 36)

Finally, for operators with a conditional sailing certificate, phase four permits “restricted passenger voyages” — but subject to several salient strictures, including a seven-day limitation on each voyage. (Doc. 1-3) The conditional sailing order describes other requirements beyond the four-phased approach, and the conditional sailing order explains that the phases “will be further determined” by both “public

⁴ The parties commonly designate this requirement “Phase 2A.” In effect, CDC’s “four-phase plan” is actually a five-phase plan (at least).

health considerations” and a cruise ship operator’s success in employing the mitigation measures specified in the conditional sailing order, including shoreside laboratory screening of crew, on-board testing capabilities for symptomatic travelers, sustained compliance with the no-sail orders’ response plans, and the frequent monitoring and reporting of conditions onboard. (Doc. 1-3 at 17) In other words, even after a cruise operator’s completion of the four phases, CDC retains unrestricted discretion to further condition or even suspend the conditional sailing certificate and to issue additional and different technical guidance.

2. The Conditional Sailing Order’s Timeline, Findings, and Legal Justifications

The feasible timeline for a cruise company’s accomplishing the four phases is unknown but certainly protracted. (As of today, few vessels have completed the four phases.) The conditional sailing order remains effective until the earliest of (1) the expiration of the HHS Secretary’s declaration of a public health emergency, (2) the rescission or modification of the order by the CDC director, or (3) November 1, 2021 (at which time CDC might renew the conditional sailing order or issue a replacement order with additional and different requirements). In other words, assuming maintenance of the status quo, the conditional sailing order likely, almost certainly, will remain in effect for a year after the October 2020 issuance of the conditional sailing order, that is, the cruise industry will have remained subject to the series of no-sail orders and the conditional sail order for more than nineteen

months — two full cruise seasons — and will remain subject to renewal (presumably without “notice and comment” under the APA).

3. Dissatisfaction with CDC’s Implementation and Guidance

After issuance of the conditional sailing order, several uncertain and distressed cruise companies and public officials began to complain because CDC issued virtually no implementing instructions for beginning the simulated voyages and no cruise company was authorized to begin a phase two simulated voyage. And even after CDC issued new guidance on April 2, 2021, cruise executives, state officials, and others criticized the guidance as impractical.

For example, the Cruise Lines International Association reports that the April 2, 2021 guidance imposes requirements that “are unduly burdensome, largely unworkable, and seem to reflect a zero-risk objective rather than the mitigation approach to COVID that is the basis for every other U.S. sector of our society.” (Doc. 45-9 at 2; Doc. 45-10 at 6; Doc. 45-28 at 3) Concerned about losing another summer sailing season, some cruise companies threatened to leave the United States if the cruise industry cannot “gain clarity and alignment on what it will take to restart cruising from the [United States].” (Doc. 45-10 at 10–11; Doc. 45-28 at 4; Doc. 45-29) Florida asserts that “the cruise industry needs certainty so they can make ready to resume sailing.” (Doc. 56 at 5) But as of April 2021, more than six months after issuance of the conditional sailing order, “no cruise company ha[d] begun phase two test voyages,” and more than “20% of cruise lines remained stuck in Phase 1.” (Doc. 56 at 5–7; Doc. 25 at 6–7, 17)

B. Florida's Complaint, Florida's Motion for a Preliminary Injunction, and Recent Developments

Contending that the April 2, 2021 (mandatory) guidance and CDC's delay ensure "that the cruise industry would not re-open" in time for the summer season, Florida sued six days later and moved for preliminary injunction. (Doc. 56 at 2)

On May 5, 2021, the day CDC's response to the motion for preliminary injunction was due, CDC issued technical guidance supposedly "providing specific instructions for how cruise ship operators may test their health and safety protocols in U.S. waters through simulated voyages, including the requirements for simulated voyages, guidance for CDC inspections, and operational procedures for risk mitigation on simulated and restricted voyages." (Doc. 31 at 11; Doc. 46-4; Doc. 46-5) CDC asserts that "cruise ship operators now have all the necessary instructions" to begin sailing. (Doc. 31 at 11) Further, in a "Dear Colleague Letter," CDC announced a "commitment to the phased resumption of passenger operations around mid-summer." (Doc. 31 at 10; Doc. 46-3) Addressing "scientific developments" since CDC issued the conditional sailing order, the letter offers several "clarifications," including an allowance for a cruise ship to avoid the requirement of a simulated voyage if a cruise operator's crew is ninety-eight percent fully vaccinated and the passengers, including children twelve and under, are ninety-five percent fully vaccinated. (Doc. 46-3 at 5)

Commenting on the May 5 technical guidance and the "Dear Colleague Letter," one cruise executive explained that "he seriously doubt[s]" whether cruise

ships could sail from the United States this summer because CDC's guidance remains "anything but a clear path to restarting." (Doc. 56 at 4) Since May 5, CDC has frequently updated the technical instructions and published new guidance for complying with the conditional sailing order. (Doc. 72 at 5) CDC supposedly updates this technical guidance to "reduce[] burdens or alleviate[] restrictions on cruise lines to better reflect the improved public health situation."⁵ (Doc. 72 at 5; Doc. 72-1) But CDC retains the discretion to issue at any time "additional requirements through technical instructions or orders relating to a cruise ship operator's processes and procedures." (Doc. 1-3 at 21, 28, 29)

As of June 4, 2021, CDC had approved port agreements for twenty-two ships. CDC has scheduled only nine ships to begin simulated voyages. Although two simulated voyages are predicted to begin on June 20, 2021, most of the simulated voyages begin in July or August. Of the estimated fifty-nine eligible cruise ships, only two ships have received conditional sailing certificates, both for "highly

⁵ This timeline reports CDC's regulations issued after May 5, 2021:

- May 14, 2021 — CDC revises the "operations manual for simulated and restricted voyages," the "technical instructions for simulated voyages," and the "technical instructions for mitigation of COVID-19 among cruise ship crew." (Doc. 72-1 at 3-4)
- May 18, 2021 — CDC clarifies "disembarkation testing."
- May 26, 2021 — CDC provides "additional discretionary considerations for ships with at least 98% of crew and 95% of passengers fully vaccinated."
- June 4, 2021 — CDC "clarify[ies] mask use for crew who are not fully vaccinated" and revises the "cruise ship color status." (Doc. 72-1)

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

vaccinated voyages,” that is, ships that satisfied the 98%–crew plus 95%–passenger, full-vaccination option mentioned earlier. (Doc. 31 at 9; Doc. 72 at 5) One of those two ships can begin restricted sailing no earlier than June 26, 2021. The other ship can begin restricted sailing no earlier than July 25, 2021. (Doc. 72-1 at 2–3) All other cruise ships remain in the conditional sailing order’s earlier phases.

C. Litigation Status

After an initial hearing (Doc. 44) on Florida’s motion for a preliminary injunction, a May 18, 2021 order (Doc. 51) referred this action to mediation. In the meantime, Alaska and Texas moved (Docs. 26, 68) to intervene in this action. Arguing, among other reasons, that Alaska and Texas lack standing to intervene, CDC opposes (Docs. 57, 83) the motions to intervene. Alaska’s and Texas’s motions to intervene are unresolved.

CDC submits a supplemental brief (Doc. 72) to report that on May 24, 2021, Congress passed the Alaska Tourism Restoration Act, which CDC contends effectively “ratifies” the conditional sailing order. (Doc. 72 at 1–4) Also, CDC reports “factual developments” that allegedly confirm the cruise ships’ expeditious progress through the conditional sailing order’s phases. (Doc. 72 at 5–6) Florida submits a supplemental brief (Doc. 82) in response. After a hearing (Doc. 84) on the supplemental briefs and after the mediator declared an impasse (Doc. 85), Florida’s motion for a preliminary injunction is ripe for determination.

STANDING

Article III of the United States Constitution limits the jurisdiction of a federal court to an actual, perceptible, and existing case or controversy. To present a justiciable case or controversy for a preliminary injunction, a plaintiff must establish by a “clear showing” each element of “standing.” *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008). Confusion about standing is widespread. William Fletcher, *The Structure of Standing*, 98 YALE L.J. 221, 221 (1988) (“The structure of standing law in the federal courts has long been criticized as incoherent.”). Despite this confusion, certain principles of standing appear reasonably clear and permit a federal court, as each court must, to confirm a plaintiff’s standing. *Bochese v. Town of Ponce Inlet*, 405 F.3d 964, 974 (11th Cir. 2005).

First, Article III imposes constitutional standing, an “irreducible [] minimum” requiring a plaintiff to show an injury-in-fact that is both fairly traceable to an act of a defendant and redressable by a favorable judicial decision. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560–61 (1992); *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016). Second, a plaintiff must sue to vindicate an interest “protected or regulated by the statute or constitutional guarantee in question.” *Ass’n of Data Processing Serv. Organizations, Inc. v. Camp*, 397 U.S. 150, 153 (1970). Here, CDC characterizes Florida’s complaint as advancing a “generalized grievance” that fails to establish Article III standing. (Doc. 31 at 13) Further, CDC argues that Florida fails to assert a justiciable APA claim in Counts I through IV because Florida’s injury falls

outside the “zone of interests” protected by the Public Health Service Act. (Doc. 31 at 21–22)

A. Article III Standing

1. Injury-in-Fact

If requesting an injunction, a plaintiff must establish an immediate danger of sustaining a “concrete” and “particularized” injury. Adducing a “concrete” and “particularized” injury requires the plaintiff to establish a risk of “imminent” future injury, not a “conjectural” or “hypothetical” injury. *City of Los Angeles v. Lyons*, 461 U.S. 95, 102 (1983). A future injury qualifies as “imminent” if the plaintiff faces a “sufficient likelihood” of suffering the alleged injury. *Sierra v. City of Hallandale Beach, Fla.*, 2021 WL 1799848, at *2 (11th Cir. 2021) (quoting *Koziara v. City of Casselberry*, 392 F.3d 1302 (11th Cir. 2004)).

Whether a sufficient likelihood exists that a state will suffer an imminent injury depends on the capacity under which the state sues. Erwin Chemerinsky, *Federal Jurisdiction* 125 (8th Ed. 2021) (“[A] distinction must be drawn between a government entity suing to remedy injuries it has suffered and suing in a representative capacity on behalf of its citizens.”). A state cannot sue as a nominal party or sue to defend the “personal claims” of a citizen. *Pennsylvania v. New Jersey*, 426 U.S. 660, 665 (1976). Rather, a state can sue to prevent either of two types of injury. First, a state can sue to prevent an imminent injury to a “quasi-sovereign interest,” including the general health or economic welfare of the state’s citizens. Second, a state can sue to prevent a direct injury to a “sovereign” or “proprietary”

interest. *Alfred L. Snapp & Son, Inc. v. Puerto Rico, ex rel., Barez*, 458 U.S. 592, 601–607 (1982); *Chiles v. Thornburgh*, 865 F.2d 1197, 1208 (11th Cir. 1989) (distinguishing between an injury to a “quasi-sovereign interest” and a direct injury).

“There is no difficulty in recognizing [a state’s] standing to protect proprietary interests or sovereign interests.” 13B WRIGHT & MILLER, FED. PRAC. & PROC. § 3531.11.1, Government Standing – States (3d ed. 2008). A state’s proprietary interests include “participat[ing] in a business venture” and extend to interests that are the same as a similarly situated private proprietor. *Alfred L. Snapp*, 458 U.S. at 601. For example, a state maintains an interest in collecting money, including taxes. *Wyoming v. Oklahoma*, 502 U.S. 437, 447–450 (1992); *Air All. Houston v. Env’t Prot. Agency*, 906 F.3d 1049, 1059 (D.C. Cir. 2018); *California v. Azar*, 911 F.3d 558, 570–571 (9th Cir. 2018). Here, Florida bases standing on three financial injuries.

First, Florida asserts that the conditional sailing order forces Florida to spend millions of dollars more than usual on state unemployment benefits. A declarant from Florida’s Department of Economic Opportunity reports — and CDC accepts — that since the start of the COVID-19 pandemic, Florida has paid about \$20 million in state benefits directly attributable to “claimants separated from the cruise industry.”

In comparison, Florida typically pays less than \$500,000 annually in state benefits attributable to lost cruise-industry jobs.⁶ (Doc. 45-19 at 2)

Second, Florida claims that since the start of the COVID-19 pandemic Florida's ports have lost hundreds of millions of dollars. (Doc. 45-26) Florida insists that at least part of the loss results directly from the shutdown of the cruise industry, which accounts for a major share of Florida's port business. (Doc. 45-20 at 5; Doc. 45-21 at 25; Doc. 45-22 at 9; Doc. 45-23 at 23; Doc. 45-24)

Third, Florida claims a loss of tax revenue directly attributable to the shutdown of the cruise industry in Florida. (Doc. 25 at 22) For example, Florida attaches reports analyzing the economic activity of several ports and detailing state tax revenue derived from the cruise industry. (Docs. 45-20, 21, 22, 23) These economic reports suggest that in a typical year Florida collects millions of dollars in state taxes from the cruise industry. (Doc. 45-20 at 44; Doc. 45-21 at 29; Doc. 45-22 at 10; Doc. 45-23 at 36; Doc. 45-24 at 27) Further, Florida estimates — and CDC again accepts — that the “continued closure of the cruise industry will result in an annual loss to Florida of sales tax revenue of approximately \$82 million.” (Doc. 45-25 at 3)

⁶ CDC argues that Florida disregards federal reimbursement for state unemployment payments. But the American Rescue Plan of 2021, Pub. L. No. 117-2 § 9017, reimburses a state for “short-time compensation” programs, which amount to a limited type of unemployment spending. “Short-time compensation” reimbursement is brief (until September 2021), and Florida attests (Doc. 47 at 148) — without opposition from CDC — that the declaration (Doc. 45-19) fully accounts for federal reimbursement.

CDC responds by characterizing Florida's injury as a loss of "general tax revenue" that creates no basis for standing. (Doc. 31 at 14) (quoting *El Paso Cty., Texas v. Trump*, 982 F.3d 332, 339 (5th Cir. 2020)). Also, CDC argues that Florida fails to allege a concrete and imminent injury. (Doc. 31 at 15) CDC posits that Florida's injury amounts to "mere conjecture" because the conditional sailing order, CDC insists, allows cruises to resume operation by "mid-summer." Citing "the possibility of a summer restart of service" if the cruise industry can comply with the conditional sailing order, CDC claims that any risk of future injury rests within the control of the cruise industry. (Doc. 31 at 15)

Although superficially appealing, CDC's argument is finally unpersuasive. CDC ignores Florida's evidence establishing an economic injury attributable to increased unemployment spending for former cruise industry employees, some of whom likely will remain unemployed. "Monetary expenditures to mitigate and recover from harms that could have been prevented absent [agency action] are precisely the kind of 'pocketbook' injury that is incurred by the state itself." *Air All. Houston*, 906 F.3d at 1059. And Florida alleges an ongoing economic injury to ports, which Florida maintains a sovereign and proprietary interest in protecting because ports are political subdivisions of the state. Title 22, Chapters 308–315, Florida Statutes; *Alabama v. U.S. Army Corps of Engineers*, 424 F.3d 1117, 1130 (11th Cir. 2005); *State of Kan. v. United States*, 16 F.3d 436, 439 (D.C. Cir. 1994) (holding that a state has standing "to sue as an employer" to protect itself from economic injury); *Chiles v. Thornburgh*, 865 F.2d 1197, 1208 (11th Cir. 1989) ("A state has standing to

sue in its sovereign capacity when it has suffered an economic injury.”). Even if relying on lost tax revenue, Florida alleges a cognizable injury owing to lost tax revenue directly attributable to the cruise industry’s closing. *Wyoming v. Oklahoma*, 502 U.S. 437, 448 (1992) (affirming a state’s standing if alleging “a direct injury in the form of a loss of specific tax revenues”).

Although the conditional sailing order purports to establish “a framework for a phased resumption of cruise ship passenger operations,” 85 Fed. Reg. at 70,153, Florida persuasively claims that the conditional sailing order will shut down most cruises through the summer and perhaps much longer. *Koziara*, 392 F.3d at 1305.⁷ (Doc. 46-3; Doc. 46-8 at 3–4) Also, Florida persuasively argues that CDC’s projection for the resumption of sailing warrants skepticism owing to CDC’s history of delay, such as the unexplained six-month delay until April 2, 2021, in issuing technical guidance, finally available just eight weeks before CDC claims the cruise industry can sail. (Doc. 1-7 at 11, 17; Doc. 46-1 at 21) And CDC presumably “intends to update” guidance as vaccines further proliferate. (Doc. 46-1 at 26; Doc. 46-3; 46-4 at 14) As of April 26, 2021, twenty percent of cruises remained in “phase one” (of the four phases) while the cruise industry tried to comply with CDC’s expanding and variable guidance, which Florida convincingly argues continues to contribute to the delay. (Doc. 31-1 at 20–21; Doc. 82) Even if

⁷ CDC resists providing a reliable and steady timeline for resuming cruises. At a March 18, 2021 Senate Committee hearing, Senator Lisa Murkowski asked the CDC director to provide a schedule for phase two. The CDC director replied “I can’t . . . I don’t believe it’s solely within our jurisdiction to address, it’s not necessarily a CDC [decision] . . . I believe Department of Transportation, OMB, there are numerous others that are making these decisions.” (Doc. 1-8 at 7)

approving a cruise to sail, CDC retains the discretion to revoke a conditional sailing certificate, which appears likely (at least for some cruises) owing to CDC's variable technical instructions and CDC's low standard for intervening during a COVID-19 "outbreak." (Doc. 1-3 at 30–36; Doc. 31-4 at 11) Florida understandably claims that CDC "keeps moving the goalposts."⁸ (Doc. 56 at 5, 7)

In sum, Florida establishes a strong likelihood that many or almost all cruise ships will remain unable to sail for the entire summer season.⁹ And each day the cruise industry faces uncertainty about when cruises can resume, Florida not only suffers a concrete economic injury resulting from reduced revenue and increased unemployment spending, but Florida faces (Doc. 45-17; Doc. 45-28; Doc. 45-29) an increasingly threatening and imminent prospect that the cruise industry will depart the state. (Doc. 45-10 at 10–11; Doc. 45-28) The dislocation of all or most of an entire industry subjects Florida to a protracted or permanent loss of revenue from

⁸ CDC implies that Florida's recent law, S.B. 2006 (Fla. 2021), prohibiting so-called "vaccine passports" might "delay cruise ships from resuming operations in Florida." (Doc. 31 at 11; Doc. 72 at 5) Although a plaintiff's contribution to an injury can defeat standing, S.B. 2006 fails to definitively impede ships from resuming operation. 15 MOORE'S FEDERAL PRACTICE, Civil § 101.41, 101-122.17 (2020). S.B. 2006 neither explicitly applies to federal regulation nor necessarily prohibits passengers from volunteering information about vaccination status when deciding the proportion of vaccinated and unvaccinated passengers a cruise can accommodate under federal law. (Doc. 31-4)

⁹ After CDC published the May 5, 2021 technical guidance (Docs. 31-4; 31-5), Norwegian Cruise Line's Chief Executive Officer laments:

I seriously doubt we will be able to stand up a vessel out of a U.S. port in July. August is also in jeopardy and it's all because of the disjointed guidelines from the CDC What we received yesterday was anything but a clear path to restarting.

<https://www.cnbc.com/2021/05/06/norwegian-cruise-ceo-says-us-ships-are-unlikely-to-sail-this-summer.html>.

one of Florida’s largest industries, the benefits of which insinuate themselves into the heart of Florida’s economy. (Doc. 45-1 at 45–47, 75); *Alfred L. Snapp*, 458 U.S. at 597–610 (considering Puerto Rico’s interest in its citizens participating in an industry). Florida faces a sufficient likelihood of continued economic harm to establish a concrete and imminent injury-in-fact. *Salcedo v. Hanna*, 936 F.3d 1162, 1167 (11th Cir. 2019) (“A concrete injury need be only an ‘identifiable trifle.’”).

2. Causation and Redressability

Also, Florida must establish that Florida’s imminent injury is “fairly traceable” to the conditional sailing order and that a favorable judicial decision can likely redress the injury. *Lujan*, 504 U.S. at 560; *Carpenters Indus. Council v. Zinke*, 854 F.3d 1, 6 n.1 (D.C. Cir. 2017) (“Causation and redressability typically overlap as two sides of a causation coin” because “if a government action causes an injury, enjoining the action usually will redress the injury.”). CDC argues that Florida’s injury results not from the conditional sailing order but from the “independent decisions of third parties, like cruise lines and passengers.” (Doc. 31 at 13, 16) Specifically, CDC argues that Florida’s injury derives “from the performance of the broader economy” in response to COVID-19 “as well as independent decisions of cruise ship operators, tourists, airlines, and businesses in the state.” Attributing Florida’s injury to “countless variables,” CDC claims that Florida fails to connect the alleged injury to the conditional sailing order. (Doc. 31 at 16) (citing *XY Planning Network LLC v. SEC*, 963 F.3d 244 (2d Cir. 2020)).

But even if other “variables” contribute to Florida’s injury, Florida can establish standing by showing that the conditional sailing order accounts for some of, or aggravates, Florida’s injury. *Attias v. Carefirst, Inc.*, 865 F.3d 620, 629 (D.C. Cir. 2017); *Const. Party of Pennsylvania v. Aichele*, 757 F.3d 347, 366 (3d Cir. 2014); *Libertarian Party of Virginia v. Judd*, 718 F.3d 308, 316 (4th Cir. 2013); *Barnum Timber Co. v. U.S. E.P.A.*, 633 F.3d 894, 901 (9th Cir. 2011); *Comer v. Murphy Oil USA*, 585 F.3d 855, 866 (5th Cir. 2009). Here, the conditional sailing order regulates a third party — the cruise industry — whose well-being and prosperity, whose “expected response,” affects Florida. *Wilderness Soc. v. Griles*, 824 F.2d 4 (D.C. Cir. 1987); *Bennett v. Spear*, 520 U.S. 154, 169 (1997) (“[I]f the injury complained of is the result of independent action of some third party not before the court . . . that does not exclude injury produced by determinative or coercive effect upon the action of someone else.”). Causation and redressability depend “on the response of the regulated (or regulable) third party to the government action or inaction.” *Lujan*, 504 U.S. at 562; *Lewis v. Governor of Alabama*, 896 F.3d 1282 (11th Cir. 2018) (holding that an “indirect” injury can qualify as “fairly traceable”).

Citing the success of foreign cruise lines, Florida shows that thousands of passengers, including Floridians, have sailed on cruise ships abroad. (Doc. 45-9; Doc. 45-10, Doc. 45-29 at 13) And after shepherding Florida’s residents through a measured plan for relaxing restrictions, distributing vaccines, and installing COVID-19 safety protocols, Florida now experiences renewed demand for sailing (among many other things). (Doc. 45-3; Doc. 45-25; Doc. 45-29; Doc. 46-1; Doc. 56 at 4,

n.4) Despite CDC's speculation to the contrary, no reasonable basis exists to believe that without the conditional sailing order the cruise industry will refrain from sailing (if the industry will not sail, removing the conditional sailing order is harmless).

Dep't of Com. v. New York, 139 S. Ct. 2551, 2566, 204 L. Ed. 2d 978 (2019) (holding that a plaintiff satisfies causation by relying "on the predictable effect of Government action on decisions of third parties"). Because the cruise industry's compliance with the conditional sailing order necessarily harms Florida by inhibiting the full resumption of, and the expected state revenue from, cruise vessels' sailing, Florida's future injury is fairly traceable to the conditional sailing order. *Bennett*, 520 U.S. at 169 ("While, as we have said, it does not suffice if the injury complained of is the result of the independent action of some third party not before the court, that does not exclude injury produced by determinative or coercive effect upon the action of someone else."); *Nw. Requirements Utilities v. F.E.R.C.*, 798 F.3d 796, 806 (9th Cir. 2015) (finding causation if a third party's compliance with an agency order necessarily injures the plaintiff).

CDC argues that a favorable decision will not necessarily redress Florida's injury because a future "outbreak" might amplify Florida's injury. (At the second hearing, CDC explained that an "outbreak" means as little as a single — one — human-to-human "transmission" of the disease.) (Doc. 31 at 17–18) But the conditional sailing order imposes regulations "in addition to other requirements in regulations or actions taken by CDC." (Doc. 1-3 at 20) For example, CDC's operations manual for simulated and restricted voyages requires cruises to continue

following the “Vessel Sanitation Program.”¹⁰ Florida describes voluntary precautions, including testing, distancing, and ventilation, that the cruise industry and Florida ports have instituted to mitigate COVID-19, which steadily subsides with the rapid administration of vaccines, abundantly and readily available in Florida. (Doc. 56 at 17–20) In fact, CDC admits that the wide availability of vaccines “will play a critical role in the safe resumption of passenger operations.” (Doc. 46-1 at 26) (CDC admits to never evaluating the efficacy of the measures instituted locally.) Because the cruise industry worldwide has developed and deployed precautions to combat COVID-19 and to contain any infection, no reasonable basis exists to believe that Florida faces a greater or equivalent injury if sailing resumes. And a decision favorable to Florida, enjoining all or part of the conditional sailing order, will allow cruises to sail more quickly and will mitigate the imminent likelihood of Florida’s injury, including the plausible and imminent prospect of the cruise industry’s leaving Florida. *Massachusetts v. E.P.A.*, 549 U.S. 497 (2007) (citing *Larson v. Valente*, 456 U.S. 228, 244, n.15 (1982) (“[A] plaintiff satisfies the redressability requirement when he shows that a favorable decision will relieve a discrete injury to himself. He need not show that a favorable decision will relieve his every injury.”)); 15 MOORE’S FEDERAL PRACTICE, Civil § 101.42 (2020).

¹⁰ CDC’s COVID-19 Operations Manual is available here:

<https://www.cdc.gov/quarantine/cruise/Covid19-operations-manual-cso.html#vsp-2018-operations-manual>

Florida suffers an immediate danger of a continuing injury fairly traceable to the conditional sailing order and redressable if an order enjoins all or part of the conditional sailing order. In sum, Florida presents such “a personal stake in the outcome of the controversy as to assure that concrete adverseness which sharpens the presentation of issues.” *Baker v. Carr*, 369 U.S. 186, 204 (1962).¹¹

B. Statutory Standing

In addition to Article III standing, in an APA action Florida must establish statutory standing, which “extends only to plaintiffs whose interests ‘fall within the zone of interests protected by the law invoked.’” *Lexmark Int’l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 129 (2014). CDC argues that Florida cannot establish statutory standing for an APA claim because Florida’s injury falls outside the “zone of interests” protected by the Public Health Service Act and the regulations promulgated under the Public Health Service Act. CDC contends that, rather than protecting a state’s revenue, Section 264(a) protects the “health conditions” aboard a vessel. (Doc. 31 at 22)

But a plaintiff suing under the APA must assert an interest only “arguably within the zone of interests [] protected or regulated by the statute” the plaintiff claims the defendant violated. *Match-E-Be-Nash-She-Wish Band of Pottawatomí Indians v. Patchak*, 567 U.S. 209 (2012) (quoting *Ass’n of Data Processing Serv. Orgs., Inc. v. Camp*, 397 U.S. 150, 153 (1970)). Because Congress enacted the APA to

¹¹ Because Florida sues to prevent financial injury, third-party standing is inapplicable. *Kowalski v. Tesmer*, 543 U.S. 125, 129 (2004).

enable judicial review of agency action, establishing statutory standing for an APA claim is not “especially demanding.” *Lexmark*, 572 U.S. at 130 (“[W]e have often conspicuously included the word ‘arguably’ in the test to indicate that the benefit of any doubt goes to the plaintiff. . . .”); *Clarke v. Securities Indus. Assn.*, 479 U.S. 388, 399 (1987). A plaintiff fails to establish statutory standing “only when a plaintiff’s interests are so marginally related or inconsistent with the purposes implicit in the statute that it cannot reasonably be assumed that Congress intended to permit the suit.” *Match-E*, 567 U.S. at 225.

Here, the applicable sections of the Public Health Service Act anticipate Florida’s interest in this action. By impeding commerce, encumbering or destroying property, or restricting or forbidding the movement of persons or things, measures promulgated by CDC under Section 264(a) necessarily strain the economy of a state, especially a state historically and deeply dependent on recreational, seasonal, and other visits by a multitude of persons from throughout the nation and from abroad and dependent on the resulting income from the accompanying services and products offered in Florida.

To enforce CDC regulations, Section 243 contemplates “comprehensive and continuing” cooperation with state authorities. Contemplating a regulation’s effect on state public health measures, 42 C.F.R. § 70.2 requires CDC to determine before imposing federal regulation that a state fails to enforce sufficient health measures. In short, the Public Health Service Act anticipates an effect on a state. By suing to avoid or mitigate the effect caused by the statute, Florida establishes statutory

standing. *Tiger Lily, LLC v. United States Dep't of Hous. & Urb. Dev.*, 992 F.3d 518, 522 (6th Cir. 2021) (considering Section 264 in an action alleging an adverse effect on rental income); *Skyworks, Ltd. v. Centers for Disease Control & Prevention*, 2021 WL 911720 (N.D. Ohio 2021); *Brown v. Azar*, 497 F. Supp. 3d 1270 (N.D. Ga. 2020).

Also, Florida claims in Count I that the conditional sailing order imposes restrictions exceeding CDC's statutory and regulatory authority. (Doc. 1 at 13) By claiming that CDC acts *ultra vires*, Florida avoids the requirements of statutory standing. *Chiles v. Thornburgh*, 865 F.2d 1197, 1210 (11th Cir. 1989). "Otherwise, a meritorious litigant, injured by *ultra vires* action, would seldom have standing to sue because the litigant's interest normally will not fall within the zone of interest of the very statutory or constitutional provision that he claims does not authorize action concerning that interest." *Haitian Refugee Ctr. v. Gracey*, 809 F.2d 794, 811 n.14 (D.C. Cir. 1987). Further, if Florida successfully claims (Count V) that Section 264 endows CDC with an unconstitutional delegation of legislative authority, CDC's regulations become invalid and the issue of statutory standing is resolved. *Massachusetts v. Mellon*, 262 U.S. 447, 485–486 (1923) (stating that a state may sue the federal government in a *parens patriae* capacity "to protect its citizens against any form of enforcement of unconstitutional acts.")

LIKELIHOOD OF SUCCESS ON THE MERITS

Determining Florida's likelihood of success on the merits requires analysis of Florida's allegations and their evidentiary and legal support. Each of Florida's

claims will receive attention to determine, based on the present record, Florida's likelihood of success on the merits.

A. Count I and Count V

Florida argues that the conditional sailing order exceeds the statutory and regulatory authority delegated to CDC, which argues in response that the conditional sailing order fits perfectly within the measures contemplated by the statutes and regulations. The history of the federal government's quarantine power clarifies the extent of the authority codified in the text.

1. The History of the Federal Government's Quarantine Powers

To contextualize CDC's asserted statutory and regulatory authority, CDC provides a brief historical account of the federal government's "acting to combat the spread of communicable disease."¹² (Doc. 31 at 4–5) Citing a federal quarantine law from 1796, CDC observes that "[t]he federal government has a long history of acting to combat the spread of communicable disease."¹³ (Doc. 31 at 5) However, CDC's generalization omits much that is necessary to fully portray the role of the federal government.

In the early years of the republic, the federal role in curbing infectious disease extended to little more than support for the effort of local government. CENTERS

¹² See, e.g., (Doc. 31 at 23) (citing the historical section of CDC's brief and arguing that deference to public health authorities constitutes a "determination made in the light of history and experience, given the death toll caused by past epidemics like yellow fever").

¹³ Of course, society has quarantined people, animals, and things for thousands of years. *Leviticus* 13:46, King James Version ("All the days wherein the plague shall be in him . . . he shall dwell alone; without the camp shall his habitation be.").

FOR DISEASE CONTROL & PREVENTION, *History of Quarantine* (Feb. 12, 2007), www.cdc.gov/quarantine/historyquarantine.html (“Protection against imported diseases fell under local and state jurisdiction[, and i]ndividual municipalities enacted a variety of quarantine regulations for arriving vessels.”). In fact, the statute CDC cites to demonstrate federal involvement authorized the president to direct federal officers to aid in the enforcement of only state quarantine law. Act of May 27, 1796, 4 Cong. Ch. 31, 1 Stat. 474 (1796) (repealed 1799). And even though CDC observes that “Congress replaced this Act with a federal inspection system for maritime quarantines” (Doc. 31 at 5), this federal inspection system — initially implemented by the Marine Hospital Service, a predecessor to the Public Health Service¹⁴ — principally provided health care to ill seamen and reinforced the federal government’s position as only an assistant to the states.¹⁵ See U.S. NAT’L LIB. OF MED., *Images from the History of the Public Health Service: Disease Control and Prevention*, www.nlm.nih.gov/exhibition/phs_history (“The major function of the Marine Hospital Service until the 1870s remained the care of sick seamen.”).

¹⁴ Today, after a series of reorganizations, the Public Health Service comprises eight agencies, including CDC.

¹⁵ See, e.g., Act of Feb. 25, 1799, 5 Cong. Ch. 12, 1 Stat. 619 (“[T]he quarantines and other restraints, which shall be required and established by the health laws of any state . . . respecting any vessels arriving in, or bound to, any port or district thereof, whether from a foreign port or place, or from another district of the United States, shall be duly observed by the collectors and all other officers of the revenue of the United States, . . . and all such officers of the United States shall be, and they hereby are, authorized and required, faithfully to aid in the execution of such quarantines and health laws, according to their respective powers and precincts, and as they shall be directed, from time to time, by the Secretary of the Treasury of the United States.”). See also *Gibbons v. Ogden*, 22 U.S. 1, 113 (1824) (“Congress have manifested a different interpretation of that instrument, and have passed several acts for giving aid and effect to the execution of the laws of the several States respecting quarantine. It will be recollected, that the first recognition by Congress of the quarantine laws, was in 1796; and that only directs the officers of the government to obey them[.]”).

For roughly a hundred years the states principally exercised the quarantine power, understood as a component of the police power of the states. *Gibbons v. Ogden*, 22 U.S. 1, 203 (1824) (explaining that the inspection laws “form a portion of that immense mass of legislation, which embraces every thing within the territory of a State, not surrendered to the general government. . . . Inspection laws, quarantine laws, health laws of every description . . . are component parts of this mass”); Ariel R. Schwartz, *Doubtful Duty: Physicians’ Legal Obligation to Treat During an Epidemic*, 60 STAN. L. REV. 657, 683 (2007) (“The Public Health Act and HHS’s emphasis on state initiative is not surprising given that healthcare regulation has primarily been within the purview of the police powers reserved to the states by the Tenth Amendment.”); Laura K. Donohue, *Biodefense and Constitutional Constraints*, 4 U. MIAMI NAT’L SECURITY & ARMED CONFLICT L. REV. 82, 112, 128 (describing “the degree to which quarantine law lay at the heart of state police powers” and “[t]he federal government’s subservient approach”). The federal government merely advised and assisted the states, provided financial support, and investigated sources of diseases. See John Yoo, NATIONAL REVIEW, “No, Trump Can’t Force States to Reopen” (April 13, 2020) (arguing that the Commerce powers “gives Washington, D.C. an important, yet supporting, role in confronting the pandemic.”); Kyle Connors, *Federalism and Contagion: Reevaluating the Role of the CDC*, 12 CONLAWNOW 75, 77, 82 (2020) (noting that “CDC has traditionally acted in an advisory role to state and local governments,” that “CDC can also provide technical

and financial support,” and that “Congress should pass formal legislation” to expand CDC’s authority).

In the mid- to late-nineteenth century, amid outbreaks of yellow fever and cholera, many began criticizing a perceived inefficiency of differing state quarantine laws, and the federal government assumed a more active role in quarantine measures, such as the inspection of arriving vessels and passengers at ports of entry. ASSISTANT SURGEON GENERAL RALPH CHESTER WILLIAMS, M.D., THE UNITED STATES PUBLIC HEALTH SERVICE: 1798-1950, at 80 (Commissioned Officers Association of the United States Public Health Service 1951). For example, in 1878, Congress enacted the first quarantine law empowering the federal government to wield quarantine measures apart from the states and installed the Marine Hospital Service as the primary agency to inspect “vessel[s] . . . coming from any foreign port . . . where any contagious or infectious disease may exist.” Act of Apr. 29, 1878, 45 Cong. Ch. 66. During this era, the federal government’s quarantine authority remained controversial, and some state and local health officials (especially from New York, New Orleans, and South Carolina) fiercely opposed federal interference in quarantines managed by the states.¹⁶ Aiming to

¹⁶ In fact, a bill aiming to increase the quarantine power within the Marine Hospital Service was rejected in light of opposition to a largely centralized system of quarantine. Among the arguments against federal interference was the argument that the bill would concentrate the quarantine power into too few hands, that the states were better situated to regulate quarantine because the states enjoy more familiarity with local conditions, that federal intervention usurped the states’ police power under the Tenth Amendment, and that federal intervention tends to infringe individual liberty. *Bill to Amend an Act Granting Additional Quarantine Powers and Imposing Additional Duties upon the Marine Hospital Service: Hearings on H.R. 4363 Before the H. Comm. On Interstate and For. Commerce*, 55 Cong. 2 (Feb. 18, 1898).

support the federal government's authority despite this opposition, Congress expansively construed and aggressively employed the Commerce Clause, and the Supreme Court continually acquiesced. *Bartlett v. Lockwood*, 160 U.S. 357, 361–62 (1896); *Hennington v. Georgia*, 163 U.S. 299, 309 (1896).

Although federal law slowly ascended over state quarantine law if a conflict arose, the federal government's measures still were bridled by economic considerations and by a wholesome allotment of respect for federalism. Further, the federal government expressly lacked the authority to interfere with a state's quarantine law or regulation.¹⁷ Act of Apr. 29, 1878 (“[T]here shall be no interference in any manner with any quarantine laws or regulations as they now exist or may hereafter be adopted under State laws.”); see WILLIAMS, PUBLIC HEALTH SERVICE, at 82–3, 156–62 (describing the cooperative relationship between the federal and state government and the federalist system of public health regulation). Also, the mid- to late-nineteenth century saw changes in the method of inspecting and quarantining an incoming vessel from a foreign port; three of the changes merit consideration.

First, quarantine stations were critical during this era, and the federal government began exercising greater control over quarantine stations. CDC, *History*

¹⁷ See, e.g. R.J. Res. 6, 42 Cong. (June 6, 1872) (instructing medical officers to “visit each town or port on the coast of the Gulf of Mexico and the Atlantic coast, which is subject [to] yellow fever, and . . . confer with the authorities of such port or town with reference to the establishment of a more uniform and effective system of quarantine, and . . . ascertain all facts having reference to the outbreaks of this disease in such ports or towns, and whether any system of quarantine is likely to be effective in preventing invasions of yellow fever, and, if so, what system will least interfere with the interests of commerce at said ports. . . .”).

of Quarantine. Situated outside a port, a quarantine station housed medical officers whose duty was to determine a vessel's previous travel and to examine travelers and cargo for signs of communicable disease. WILLIAMS, PUBLIC HEALTH SERVICE, at 80–1. An arriving vessel was required to anchor at a port's quarantine station and to receive an officer aboard for these inspections. And if a vessel had arrived from a port with an extensive outbreak of a disease or if a traveler exhibited symptoms, a more exacting inspection occurred and temporary detention might result. WILLIAMS, PUBLIC HEALTH SERVICE, at 80. But detention of a vessel was disfavored and almost invariably lasted only for the duration of the disease's incubation period (typically from five to twenty days).¹⁸ WILLIAMS, PUBLIC HEALTH SERVICE, at 73–83. The federal government gradually began acquiring and establishing quarantine stations, and New York transferred the last quarantine station to the federal government in 1921. WILLIAMS, PUBLIC HEALTH SERVICE, at 80; CDC, *History of Quarantine*.

Second, if the quarantine officer declared the vessel disease-free, the officer issued to the vessel a “pratique” or “provisional pratique.” WILLIAMS, PUBLIC HEALTH SERVICE, at 80. A pratique permitted a vessel to enter and operate in a port. By contrast, a provisional pratique permitted a vessel to enter the port only

¹⁸ In fact, Surgeon General Woodworth, the chief pioneer for establishing a national health service and re-invigorating the federal government's role in quarantine, “considered the detention of a vessel from an infected port, whether sickness existed aboard or not, as unjustifiable beyond the known period of incubation of the disease for which quarantine was to be enforced.” WILLIAMS, PUBLIC HEALTH SERVICE, at 73. *See also id.* at 80 (“[The vessel] might be detained for the full incubation period.”); *accord id.* at 83 (permitting detention of “suspects . . . only long enough to demonstrate that they were not infected.”).

after completing some narrow and discrete task, typically fumigation of cargo or the like.

Third, Congress further federalized the quarantine power by adopting a “bill of health” system. In 1893, Congress enacted the “last significant quarantine legislation before the [] enactment of the Public Health Service Act in 1944,” WEN SHEN, SCOPE OF CDC AUTHORITY UNDER SECTION 361 OF THE PUBLIC HEALTH SERVICE ACT, at 8 (Congressional Research Service, 2021), which conscripted the Marine Hospital Service to, among other things, obtain a “bill of health” from a vessel arriving from abroad.¹⁹ Act of Feb. 15, 1893, 52 Cong., Ch. 114. The bill of health, obtained from a U.S. “consular officer . . . at the port of departure,” was required to “set[] forth the sanitary history and condition of [a] vessel” and to affirm the vessel’s compliance with sanitation rules and regulations. Upon arrival at a U.S. quarantine station, a vessel would display the bill of health to a quarantine officer. *See* ALEX CHASE-LEVENSON, THE YELLOW FLAG: QUARANTINE AND THE BRITISH MEDITERRANEAN WORLD, 1780-1860, at 13–16 (Cambridge Univ. Press, 2020) (discussing the development of these practices). Although later abandoned and replaced by casual “radio pratique” practices in 1985, 42 C.F.R. § 71.11, the bill of health served as an important quarantine tool during this period.

¹⁹ Also noteworthy, the law limited the Secretary’s exercise of authority by first requiring a determination that local and state quarantine laws were insufficient before implementing interstate quarantine measures. Act of Feb. 15, 1893, 52 Cong., Ch. 114.

Among the more “extreme” regulatory conduct initiated in the late nineteenth century, the Surgeon General (1) issued a circular temporarily forbidding “[v]essels from cholera-infected districts” from entering a port without a “certificate of disinfection”;²⁰ (2) banned temporarily the importation of discrete items, such as “rags, furs, skins, hair, feathers, boxed or baled clothing or bedding, or any similar article,” unless the vessel operator furnished a certificate of disinfection;²¹ and (3) declared “under the laws of the several States” a twenty-day quarantine of all ships “from any foreign port carrying immigrants.”²² *See* VICTORIA BENNETT, MEDICAL EXAMINATION OF ALIENS: A POLICY WITH AILMENTS OF ITS OWN?, 12 U. ARK. LITT. ROCK L.J. 739, 741–42 (1989) (discussing the three policies mentioned above). However, more common measures included rapid inspection and sanitation. For instance, when a rag, bag, or other item was suspected of infection, the item was “subjected to a process of disinfection,” typically either steaming or fumigation. Treasury Dep’t, Circular on Vessels from Cholera-Infected Districts, Vol. 7, No. 29 (July 15, 1892).

²⁰ Treasury Dep’t, Circular on Vessels from Cholera-Infected Districts, Vol. 7, No. 29 (July 15, 1892).

²¹ *Id.*

²² Treasury Dep’t, Circular on Quarantine Restrictions Upon Immigration to Aid in the Prevention of the Introduction of Cholera, No. 150 (Sept. 1, 1892). *See* HOWARD MARKEL, QUARANTINE!: EAST EUROPEAN JEWISH IMMIGRANTS AND THE NEW YORK CITY EPIDEMICS OF 1892, 96–7 (Johns Hopkins Univ. Press, 1997) (detailing the attendant circumstances of the twenty-day quarantine).

After the turn of the century, as states and courts persisted in regarding quarantine authority as firmly within the domain of the states,²³ World War I severely depleted the Public Health Service's²⁴ resources and forced the Public Health Service to streamline quarantine practice. For example, in 1937, the Public Health Service began to permit "radio pratique," which authorized quarantine stations to issue a pratique without first inspecting a vessel if the vessel's operator declared in advance the health of the vessel. WILLIAMS, PUBLIC HEALTH SERVICE, at 99. Nevertheless, despite strained resources in the early twentieth century, the federal government's quarantines continued "by a process of accretion and erosion." Sidney Edelman, *International Travel and Our National Quarantine System*, 37 TEMP. L. Q. 28, 35 (1963).

Amid disquiet about the spread of malaria, Congress in 1944 passed the Public Health Service Act, the statute central to this action. Rather than conferring new duties, the Public Health Service Act largely organized, consolidated, and clarified

²³ See, e.g., *Ex parte Co.*, 106 Ohio St. 50, 57 (1922) ("The power to so quarantine in proper case and reasonable way is not open to question. It is exercised by the state and the subdivisions of the state daily."); *Ex parte Johnston*, 40 Cal. App. 242, 244 (Cal. Ct. App. 1919) ("The adoption of measures for . . . the public health is universally conceded to be a valid exercise of the police power of the state, as to which the Legislature is necessarily vested with large discretion . . . in determining what are contagious and infectious diseases [and] in adopting means for preventing the spread[.]"); *Jacobson v. Commonwealth of Massachusetts*, 197 U.S. 11, 25 (1905) (upholding a vaccine mandate and reasoning that the Supreme Court "has distinctly recognized the authority of a state to enact quarantine laws and 'health laws of every description;' . . . According to settled principles, the police power of a state must be held to embrace, at least, such reasonable regulations established directly by legislative enactment as will protect the public health[.]"); *Simpson v. Shepard (U.S. Reps. Title: Minnesota Rate Cases)*, 230 U.S. 352, 406 (1913) (affirming the states' authority to adopt quarantine regulations that do not conflict with federal law and observing that "Congress from the beginning has been content to leave the matter for the most part, notwithstanding its vast importance, to the states, and has repeatedly acquiesced in the enforcement of state laws.").

²⁴ The Marine Hospital Service's name was changed to the Public Health Service in 1912.

the federal government's existing legal authority, as CDC observes.²⁵ (Doc. 31 at 5) Also, the Public Health Service Act maintained the Public Health Service's management of quarantine stations, confirmed a vessel operator's duty to furnish a bill of health if required, formalized the cooperative dynamic between health officials of the federal and state governments, and codified other powers.²⁶ Yet the measures — inspection, fumigation, disinfection, sanitation, pest extermination, and similar measures — introduced by the Public Health Service Act accorded comfortably with historical precedent.

Although the enactment of the Public Health Service Act represented a crest for the federal government's quarantine power, quarantine regulation looked virtually the same as the regulation at the turn of the century, and the decades following the Public Health Service Act witnessed a distinct and unmistakable lull in federal quarantine regulation. Shen, *Scope of CDC Authority Under Section 361*, at 11 (discussing the “more limited exercise of agencies’ Section 361 authority” in light of medical advances, such as vaccines). For instance, routine inspections waned, and

²⁵ This is not to say that Congress enabled no new authority or duty. For example, Section 361 of the act, codified as 42 U.S.C. § 264, added to the federal government's quarantine powers the authority to destroy “animals or articles found to be so infected.” *Consolidation and Revision of Laws Relating to the Public Health Service*, by Mr. Bulwinkle, from the Committee on Interstate and Foreign Commerce, 78th Congress, 2d Session, House of Representatives, Report No. 1364, pp. 3-4 (April 20, 1944) (“Destruction of infected animals or contaminated articles would be permitted as a part of interstate or foreign quarantine procedures, where such animals or articles are likely to infect human beings with a dangerous disease and no disposition other than destruction can safely be made.”).

²⁶ For instance, the Act confers special power to the Surgeon General during war, empowers the federal government to conduct medical examinations and to exclude the introduction of people, and extends the quarantine power to aircraft.

vessels and cargo became exempt from inspection unless infection was found first. 38 Fed. Reg. 16,861 (1973). Also, the role of quarantine stations decreased. CDC, *History of Quarantine*. When in 1967 an organizational restructuring caused CDC to share control over federal quarantine power, CDC controlled fifty-five quarantine stations dispersed throughout the major points of entry into the United States. In the 1970s, CDC pruned the quarantine program to shift focus from inspections to surveillance and program management. CDC, *History of Quarantine*. Consequently, only seven quarantine stations remained by 1995. This regulatory relaxation culminated in the regulations discussed in this order.

Although re-organizing the quarantine-station system and expanding to twenty quarantine stations after the 2003 epidemic of SARS (severe acute respiratory syndrome), CDC's quarantine regulation during the past fifty years was largely episodic and limited to an *ad hoc* response to an acute circumstance. For example, in 1975 after gastrointestinal illness became more widespread on cruise ships, CDC's quarantine division launched the Vessel Sanitation Program under Section 264. Yet the voluntary Vessel Sanitation Program was a "cooperative activity between the cruise ship industry and the CDC," the program was financed by a fee charged to each cruise vessel, and the program's enforcement mechanism was slight and

largely impelled by insurance incentives.²⁷ CENTERS FOR DISEASE CONTROL & PREVENTION, *Vessel Sanitation Program Operations Manual*, at ii (2018). The Vessel Sanitation Program exhibits the attributes of the more recent employment of the quarantine power, which is markedly more limited in scope than the power exercised at the beginning of the twentieth century.

In sum, the history of federal involvement in quarantine regulation confirms that the power peaked in the late-nineteenth and early twentieth century amid the threat of yellow fever, cholera, malaria, and the like, but the power receded during the past fifty years (at least, until quite recently). The history shows (1) that the public health power, including the power to quarantine, was traditionally understood — and still is understood — as a function of state police power; (2) that the federal quarantine power has both expanded and contracted; (3) that historically the federal quarantine power was limited to a discrete action, such as inspection and sanitation at a port of entry, as well as detention for the duration of a disease's incubation period; (4) that although the federal government has detained vessels, conditioned pratique, and banned a discrete item, federal deployment of these measures has been distinctly limited in time, scope, and subject matter; and (5) that

²⁷ If a cruise vessel failed a Vessel Sanitation Program inspection, the vessel was re-inspected within a month or two. If the vessel still failed to conform to sanitation standards, the inspector could recommend against the cruise vessel's departure or detain the vessel. But penalties of this sort have been extremely rare and, typically, a cruise ship must simply pay the cost of a re-inspection as a penalty. CENTERS FOR DISEASE CONTROL & PREVENTION, *Vessel Sanitation Program Operations Manual*, at §§ 11.6–10 (Aug. 2005).

the Public Health Service Act of 1944 codifies the limited regulatory power typical of preventing diseases caused by a discrete item or a person at a major port of entry.

Never has CDC (or a predecessor) detained a vessel for more than fifteen months; never has CDC implemented a widespread or industry-wide detention of a fleet of vessels in American waters; never has CDC conditioned pratique as extensively and burdensomely as the conditional sailing order; and never has CDC imposed restrictions that have summarily dismissed the effectiveness of state regulation and halted for an extended time an entire multi-billion dollar industry nationwide. In a word, never has CDC implemented measures as extensive, disabling, and exclusive as those under review in this action.

However, in this action CDC claims a startlingly magnified power. But as CDC concedes, the Public Health Service Act “consolidates and codifies” the federal quarantine practices applied during the previous century (Doc. 31 at 5), and “over the 20th and into the 21st century, the legislative framing for quarantine has remained relatively constant.” Donohue, *Biodefense and Constitutional Constraints*, at 156. Thus, viewed with the benefit of history, CDC’s assertion of a formidable and unprecedented authority warrants a healthy dose of skepticism. *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 324 (2014) (“When an agency claims to discover in a long-extant statute an unheralded power to regulate ‘a significant portion of the American economy,’ we typically greet its announcement with a measure of skepticism.”) (quoting *Food & Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 121 (2000)).

2. 42 U.S.C. § 264

The text of the Public Health Service Act lends support to a narrower quarantine power for CDC. The provision of the Public Health Service Act that most directly addresses quarantine and inspection is 42 U.S.C. § 264(a). Congress enacted Section 264(a) to delineate the contours of the authority intended for the Secretary of Health and Human Services and, consequently, for CDC:

The Surgeon General,²⁸ with the approval of the Secretary, is authorized to make and enforce such regulations as in his judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession. For purposes of carrying out and enforcing such regulations, the Surgeon General may provide for such inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings, and other measures, as in his judgment may be necessary.

Section 264(a) is best understood by displaying the second sentence as the sentence's grammatical structure dictates:

For purposes of carrying out and enforcing such regulations,
the Surgeon General may provide for such

- (1) inspection,
- (2) fumigation,
- (3) disinfection,
- (4) sanitation,
- (5) pest extermination,

²⁸ The statute refers to the Surgeon General, but for reasons not relevant here, administrative reorganizations transfer to the Secretary of HHS the authority conferred to the Surgeon General. 31 Fed. Reg. 8855, 80 Stat. 1610 (1966).

- (6) destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings, and
- (7) other measures,

as in his judgment may be necessary.

A perhaps important observation is that items (1) through (7) form a grammatical series succinctly expressed as “1, 2, 3, 4, 5, 6, and ‘other measures.’” If an “and” were to appear between (5) and (6), the sentence becomes “1, 2, 3, 4, 5, and 6, and other measures.” (The comma after 6, which appears in the statute, is grammatically superfluous in this hypothetical version.) The two versions deliver different results. The principal difference is that in the former version (the real version) the words “of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings” apply only to “destruction” and not to inspection, fumigation, disinfection, sanitation, or pest extermination, none of which requires a preliminary “finding” of “dangerous infection,” as “destruction” requires. Also, the word “article” (which CDC construes to include a cruise line vessel and any other object) pertains only to “destruction” but not to “inspection” and the other terms in the series.

CDC interprets the provision to confer almost boundless authority; Florida interprets this provision more narrowly. The parties’ dispute presents a controlling question of statutory interpretation.

i. The Parties' Interpretations

Florida argues that CDC's conditional sailing order exceeds the authority granted by the statute. Relying on several canons of construction, especially *ejusdem generis*, *noscitur a sociis*, and the canon of constitutional avoidance, Florida argues that Section 264(a)'s "second sentence clarifies the narrow nature of the CDC's authority." (Doc. 9 at 9) Thus, on Florida's reading, Section 264(a) confines CDC's actions to those that resemble or have scope and attributes similar to "inspection, fumigation, disinfection, sanitation, or pest extermination," and CDC may pursue one or more of those discrete actions or a similar discrete action. In other words, the second sentence exemplifies the action Congress authorized in the first sentence. That is, the second sentence provides examples that delimit the action contemplated by Congress in the first sentence. And given the practically unlimited authority asserted by CDC, Florida argues that CDC fails to identify a clear statement from Congress granting the broader authority. (Doc. 9 at 10)

CDC argues that the "other measures" clause in Section 264(a) confers on CDC "broad authority" to enact and enforce regulations and pursue remedies, limited only to the director's determination that the measure is "necessary" to prevent transmission of a communicable disease. (Doc. 31 at 23) According to CDC, because Section 264(a)'s plain language exhibits "a legislative determination to defer to the 'judgment' of public health authorities" (Doc. 31 at 23), resort to canons of statutory interpretation is unnecessary, and that ends the matter. (Doc. 31 at 29 n. 20)

According to CDC, examining the other subsections, Section 264(b) through (d), reveals CDC’s expansive “breadth of [] authority . . . , [which] include[s] the ‘detention’ of individuals . . . and even the ‘destruction’ of property.” (Doc. 31 at 23, 29) CDC argues that these subsections “make plain that the broad grant of authority in the first sentence of § 264(a) is not confined to the specific intrusions on private property described in the second sentence.” (Doc. 31 at 29) In light of this perceived “breadth,” CDC maintains that “the agency’s regulations reflect the commonsense notion that, to avert the spread of communicable diseases, ships entering U.S. ports may be detained, inspected, and permitted to disembark only under specified circumstances.” (Doc. 31 at 23)

Next, even if the second sentence of Section 264(a) narrows the first sentence, as Florida suggests, CDC argues that the conditional sailing order “is still squarely within the agency’s statutory authority” because the conditional sailing order imposes on the cruise industry a set of conditions similar to “inspection, disinfection, destruction of property, and ‘other measures.’” (Doc. 31 at 30) CDC regards the conditional sailing order not as a “detention” of the cruise ships — moored already for fifteen months — but as a phased approach to conditioning “free pratique,” defined as “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); (Doc. 1-3 at 22) (characterizing the conditional sailing order “as a condition of obtaining or retaining controlled free pratique for operating a cruise ship in U.S. waters”).

And according to CDC, the regulation of free pratique is a direct outflow of the “measures” contemplated by Section 264(a), which “are not different in kind than the other types of inspection, hygiene, and safety protocols listed in the statute.” (Doc. 31 at 30) On CDC’s reading, the “articles” described in Section 264(a), that is, the objects of the specifically enumerated measures, encompass a cruise ship. *See* First Preliminary Injunction Hearing Transcript at 94–8 (arguing that “article” includes a cruise ship); (Doc. 31 at 30). Thus, in CDC’s view, the conditional sailing order is “less intrusive” than the enumerated measures because the conditional sailing order requires no “detention” or “destruction” of property; the conditional sailing order merely regulates the pratique of a cruise ship. (Doc. 31 at 30)

In sum, CDC argues that the statute authorizes the Secretary to freely employ his “judgment” about restrictions “necessary” to prevent the transmission of communicable disease. (Doc. 31 at 27) Under CDC’s characterization, the statute “exudes flexibility and deference to the judgment of the public health experts” and this broad discretion comports with the “commonplace” legislative determination to defer to a specialized agency in an area of “scientific uncertainty.” (Doc. 31 at 28, 32–33) Included in this discretion is the authority to impose conditions for operating a conveyance in international and interstate travel during a pandemic. (Doc. 31 at 28) And included in this discretion is the legal authority to implement measures necessary to “get[] transmission to zero.” Second Preliminary Injunction Hearing Transcript, at 109 (Jun. 10, 2021). Thus, CDC argues explicitly that the second sentence of Section 264(a) places virtually no restraint on the director, who is free to

regulate the nation as a whole, including any form of industry, enterprise, and activity, subject only to the director’s finding a measure “necessary” to prevent the interstate or international transmission of a communicable disease — and “transmission” to CDC means a single human-to-human infection.

ii. Precedent Interpreting Section 264

Just as the parties disagree about the meaning of Section 264(a), recent cases interpreting Section 264(a) disagree — in the context of a rent moratorium imposed by CDC — about the scope of authority that Section 264(a) confers on CDC.

Compare Tiger Lily, LLC v. United States Dep’t of Hous. & Urb. Dev., 992 F.3d 518, 523 (6th Cir. 2021) (analyzing Section 361 and holding that the rent moratorium “falls outside the scope of the statute”); and *Skyworks, Ltd. v. Centers for Disease Control & Prevention*, 2021 WL 911720, at *11 (N.D. Ohio 2021) (discussing *Brown* and *Chambless* and observing that those “decisions have the feel of adopting strained or forced readings of the statute, stretching to rationalize the governmental policy at issue”); *Alabama Ass’n of Realtors v. United States Dep’t of Health & Hum. Servs.*, 2021 WL 1779282, at *6 (D.D.C. 2021) (enjoining CDC’s rent moratorium because “[t]he Department’s interpretation goes too far”); *with Brown v. Azar*, 2020 WL 6364310, at *7 (N.D. Ga. 2020), *appeal docketed*, No. 20-14210 (11th Cir.); and *Chambless Enters., LLC v. Redfield*, 2020 WL 7588849, at *5 (W.D. La. 2020) (reasoning that the specific enumerations in the second sentence “underscore the breadth of [CDC’s] authority, showing that it may infringe on personal liberties or property rights where appropriate to protect the public health”), *appeal docketed*, No. 21-30037 (5th Cir.).

Some courts read sentence one of Section 264(a) in light of sentence two and hold that the statute empowers a narrower array of regulatory activity. *See, e.g., Tiger Lily*, 992 F.3d at 523 (“Plainly, government intrusion on property to sanitize and dispose of infected matter is different in nature from a moratorium on evictions.”). For example, *Alabama Association of Realtors* explains that the “rulemaking authority in the first sentence of § 264(a) is tethered to — and narrowed by — the second sentence.” 2021 WL 1779282, at *5 (D.D.C. 2021). This conclusion hinges on the canon against surplusage, which aims to acknowledge and effect each provision of a statute; the constitutional avoidance canon, which favors an interpretation that forbears raising nettlesome constitutional issues; and the major questions doctrine, which assumes that Congress provides a clear delegation of authority for an agency charged with the most salient and consequential issues.

By contrast, *Chambless* “finds that the plain text of the statute is unambiguous and evinces a legislative determination to defer to the ‘judgment’ of public health authorities about what measures they deem ‘necessary’ to prevent contagion.” 2020 WL at *5.²⁹ Relying on an opinion addressing an FDA ban on small turtles,³⁰ *Chambless* reasons that Congress frequently grants broad flexibility to an agency implementing public health measures and that the list of enumerated items reinforces

²⁹ On appeal, the D.C. circuit likewise relied on “expert public-health judgments” to affirm the district court’s stay. *Alabama Ass’n of Realtors v. United States Dep’t of Health & Hum. Servs.*, 2021 WL 2221646, at *1 (D.C. Cir. 2021).

³⁰ *Indep. Turtle Farmers of Louisiana, Inc. v. United States*, 703 F. Supp. 2d 604 (W.D. La. 2010).

(rather than limits) CDC’s authority. 2020 WL at *6. Further, *Chambless*, like CDC, reasons that subsections (b) through (d) demonstrate that “the list contained in the first subsection is not an exhaustive list of the permissible measures available.” 2020 WL at *6.³¹

Although the former interpretation (the district court’s interpretation in *Alabama Association of Realtors*) offers a much clearer and more intuitive rendering of the statute, each of these decisions interprets Section 264(a) in the context of a rent moratorium, and none of these cases addresses CDC’s authority in the context of regulating the transmission of a disease aboard a ship, an airplane, or another common carrier. To determine the scope of CDC’s authority, Section 264(a) requires consideration of both the history and the accompanying statutory text.

iii. Analysis of Section 264(a)

The first sentence of Section 264(a) appears to provide the Secretary with broad authority to implement regulations that “in his judgment” prevent contagion. However, the next sentence explains that, to “carry out and enforc[e]” these regulations, the Secretary “may provide for such inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected . . . , and other measures.” CDC focuses on the more expansive words in the second sentence of subsection (a) — empowering “other measures, as in his judgment may be necessary” (Doc. 31 at 29–30) — and Florida focuses on the

³¹ See also *Alabama Ass’n of Realtors v. United States Dep’t of Health & Hum. Servs.*, 2021 WL 2221646, at *2 (D.C. Cir. 2021) (same).

narrower language that authorizes “inspection, fumigation, disinfection, sanitation, pest extermination, [and the] destruction of animals or articles found to be so infected.” (Doc. 9 at 9–10)

But Florida correctly observes that the second sentence operates to limit CDC’s enforcement and implementation authority to only those actions resembling “inspection, fumigation, disinfection, . . . [and] pest extermination.” As explained in *Alabama Ass’n of Realtors v. United States Dep’t of Health & Hum. Servs.*, 2021 WL 1779282, at *5 (D.D.C. 2021), “the first sentence of § 264(a) is tethered to — and narrowed by — the second sentence.” The second sentence of Section 264(a) discloses, illustrates, exemplifies, and limits to measures similar in scope and character the measures contemplated and authorized by Congress when enacting the statute. *Yates v. United States*, 574 U.S. 528, 546 (2015) (applying specific statutory terms to cabin the meaning of a broad statutory term). Needless to say, the statute includes nothing in scope or character similar to, for example, governing landlord and tenant law nationwide or halting commerce by a fifteen-month closure of one or more industries or halting other public movement and activity nationwide.

Thus, if CDC promulgates regulations the director finds “necessary to prevent” the interstate or international transmission of a disease, the enforcement measures must resemble or remain akin to “inspection, fumigation, disinfection, sanitation, pest extermination, [or the] destruction of infected animals or articles.” Any other reading of the statute renders “inspection, fumigation, disinfection” — renders the entire second sentence — superfluous. *Yates v. United States*, 574 U.S.

528, 546 (2015) (“The Government’s unbounded reading of ‘tangible object’ would render [the more specific] words misleading surplusage.”); *Williams v. Taylor*, 529 U.S. 362, 364 (2000) (“[C]ourts must give effect, if possible, to every clause and word of a statute.”).

Nor does the residual “and other measures” broaden Section 264(a)’s scope. As explained in *Tiger Lily, LLC v. United States Dep’t of Hous. & Urb. Dev.*, “[t]he residual phrase in § 264(a) is ‘controlled and defined by reference to the enumerated categories . . . before it.’” 992 F.3d 518, 522–23 (6th Cir. 2021) (quoting *Cir. City Stores, Inc. v. Adams*, 532 U.S. 105, 106 (2001)). The *ejusdem generis* canon counsels that Section 264(a)’s residual phrase fails to expand CDC’s authority beyond the authority suggested by the enumerated terms. And this is confirmed by the historical employment of these measures, which resemble the enumerated categories but lacks any resemblance to the conditional sailing order’s mandates.

Likewise, the *noscitur a sociis* canon relies on the assumption that the reader can determine the meaning of a word according to the company the word keeps. *Bilski v. Kappos*, 561 U.S. 593, 604 (2010) (“Under this canon, ‘an ambiguous term may be given more precise content by the neighboring words with which it is associated.’”) (quoting *United States v. Stevens*, 559 U.S. 460, 474 (2010)). In other words, “[a]ssociated words bear on one another’s meaning.” ANTONIN SCALIA & BRYAN A. GARNER, *READING LAW: THE INTERPRETATION OF LEGAL TEXTS* 195 (2012).

Further, CDC argues that the only limitation on the director's authority is whatever the director finds "necessary." Preliminary Injunction Hearing Transcript at 80–85. This practically unbounded interpretation causes separation-of-powers problems, discussed in greater depth below, and naturally stirs suspicion about the constitutionality of Section 264(a). But as Justice Holmes explains, "A statute must be construed, if fairly possible, so as to avoid not only the conclusion that it is unconstitutional, but also grave doubts upon that score." *United States v. Jin Fuey Moy*, 241 U.S. 394, 401 (1916).

Similarly, CDC's permissive reading fails to acknowledge the "major questions doctrine," which assumes that Congress speaks clearly if aiming to assign "to an agency decisions of vast economic and political significance."³² *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 324 (2014) (reasoning that the agency's "interpretation is also unreasonable because it would bring about an enormous and transformative expansion in [the agency's] regulatory authority without clear congressional authorization") (internal citation and quotation omitted). In *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000), the FDA attempted to regulate tobacco under a strained reading of 21 U.S.C. § 301. Citing tobacco regulation's "unique place in American history," citing the FDA's attempt "to regulate an industry constituting a significant portion of the American economy,"

³² Whatever the future application of the "major questions doctrine" may include, the doctrine at minimum serves as a "statutory interpretation doctrine." *Paul v. United States*, 140 S. Ct. 342 (2019) (Kavanaugh, J.).

and citing the unprecedented “breadth of authority that the FDA [] asserted,” *FDA v. Brown* holds that the FDA exceeded its statutory authority by regulating tobacco without clear congressional blessing. 529 U.S. at 159–61. As exemplified in *FDA v. Brown*, the federal government’s role in quarantine regulation throughout American history — addressed above — confirms CDC’s historically limited application of inspection, sanitation, and isolation. In contrast, the expansive breadth of authority asserted by the conditional sailing order to microscopically regulate a multi-billion-dollar industry is breathtaking.

CDC acknowledges that, if considered a rule, the conditional sailing order constitutes a “major rule” under 5 U.S.C. § 804(2) (meaning the order is likely to affect the economy by more than \$100,000,000 or is likely to increase costs for individual industries or state governments). In light of CDC’s unprecedented assertion of power and the conditional sailing order’s broader economic implications, a predominant doubt remains that Congress would convey such formidable authority by the vague terms of Section 264(a).

In short, several canons of statutory interpretation — such as *ejusdem generis*, *noscitur a sociis*, the canon against surplusage, the constitutional avoidance canon, and the major questions doctrine — gravitate against CDC’s broad interpretation.

Next, the statute, according to Florida, permits CDC to destroy “animals or articles” if “found to be so infected.” See *Alabama Ass’n of Realtors v. United States Dep’t of Health & Hum. Servs.*, 2021 WL 1779282, at *5 (D.D.C. 2021). This view comports with the historical antecedents of the enforcement methods specified in the

statute. *See, e.g.*, Treasury Dep’t, Circular on Vessels from Cholera-Infected Districts, Vol. 7, No. 29 (July 15, 1892) (banning “rags, furs, skins, hair, feathers, boxed or baled clothing or bedding, or any similar *article*”). CDC resorts to a hermeneutical stretch to conclude that, “article” includes a cruise vessel. Only a severely strained interpretation of the statute permits an “article” to include a cruise ship, much less an entire fleet of cruise ships. *See Skyworks, Ltd. v. Centers for Disease Control & Prevention*, 2021 WL 911720, at *10 (N.D. Ohio 2021) (discussing the meaning of “articles” within the context of the statute). Common sense and common usage (and any English dictionary) dictate that the definition of “article” excludes a fleet of 40,000-ton, thousand-plus-passenger vessels. For example, *The American Heritage Dictionary* (5th ed. 2020) defines article as “a particular object or item”). The more natural interpretation is additionally confirmed by CDC’s regulation addressing the disinfection of imports: “When the cargo manifest of a carrier lists articles which may require disinfection . . . , the Director shall disinfect them on board or request . . . to keep the articles separated from the other cargo pending appropriate disposition.” 42 C.F.R. § 71.42. And other sanitation regulations understand “article” to mean a discrete item found “on board” a ship, not the ship itself. *See, e.g.*, 42 C.F.R. § 71.32(b) (allowing quarantine measures “[w]hen the Director has reason to believe that any arriving carrier or article or thing on board the carrier is or may be infected”). In accord with a disinterested reading of the statute, a cruise ship falls outside the definition of an “article.”

Moreover, the “found to be so infected or contaminated” clause further limits the statute by suggesting that an animal or article must present more than a possibility or a remote risk of infection due to an instance of infection in another animal or article. *Skyworks*, 2021 WL at *9 (“Congress directs the agency to act on specific animals or articles which are themselves infected[.]”). In other words, Section 264(a) allows the regulation of only an infected or infecting item. *Alabama Ass’n of Realtors v. United States Dep’t of Health & Hum. Servs.*, 2021 WL 1779282, at *5 (D.D.C. 2021) (“[A]ny regulations enacted pursuant to § 264(a) must be directed toward specific targets ‘found’ to be sources of infection.”) (quoting *Skyworks*, 2021 WL at *9) (internal quotations omitted and emphasis added)).

iv. Other Provisions

CDC alludes to other provisions in Section 264 to “underscore the breadth of [] authority” under the statute. (Doc. 31 at 23) According to CDC, because subsections (b) through (d), the quarantine provisions, authorize the “detention” of an “individual,” these subsections show that “other measures” include measures far beyond fumigation, extermination, and the like. (Doc. 31 at 23)

Additionally, rather than significantly expanding the scope of CDC’s quarantine powers, subsections (b) through (d) provide a limitation on the quarantine of a person. In example, 42 U.S.C. § 264(c) provides that “regulations prescribed under this section . . . shall be applicable only to individuals coming into a State or possession from a foreign country.” This provision shows, among other things, that CDC’s quarantine powers recede if CDC regulates a person who is not arriving at a

U.S. port from abroad.³³ And this limited quarantine of a person comports with the historical practices implemented by the federal government to temporarily inspect and detain a foreign person arriving to a U.S. port. WILLIAMS, PUBLIC HEALTH SERVICE, at 102–07 (detailing the Marine Hospital Service’s role in temporarily inspecting and detaining immigrants). Hence, even though these subsections, if read in isolation, expand the authority suggested by subsection (a) beyond fumigation and the like, “the additional subsections do not supplant the reach of the first or create other grounds justifying the orders at issue.” *Skyworks, Ltd. v. Centers for Disease Control & Prevention*, 2021 WL 911720, at *10 (N.D. Ohio 2021).

Next, the conditional sailing order invokes Sections 264 and 268 of the Public Health Service Act. Although neither party delves into the broader statutory regime, other provisions in the Public Health Service Act complement and clarify the powers and duties described in Section 264 and, consequently, inform the most natural reading of Section 264(a). *Hueso v. Barnhart*, 948 F.3d 324, 333 (6th Cir. 2020) (describing a district court’s obligation to “consider the entire text, in view of its structure and of the physical and logical relation of its many parts”) (quoting ANTONIN SCALIA & BRYAN A. GARNER, *READING LAW: THE INTERPRETATION OF LEGAL TEXTS* 167 (2012)); *see also Sorenson v. Secretary of Treasury*, 475 U.S. 851, 860 (1986) (discussing the importance of examining different parts of the same act to help

³³ *Cf.* 42 U.S.C. § 264(d) (allowing interstate apprehension of an individual “infected with a communicable disease *in a qualifying stage*” and requiring the individual “to be moving or about to move from a State to another State” or “to be a probable source of infection to individuals who . . . will be moving from a State to another State”).

construe a statute). The pertinent sections appear in Part G (Quarantine and Inspection), within which Section 264(a) appears.

Sections 264 through 272 authorize the Secretary, among other things, (1) “to prohibit . . . the introduction of persons and property from [foreign] countries” with regulations approved by the president (Section 265); (2) to “apprehen[d] and examin[e], in time of war, [] any individual reasonably believed” to have an infection or risking contagion to members of the armed forces” (Section 266); (3) to create and manage quarantine stations (Section 267); (4) to utilize customs and Coast Guard officers to enforce the quarantine regulations (Section 268); and (5) to require a “bill of health” from any vessel headed to the United States from any foreign port not “near the frontiers of the United States,” which bill “shall set forth the sanitary history and condition of said vessel” (Section 269).

These statutes contemplate a regime in which the Secretary maintains the authority to inspect an incoming vessel at a quarantine station, to quarantine an infected person arriving from abroad (or, in a very limited circumstance, “any individual”), to require a bill of health as a condition of entering a U.S. port from abroad, and to detain an arriving carrier for the time necessary to sanitize or treat an animal or an article on board “found to be [] infected or contaminated.” These sections authorize measures that resemble Section 264(a)’s enumerated provisions and that accord with the federal government’s quarantine activity throughout American history. Thus, the broader statutory context confirms that CDC’s authority lies perfectly within the enumerated provisions in Section 264.

A reasonable interpretation of the statutes (in conjunction with the animating history) reveals that the conditional sailing order exceeds the powers described in the statutes, including Section 264. The conditional sailing order includes a few requirements that resemble CDC's statutory authority, such as reporting requirements about a vessel's "ill" passengers and requirements to sanitize certain areas of a vessel. However, the conditional sailing order also requires a vessel operator, among other unauthorized measures, 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. Even if granting CDC's tortured explanation that the conditional sailing order merely conditions free pratique, the conditional sailing order imposes an indiscriminate and burdensome conditioning of free pratique that amounts to an unprecedented detention of an entire fleet of recreational cruising vessels. With this statutory context in mind, the regulations implementing the statutes require brief examination.

3. The Regulatory Landscape

Despite the lack of authority explicitly appearing in Section 264(a), the conditional sailing order invokes 42 C.F.R. §§ 70.2, 71.31(b), 71.32(b), and 71.1 as well. Florida disagrees with CDC's invocation of these regulations and asserts that CDC's failure to investigate and reasonably articulate the inadequacy of state health measures forces CDC's conduct outside 42 C.F.R. § 70.2. Further, Florida argues

that the inspection and detention of vessels authorized by Section 71.31 is limited to brief, “non-invasive” measures so “CDC cannot detain cruise ships indefinitely.” (Doc. 9 at 13) Thus, Florida understands the regulations to constitute a limited “outflow of § 264.” (Doc. 9 at 13)

CDC reads the implementing regulations more broadly and again focuses on the language permitting CDC director to “take such measures to prevent such spread of the diseases as he/she deems reasonably necessary.” (Doc. 31 at 7) CDC observes that 42 C.F.R. §§ 71.32(b) and 71.31(b) explicitly authorize the detention of “an arriving carrier” to stop the “introduction or spread of a communicable disease.” And CDC observes that under 42 C.F.R. § 71.31(b) CDC may condition a carrier’s movement by issuing a controlled free pratique. (Doc. 31 at 6, 23–24)

CDC relies principally on the free pratique provision to justify the conditional sailing order and argues that a cruise ship is an “arriving carrier” within the meaning of § 71.32(b). (Doc. 31 at 24) According to CDC, “nothing in the statute forbids the agency from withholding controlled free pratique to any ship — or many ships, even for an extended period of time — until it is safe for them to resume operations.” (Doc. 31 at 27) CDC asserts that under the presumably broad authority granted to CDC, including the authority to condition free pratique, “[t]he conditional sailing order falls squarely within these regulations.” (Doc. 31 at 24)

Charging CDC with the authority granted to CDC under Section 264(a), 42 C.F.R. §§ 70 through 71 include regulations to contain communicable disease. But Part 70 differs importantly from Part 71. Part 70 applies only to a vessel in

interstate transit. Part 71 applies only to a vessel in international transit, that is, to “regulations to prevent the introduction . . . of a communicable disease from foreign countries.” 42 C.F.R. § 71.1.

i. Part 70 and Interstate Quarantine Powers

The only provision from Part 70 cited by CDC is 42 C.F.R. § 70.2, which resembles Section 264(a) by authorizing the director of CDC to “take such measures to prevent such spread of the diseases as he/she deems reasonably necessary, including inspection, fumigation, disinfection, sanitation, pest extermination, and destruction of animals or articles believed to be sources of infection.” However, Section 70.2 adds to Section 264(a) that the director may “take such measures” only after “determin[ing] that the measures taken by health authorities of any State or possession . . . are insufficient to prevent” disease from spreading. Otherwise, the analysis of Section 70.2 is in all respects similar to that of Section 264. Consequently, Section 70.2 fails to suggest any broader authority.

The other regulations governing the interstate quarantine power confirm this conclusion. Within Part 70, “vessel” is mentioned only once. Specifically, Section 70.4 obligates the “master of any vessel . . . in interstate traffic” to report to a local health authority at the next port of call if a case of a communicable disease occurs on board. Part 70 instead describes the extensive limitations on the federal

government's power to impose a domestic quarantine on a person.³⁴ Because Part 70 says nothing meaningful about the regulation of a vessel and because Section 70.2 imposes an additional requirement before triggering the quarantine measures (which only duplicate those in Section 264(a)), Section 70.2 fails to expand the scope of CDC's authority. In fact, the only thing Part 70 clarifies is the federal government's much more modest authority if regulating interstate activity or vessels — a point already acknowledged by CDC at the preliminary injunction hearing. Second Preliminary Injunction Hearing Transcript, at 116–17 (Jun. 10, 2021) (“CDC has claimed more authority over arriving international vessels . . . because they’re arriving from outside U.S. borders and should be subject to additional inspection[.]”). Therefore, Section 70.2 not only fails to provide further support for CDC's authority to impose the conditional sailing order, Section 70.2 presents an additional hurdle to that authority.

ii. Part 71 and Foreign Quarantine Powers

In contrast, Part 71 includes regulations to prevent contagion “from foreign countries into the States,” and the regulations permit an array of tools to accomplish

³⁴ For example, Section 70.10 permits the director to assess a person's health by “non-invasive procedures” and Section 70.15 authorizes the quarantine of an “individual” but requires the director to reassess within seventy-two hours “whether less restrictive means would adequately serve to protect the public health.”

the director's international quarantine objectives. 42 C.F.R. § 71.1(a).³⁵

Structurally, Part 71 defines terms and next describes measures (1) for vessels at foreign ports (Subpart B), (2) for vessels in transit to an American port (Subpart C), (3) for health measures at an American port (Subpart D), and (4) for inspection upon arrival from a foreign port (Subpart E). The primary foreign-quarantine regulations invoked by the conditional sailing order appear in Sections 71.29 through 71.40, Subpart D. These provisions warrant closer review.

CDC prominently features 42 C.F.R. § 71.31 in defending the agency's claim to greater authority. (Doc. 32 at 24–5) Section 71.31(a) exempts an arriving carrier from inspection “unless the Director determines that a failure to inspect will present a threat of introduction of communicable diseases into the United States.” (This exemplifies CDC's more recent regulatory relaxation for an incoming vessel.)

On the other hand, Section 71.31(b) contains two sentences that enable CDC to enforce the rest of Part 71 governing foreign quarantine powers. The first sentence permits the director to “require detention of a carrier until the completion of the measures outlined in this part,” and the second sentence permits “[t]he Director [to] issue a controlled free pratique to the carrier stipulating what measures are to be met[.]” In both instances, however, detention and controlled pratique are limited by

³⁵ For instance, the director can compel contact information from a person who presents a risk of transmitting disease (Sections 71.5 and 71.20(b)); require a report for “any death or any ill person” travelling on a ship destined for an American port (Section 71.21); and suspend the introduction of a person into the United States from abroad (although only for “such period of time that the Director deems necessary to avert [] serious danger” of introducing a communicable disease) (Section 71.40).

the temporal component of subsection (b): “until the completion of the measures outlined in [] part [71].” And in both instances, the detention and the controlled free pratique are ancillary powers that enable and serve the implementation of other measures in Part 71.³⁶ In other words, to implement any of the foreign quarantine measures included in Part 71, CDC may detain a vessel and issue a controlled free pratique to that vessel until the measures from Part 71 are completed.

For instance, if CDC intends to disinfect a vessel’s cargo under Section 71.42 or require “disinfestation” of vermin under Section 71.41, “[t]he Director may require detention” of the vessel until completion of either the disinfection or the disinfestation, the director may issue a controlled free pratique until completion of either the disinfection or the disinfestation, or the director may do both until completion of the measures. In any of these instances, the detention and the conditioned free pratique serve as temporary tools directed to a specific vessel to accomplish the other measures appearing in Part 71.

Yet, the conditional sailing order requires several “measures” not outlined in Part 71. The conditional sailing order serves as a long-term detention unless and until CDC issues further “measures,” which are subject to change and which fail to appear in Part 71. The record shows that this detention has lasted several months — far longer than any pertinent incubation period and far longer than required by any

³⁶ In these adjoining sentences, the transition from the broad article, “a,” to the more specific article, “the,” preceding “carrier” strongly implies that the section contemplates the same vessel and the same “measures outlined in this part.”

“measure” from Part 71. 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. Whether a detention or a conditioned pratique, the conditional sailing order is unprecedented in duration and scope, and CDC exceeded its regulatory authority under the provision on which CDC stakes the conditional sailing order — Section 71.31.

Next, the conditional sailing order cites 42 C.F.R. § 71.32(b) to substantiate CDC’s authority. Subsection (b) empowers the director to “require detention, disinfection, disinfestation, fumigation, or other related measures respecting [an arriving] carrier or article or thing as he/she considers necessary to prevent the introduction, transmission, or spread of communicable diseases.”³⁷ Although this section, like Section 70.2, hardly clarifies CDC’s authority (given the provision’s similarity to Section 264(a)), two features of Section 71.32(b) are noteworthy. First, the “other related measures” clause suggests that the other catch-all provisions include only measures “related” to the enumerated measures — for example,

³⁷ This authority attaches only if the director “has a reason to believe” the carrier or item is infected.

“detention, disinfection, disinfection, [and] fumigation.” This again commends a narrower reading of the similar provisions appearing in Section 264(a) and Section 70.2.

Second, subsection (b) targets an “arriving carrier.” In fact, both Sections 71.31 and 71.32 apply only to an “arriving carrier,” as conceded by CDC. Preliminary Injunction Hearing Transcript, at 122 (May 12, 2021). Thus, whatever interpretation of Section 71.31 and 71.32 is contrived, CDC can implement the measures from neither Section 71.31 nor 71.32 unless a vessel is inbound. But the conditional sailing order forces regulation on vessels that have been moored in U.S. ports for more than fifteen months. This presents a formidable interpretive hurdle for CDC.

To begin with, the plain meaning of “arriving” suggests that a fleet of vessels moored in a U.S. port — that is, a fleet of vessels that is decidedly not arriving — cannot constitute an “arriving carrier” to trigger application of the measures in 71.31 and 71.32. Attempting to overcome this hurdle, CDC interprets an “arriving carrier” to include the locally moored cruise vessels under the theory that the vessels might arrive after an earlier departure. (Doc. 31 at 24; Doc. 47 at 122); Yet the conditional sailing order imposes restrictions (coupled with penalties) on a vessel’s ability to embark in the first instance, and, consequently, prevents the conditions required for a vessel to acquire status as “arriving.” Even CDC defines “controlled free pratique” as “permission for a carrier to enter a U.S. port, disembark” passengers, and conduct

other operations at the port. In other words, CDC's circular pretext precludes the conditions required to trigger application of the "arriving vessel" regulation.

CDC attempts to "fill this gap" by arguing that Section 70.2 otherwise authorizes the conditional sailing order if the cruise vessels fail to constitute an "arriving carrier." First Preliminary Injunction Hearing Transcript, at 86 ("[I]f there were any gaps in the CDC's regulatory authority here with respect to arriving carriers, . . . it's amply filling in by Part 70.2[.]"). But as discussed above, CDC's authority to regulate interstate voyages in accord with the conditional sailing order is unmistakably lacking in Part 70.

In any event, assuming the provisions invoked by CDC arguably include cruise ships as an "arriving carrier," CDC's authority to issue the conditional sailing order remains suspect. "Controlled free pratique," although vague in the regulation, has historically included limited measures required to resolve a specific infection or the like reported during an inbound voyage or encountered during an inspection. And history shows controlled free pratique was designed to lessen and to replace³⁸ the bill-of-health requirement, not to impose even more burdensome and comprehensive industry-wide requirements that detain a fleet in port indefinitely.

In short, none of the regulations invoked by CDC justifies the conditional sailing order. Even if ignoring Sections 71.31 and 71.32's application to only an

³⁸ 42 C.F.R. § 71.11 abolishes the bill-of-health requirement prescribed by Section 269. This replacement was coupled with the requirement that "the master of a ship destined for a U.S. port . . . report immediately to the quarantine station . . . the occurrence, on board, of any death or any ill person among passengers or crew." 42 C.F.R. 71.21.

“arriving carrier,” the measures appearing in both regulations and the history of conditioning pratique demonstrate CDC’s authority to implement pointed, discrete, and temporary measures. CDC cites no historical precedent in which the federal government detained a fleet of vessels for more than a year and imposed comprehensive and impossibly detailed “technical guidelines” before again permitting a vessel to sail. That is, CDC cites no historical precedent for, in effect, closing an entire industry. The closest historical antecedent CDC identifies (perhaps in jest) is a former ban on baby turtles with a shell less than four inches wide. First Preliminary Injunction Hearing, at 60–61. Thus, although CDC enjoys the authority to temporarily detain a vessel and to condition pratique, that authority is not boundless. The authority extends to and serves other measures, which look a lot like those specified in Section 264(a): “inspection, fumigation, disinfection, sanitation, pest extermination, [and] destruction of animals or articles.”

Both text and history confirm that the conditional sailing order exceeds the authority granted to CDC by Section 264(a). And if Section 264 fails to confer the statutory authority for the conditional sailing order, the regulations implementing Section 264 can grant no additional authority. *See Nat’l Petroleum Refiners Ass’n v. F.T.C.*, 482 F.2d 672, 674 (D.C. Cir. 1973) (“The extent of [the Federal Trade Commission’s] powers can be decided only by considering the powers Congress specifically granted it in the light of the statutory language and background.”); *Civ. Aeronautics Bd. v. Delta Air Lines, Inc.*, 367 U.S. 316, 322 (1961) (“[T]he determinative question is not what the Board thinks it should do but what Congress has said it can

do.”). Even if the statutes and regulations did somehow grant the expansive authority claimed by CDC, such a broad grant of authority would present a slew of other legal issues.

4. Ratification

In a supplemental memorandum (filed after the first hearing), CDC argues (Doc. 72) that Congress ratified the conditional sailing order by passing the Alaska Tourism Restoration Act, Pub. L. No. 117-14, 117th Cong. (May 24, 2021), which removes a restriction imposed by the Passenger Vessel Services Act, 46 U.S.C. § 55103, prohibiting a foreign-flagged cruise ship (that includes most cruise ships) from sailing from a U.S. port to another U.S. port unless the cruise ship stops in transit at a foreign port. 50 Fed. Reg. 26,961, 26,982 (July 1, 1985). Because Canada currently bars a foreign-flagged cruise ship’s entering a Canadian port, a foreign-flagged cruise ship intending to sail between Alaska and Washington cannot comply with the Passenger Vessel Services Act. (Doc. 46-11) The Alaska Tourism Restoration Act creates a temporary and narrow exception allowing a foreign-flagged cruise ship to sail between Alaska and Washington without violating the Passenger Vessel Services Act. The Alaska Tourism Restoration Act defines as a “covered cruise ship” a foreign-flagged cruise ship that “has been issued, operates in accordance with, and retains a COVID-19 Conditional Sailing Certificate of the Centers for Disease Control and Prevention.”

Arguing that — by mentioning the conditional sailing certificate in the Alaska Tourism Restoration Act — Congress has confirmed that CDC has the statutory

authority to issue a COVID-19 conditional sailing certificate, CDC correctly contends that “Congress ‘has the power to ratify the acts which it might have authorized’ in the first place, *Thomas v. Network Sols., Inc.*, 176 F.3d 500, 506 (D.C. Cir. 1999) (quoting *United States v. Heinszen & Co.*, 206 U.S. 370, 384 (1907)), “and give the force of law to official action unauthorized when taken,” *Swayne & Hoyt v. United States*, 300 U.S. 297, 301–02 (1937). But Congress must speak clearly to expressly ratify agency action. *Heinszen*, 206 U.S. at 390.

Here, Congress has not expressly ratified CDC’s “interpretation of its own authority” to issue a COVID-19 conditional sailing order. (Doc. 72 at 4) Rather, the Alaska Tourism Restoration Act identifies the category or class of ships exempt temporarily from the Passenger Vessel Services Act. Identifying the class of ships to which a statute grants a benefit is far different from — and much less than — expressly ratifying an agency’s authority to issue a certificate, the holders of which constitute the affected category or class. If Congress intended to ratify an interpretation of Section 264 that authorizes CDC to impose the restrictions governing a COVID-19 conditional sailing certificate, Congress “would have explicitly so declared.” *Heinszen*, 206 U.S. at 390; *Hannah v. Larche*, 363 U.S. 420, 439 (1960) (finding that “mere acquiescence” cannot substantiate express congressional ratification); *Network Sols., Inc.*, 176 F.3d at 507 (D.C. Cir. 1999).

“Congressional acquiescence to administrative interpretations of a statute” is “[r]ecognized with extreme care.” *Solid Waste Agency of N. Cook Cty. v. U.S. Army Corps of Engineers*, 531 U.S. 159, 160 (2001); *Alabama Ass’n of Realtors v. United States*

Dep't of Health & Hum. Servs., 2021 WL 1779282, at *9 (D.D.C. 2021). Congress must show its “extensive awareness of the interpretation to which it had allegedly acquiesced.” *Schism v. United States*, 316 F.3d 1259, 1289, 1295–96 (Fed. Cir. 2002) (citing cases). The Alaska Tourism Restoration Act — spanning about three pages — offers little, if anything, to demonstrate that Congress understood CDC’s broad interpretation of Section 264, the conditional sailing order, or the series of implementing orders. (Doc. 72 at 3) The Alaska Tourism Restoration Act provides that the exemption to the Passenger Vessel Services Act “shall not apply to a roundtrip voyage” if the CDC directors issued “an order under [42 U.S.C. §§ 264 and 268] that requires covered cruise ships to suspend vessel operations,” in other words, if a ship is unauthorized to transit between U.S. ports. A mention of a conditional sailing certificate or whether a ship is unauthorized to sail — as a convenient means of identifying the targeted class of ships — falls well short of ratifying the conditional sailing order or endorsing CDC’s expansive interpretation of Section 264. More to the point, the Alaska Tourism Restoration Act aims to permits ships to sail without unintended impediment. *Cf. Bob Jones Univ. v. United States*, 461 U.S. 574, 595, 600–01 (1983) (finding implied ratification because Congress “had held hearings on this precise issue.”); *North Haven Bd. of Educ. v. Bell*, 456 U.S. 512, 535 (1982); *Dames & Moore v. Regan*, 453 U.S. 654, 686, (1981).

Further, Congress cannot ratify an interpretation of a statute that violates the Constitution, including an unconstitutional delegation of legislative authority, which Florida alleges (Count V). *Heinszen*, 206 U.S. at 384; *E.E.O.C. v. CBS, Inc.*, 743 F.2d

969, 974 (2d Cir. 1984) (requiring Congress to ratify by “explicit action, especially in areas of doubtful constitutionality.”). For these reasons and for many of the reasons stated by Florida, the Alaska Tourism Restoration Act falls short of ratifying CDC’s interpretation of Section 264(a).

5. Non-Delegation Doctrine

Again, the enabling statute at the core of the present dispute, 42 U.S.C. § 264(a) states:

(a) **Promulgation and enforcement by Surgeon General**

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

The first sentence grants to CDC authority to “make and enforce such regulations as in his judgment are necessary” to combat “the spread of communicable diseases.” The first sentence says nothing about the means of enforcement. The second sentence of Section 264 grants authority for “carrying out and enforcing such regulations.”

Although this order decides otherwise for the purpose of the pending motion, this portion of the order assumes that the “other measures” term is not cabined by

the balance of the listed remedies and that “other measures” means whatever the CDC director’s discretion finds “necessary,” the interpretation advanced by CDC.

CDC characterizes the statute as containing “capacious” terms that are “especially broad,” “exud[ing] flexibility and deference to the judgment of the public health experts at the CDC.” (Doc. 31 at 27–28) More specifically, CDC insists that “the broad grant of authority in the first sentence of § 264 is not confined to the specific intrusions on private property described in the second sentence.” CDC concludes in the single paragraph of the response addressing non-delegation, “Plaintiff’s non-delegation challenge here easily fails.” (Doc. 31 at 43)

At the first hearing on the preliminary injunction, counsel for CDC was asked to identify the outer boundary on CDC’s authority under Section 264(a). Although the exchange consumes several pages of the transcript and wanders a bit (Doc. 47 at 81–87), counsel for CDC was either unable or unwilling to specify any remedial or preventative measure that was beyond the authority of CDC, assuming only two findings by CDC:

Q: Is there some bound to . . . your authority?

A: Yes. At a bare minimum, the CDC needs to be making a finding that there is a risk of the interstate or international transmission of the disease at issue. So that’s one very important bound, and they have to find that the measures are necessary to control it.

(Doc. 47 at 81–82) But that response from CDC’s counsel answered the question only to the extent of identifying the conditions precedent to CDC’s exercise of authority and omitted the more revealing answer that might explain the outer bound

of the enforcement measures CDC can impose consequent on the two identified findings by CDC.

During further questioning, counsel for CDC maintained that CDC could indefinitely shut down an industry, such as the airline industry and other “conveyances of interstate and international travel during an emergency in which those specific conveyances as a category were found to pose a risk of transmission.” (Doc. 47 at 82–83) (Note the term “a risk of” transmission and not the term, for example, “a history of” or “an outbreak of” transmission.) CDC simultaneously claimed that CDC, subject to the two “findings,” could issue an order to “shut down transportation in general” in the United States, subject only to a challenge in court based on a claim that the order was “arbitrary and capricious.” But CDC in that prospective litigation would remain shielded by the persistent administrative claim to “deference,” which the judiciary manufactured and in which the judiciary persists.

Another question was this: If the president hadn’t restricted air travel in early 2020 (“very prominent people in government said the president shouldn’t have done it”) and “had come out and said ‘I won’t do it,’” can the director of CDC announce the next day, ‘Well, I’m going to do it.’” CDC’s counsel (I say this respectfully) tiptoed a bit around the question and this was the result:

Q: . . . [I]f the President of the United States said, I refuse to stop airline flights back and forth from – where was it – Europe and China and maybe some other places and the CDC director could come out or HSS secretary could come out the next day and say, Well, I’m going to do it under this authority.

A: [They] just might have some compelling arbitrary [and] capricious arguments in that case.

Q: And they would be – they would be subject to litigation.

....

A: But again, all of that goes to sort of the outer limits of what the CDC can do. What the CSO does –

Q: Well, I'm trying to get to the point of what the outer limit is, and you just say it's just what they find necessary.

A: Yes, I think that's correct. There are –

Q: Which means it's not identifiable.

A: Well, it means that it's flexible based on discretion intentionally conferred upon the Secretary with these specific kinds of findings, right? It is intended to be flexible language. Congress knows how to legislate broadly and how to do so narrowly. They legislated broadly here.

(Doc. 47 at 86–87)

At the second hearing on the preliminary injunction, additional questions were asked to CDC about the bounds of CDC's authority. An ever-broader interpretation emerged. The questions, assuming an irreducible minimum of risk exists in every aspect of human life, were directed to identifying the level of risk for the transmission of disease that CDC would permit if the cruise industry achieved that level and resumed "safe" sailing (understanding "safe" to mean sailing at or below the "acceptable" risk as defined by CDC).

Q: What intelligible principle was conveyed to the CDC by the statute to guide the CDC in determining the level of risk or the degree of transmission that was acceptable before constraining interstate and international travel by a common carrier?

A: The – the interstate and international transmission, the requirement of necessity in the secretary’s judgment, those are meaningful limits, those are intelligible principles on how the CDC can set the risk level.

And they’re judicially reviewable to as a matter of – of, uh, under – under the APA courts can consider that. But whether or not the risk that is reasonable and consistent with the evidence, that is not, uh, the statute –

Q: You think necessary is an intelligible principle?

A: It – combined with the other language in the statute, yes.

. . . .

Q: The point here is you’ve agreed with me two or three times that in – in practicality we can’t guarantee a zero. Uh, this is a virus that’s loose in the world, and there are other viruses loose in the world and you’ve spent a good deal of time pointing out that there may be variations and mutations of this virus loose in the world about which we don’t know yet.

And we’ve all agreed throughout the day that we have some risk always in whatever we do. And the question that I’m asking, which I think is implicit at least in one major component of this case is, has Congress conveyed an intelligible principle to guide the CDC in determining when and under what circumstances to intervene in . . . what [Justice] Kavanaugh might call a major policy decision?

A: I think that listening to you explain the point, I think I would probably say that CDC has the authority given by Congress to legislate up to eliminating the risk. It’s not an option here, it’s a factual matter. But their legal authority extends that far, and where they draw the line is a question of how they find the facts and –

Q: It’s up to them, right?

A: It – well, their legal authority goes all the way to getting transmission to zero. Right? Ha. Just because that’s not factually an option doesn’t mean that they don’t have the legal authority to try.

(This exchange extended over several minutes (Doc. 89 at 104–110), and this segment is an edited — a fairly edited — compaction.)

In sum, defining “transmission” as a single human-to-human infection, CDC claims authority to impose nationwide any measure, unrestrained by the second sentence of Section 264(a), to reduce to “zero” the risk of transmission of a disease — all based only on the director’s discretionary finding of “necessity.” That is a breathtaking, unprecedented, and acutely and singularly authoritarian claim.

One is left to wonder, given the persistent risk of transmission of a communicable disease and, in fact, the frequent, debilitating, and sometimes deadly history of transmission of a communicable disease, whether the director of CDC could have — or, perhaps, should have — generally shut down sexual intercourse in the United States or, at the very least, imposed in accord with Section 264(a) strict requirements for inspection, disinfection, sanitation, and “other measures, as in his judgment may be necessary” to reduce to “zero,” for example, the human-to-human transmission of AIDS or syphilis or herpes. Political prudence (and difficulty of enforcement) might counsel CDC against this particular prohibition, but the statute, as understood by CDC, certainly erects no barrier.

Also, one is left to wonder whether Congress could rid itself of the burdensome income tax issue by enacting a law commanding the Commissioner of the Internal Revenue Service in his discretion to “collect tax at a fair rate as the commissioner finds necessary” and stating that the rate “must be no more or less than required to pay for necessary and beneficial public programs especially for the

poor, the disabled, those with special needs, and others needful of public support; must be disproportionately or unfairly burdensome to neither the poor nor the rich but reach all those able to pay; must not be so great as to depress productive and publicly desirable economic activity or to deter individual initiative but must touch each aspect of gainful economic activity; and must be calculated to enhance economic growth and technological advancement without favorable treatment for the rich or powerful.” This hypothetical directive to the IRS says, in so many words “You do it, but do it right!” This hypothetical revenue code neither prescribes or prohibits any particular tax or tax rate on anyone or any entity and, although containing some happy aspirational words, contains no effective “intelligible principle” for establishing a regime of taxation, although this hypothetical revenue code contains much more than Section 264(a), as understood by CDC.

CDC claims a remarkable and generally unbounded power of the director of CDC to act athwart the president; to close industries; to restrict the movement of citizens in an out of their country, their state, their county, and city, and their home. And recent history demonstrates that the power of the director of CDC, unless and until corrected by the judiciary, can oust the ability of a state to exercise the police power — all without formal notice and comment from the public and continuing from year-to-year.

Florida argues in Section 1(b) of the motion for preliminary injunction that “[i]f the Conditional Sailing Order does not exceed the authority under § 264 and the relevant regulations, then § 264 and those regulations constitute an unconstitutional

exercise of lawmaking by the executive branch.” (Doc. 9 at 20) Florida cites in support only *Tiger Lily, LLC v. United States Dep’t of Health and Human Services*, 992 F.3d 518 (6th Cir. 2021), which notes in passing that the “broad construction” of Section 264 “raises not only concerns about federalism, but also concerns about the delegation of legislative power to the executive branch.” Of course, *Tiger Lily* rejects the “broad construction” and, as a result, the court’s comment about “delegation of legislative power to the executive” remains merely an interesting and mildly provocative aside.

This order earlier rejects the “broad construction” but, especially in consideration of the somewhat conflicting opinions on the proper construction of the statute, this order must determine alternatively Florida’s likelihood of success in the non-delegation challenge if CDC’s “broad construction” of Section 264(a) prevails. Although accounts of the non-delegation doctrine — the constitutional prohibition against congressional delegation of legislative power to an executive agency — are many and familiar, a brief summary of the most conspicuous precedents, incomplete but illustrative, might clarify.

Except for a quick and ambiguous dispute in *The Brig Aurora*, 11 U.S. 382 (1813), and a few similar cases, the Supreme Court spoke only rarely about legislative delegation until the early twentieth century when the administrative state began to surge and cases appeared such as *Buttfield v. Stranahan*, 24 S. Ct. 349 (1904), in which Congress authorized the Secretary of the Treasury to promulgate regulations to exclude importation into the United States of “the lowest grades of

tea.” The Secretary, of course, promptly created a “board of tea experts” to “prepare and submit to him standard samples of tea” so that he could “fix and establish uniform standards.” 24 S. Ct. at 354. An unfortunate importer of tea challenged the Secretary and claimed that “such power is legislative and cannot constitutionally be delegated by Congress to administrative officers” 24 S. Ct. 353. Rejecting that argument, Chief Justice White wrote:

[T]he statute, when properly construed, as said by the circuit court of appeals, but expresses the purpose to exclude the lowest grades of tea, whether demonstrably of inferior purity, or unfit for consumption, or presumably so because of their inferior quality. This, in effect, was the fixing of a primary standard, and devolved upon the Secretary of the Treasury the mere executive duty to effectuate the legislative policy declared in the statute.

24 S. Ct. 355. Relying on Congress’s “fixing of a primary standard,” *Buttfield* vindicates the constitutionality of the congressional delegation of authority. *Buttfield* echoes *The Brig Aurora*’s discussion of Congress’s ability to delegate to the president the power to forfeit cargo if he declared the existence of certain congressionally stated facts that were a *sine qua non* of his authority.

A similar result appears in *United States v. Grimaud*, 31 S. Ct. 480 (1911), which finds that “it was impracticable for Congress to provide general regulations for these various and varying details of [forest] management” and which permits an agency “the power to fill up the details,” including criminal penalties. Searching for some boundary to delegation, *Grimaud* remarks that agencies must “confin[e] themselves within the field covered by the statute,” which in *Grimaud* was eliminating from navigation “unreasonable obstructions arising from bridges of insufficient height,

width of spur, or other defects.” Citing *Marshall Field & Co. v. Clark*, 12 S. Ct. 495 (1892), *Grimaud* suggests that, although the principle that “Congress cannot delegate legislative power is a principle universally recognized,” Congress:

can make a law to delegate a power to determine some fact or state of things upon which the law makes or intends to make its own action depend. To deny this would be to stop the wheels of government. There are many things upon which wise and useful legislation must depend which cannot be known to the lawmaking power, and must therefore be a subject of inquiry and determination outside of the halls of legislation.

Based on the “impracticality” of Congress’s managing particulars, *Grimaud* seems to authorize Congress to empower an agency to implement a congressional policy by “determin[ing] some fact or some state of things upon which the law makes or intends to make its own action depend,” a formulation that again echoes *The Brig Aurora* and *Buttfield*.

Mahler v. Eby, 44 S. Ct. 283 (1924), discusses a delegation by Congress to the Secretary of Labor to determine the categories of persons subject to deportation as “undesirable residents of the country,” that is, persons who were not “of good character, attached to the principles of the Constitution of the United States, and well disposed to the good order and happiness of the same.” *Mahler* next announces a premise that jolts a reader in 2021 but that served as the convenient mechanism used at the time to evade the law of legislative non-delegation:

Our history has created a common understanding of the words “undesirable residents” which gives them the quality of a recognized standard.

In other words, Congress ordered the deportation of “undesirable residents” and the Secretary of the Treasury complied, putatively informed by the historical and “common understanding” of who exactly is an “undesirable.” (Surely a reasonable person ought to experience discomfort if considering whether a grant of power over people’s lives based on a presumed “common understanding” of who is an “undesirable” — or perhaps, more recently, a “subversive” or a “radical” or a “deplorable” — is too great a license in a constitutional republic.)

Not long after *Grimaud* and *Mahler* and amid the turbulence of The Great Depression and the accompanying and aggressive implementation of the New Deal, the so-called “non-delegation doctrine” reached a zenith in *Panama Refining Co. v. Ryan*, 55 S. Ct. 241 (1935) (invalidating a delegation of power to “eliminate unfair competitive prices” and “to conserve natural resources”), and *A.L.A. Schechter Poultry Corp. v. United States*, 55 S. Ct. 837 (1935) (invalidating a delegation of power “to eliminate unfair competitive prices, to promote the fullest possible utilization of the present productive capacity of industries, and otherwise to rehabilitate industry”). Several legal scholars and historians and the Supreme Court confirm that *Panama Refining* and *Schechter Poultry* are the only two instances of a federal statute’s invalidation based on an unconstitutional delegation of legislative authority.

But sentiment abruptly pivoted on the Supreme Court after *Panama Refining* and *Schechter Poultry*. Legal and other historians still debate why the pivot occurred. But for the present purpose, no more is necessary than to note, for example, that *National Broadcasting Co. v. United States*, 63 S. Ct. 997 (1943), upholds a delegation to

the Federal Communications Commission to regulate broadcasting to further the “public interest, convenience, or necessity.” In eight years, the non-delegation doctrine transformed from “universally recognized” and governing constitutional law to a ritual, meek recitation.

Concurring in *Industrial Union Dept. v. American Petroleum Institute*, 100 S. Ct. 2844 (1980), and dissenting with Chief Justice Burger in *American Textile Manufacturers Institute v. Donovan*, 101 S. Ct. 2478 (1981), Justice Rehnquist attempted to stimulate interest in a renewal of limits on delegation, but the effort came to nothing. The non-delegation doctrine was decidedly inert after *Whitman v. American Trucking Associations, Inc.*, 121 S. Ct. 903 (2001); *Loving v. United States*, 116 S. Ct. 1737 (1996); *Touby v. United States*, 111 S. Ct. 1752 (1991); *Skinner v. Mid-America Pipeline Company*, 109 S. Ct. 1726 (1989); and similar decisions.

From the earliest days of the United States the federal courts have affirmed the existence of the non-delegation doctrine but neither formally abandoned nor fully (or even earnestly) formulated and enforced non-delegation in practice. Apparently the present requirement, if any, for Congress to avoid an unconstitutional delegation — the best available summary phrase, which echoes *J.W. Hampton, Jr., & Company v. United States*, 276 U.S. 394, 409 (1928) — is that no unlawful delegation of legislative authority occurs if Congress statutorily states an “intelligible principle” on which to judge the conformity of agency action to the congressional grant of power.

However, a reasonable and telling question is whether the simple phrase “intelligible principle” effectively conveys any intelligible principle by which to judge a

delegation. Both “be fair” and “do right” convey, at least abstractly, an “intelligible principle” but neither conveys substance (other than “don’t be unfair” and “don’t do wrong”) because to use ethereal terms such as “fair” and “right” is merely to re-state succinctly the governing conundrum: What is fair? What is right? What is needed to accomplish either or both?

More recently, *Gundy v. United States*, 139 S. Ct. 2116 (2019), considers whether the Sex Offender Registration and Notification Act’s grant of authority to the Attorney General exceeds the bounds permitted by the Constitution, as expressed in the non-delegation doctrine, a constitutional imperative given the content of Article I of the Constitution. With only eight justices participating, the Supreme Court sustained the statute but in an atypical manner. Four justices endorsed the statute; two justices joined Justice Gorsuch in dissent. Justice Alito, in a brief concurrence “in the judgment” but not in the plurality opinion, found that the plurality opinion must govern, based on existing precedent and absent a full court able to revisit authoritatively and modify or reverse existing precedent. In sum, Justice Alito signals in *Gundy* his agreement in whole or in part with the dissenters on the merits but remained bound by his view of the force of precedent to vote consistent with that precedent until overturned.

Justice Kavanaugh took no part in the consideration or decision of *Gundy*, although in a dissent from a denial of certiorari in *Paul v. United States*, 140 S. Ct. 342 (2019), Justice Kavanaugh signals at least a need to re-visit the Supreme Court’s precedent on non-delegation and apparently signals agreement in whole or in part

with Justice Gorsuch's dissent and Justice Rehnquist's earlier dissents. Of course, in the interim, Justice Barrett has replaced Justice Ginsburg, a member of the plurality in *Gundy*.

Justice Gorsuch's dissent re-states that "[t]he Constitution promises that only the people's elected representatives may adopt new federal laws restricting liberty." 139 S. Ct. 2131. Part II of Justice Gorsuch's opinion begins with a recapitulation of the constitutional design and purpose of the branches of government, expounds the court's precedent on non-delegation (more fully and ably than the summary in this order), responds to some popular objections to non-delegation, and concludes by marshalling the salient features of a sound rule of non-delegation.

Justice Gorsuch emphasizes that "laws" promulgated by executive and administrative actors are not "few in number," not "the product of widespread social consensus," not "likely to protect minority interests," and not "apt to provide stability and fair notice." 139 S. Ct. at 2135. Further, Justice Gorsuch emphasizes the political accountability that is a signal attribute of a constitutional republic:

And if laws could be simply declared by a single person . . . [l]egislators might seek to take credit for addressing a pressing social problem by sending it to the executive for resolution, while at the same time blaming the executive for the problems that attend whatever measures he chooses to pursue. In turn, the executive might point to Congress as the source of the problem. These opportunities for finger-pointing might prove temptingly advantageous for the politicians involved, but they would also threaten to " 'disguise ... responsibility for ... the decisions.' "

139 S. Ct. at 2135.

Further, Justice Gorsuch wisely and strongly insists on the irreplaceable role of each Article III judge to enforce diligently the distinction between the executive branch and the legislative branch, a distinction on which the maintenance of a constitutional republic depends:

The framers knew, too, that the job of keeping the legislative power confined to the legislative branch couldn't be trusted to self-policing by Congress; often enough, legislators will face rational incentives to pass problems to the executive branch. Besides, enforcing the separation of powers isn't about protecting institutional prerogatives or governmental turf. It's about respecting the people's sovereign choice to vest the legislative power in Congress alone. And it's about safeguarding a structure designed to protect their liberties, minority rights, fair notice, and the rule of law. So when a case or controversy comes within the judicial competence, the Constitution does not permit judges to look the other way; we must call foul when the constitutional lines are crossed. Indeed, the framers afforded us independence from the political branches in large part to encourage exactly this kind of "fortitude ... to do [our] duty as faithful guardians of the Constitution."

139 S. Ct. at 2135.

Along with the Chief Justice and Justices Thomas, Alito, and Kavanaugh, Justice Gorsuch is manifestly dissatisfied with "the intelligible principle misadventure" or, at least, "this mutated version of the 'intelligible principle'" doctrine, with which only three justices seem content. That bodes ill for the "intelligible principle misadventure." Accordingly, Justice Gorsuch proposed some components, in the form of questions, that describe a better and more effective device to preserve the constitutional arrangement and the correspondent protections identified by Justice Gorsuch:

To determine whether a statute provides an intelligible principle, we must ask: Does the statute assign to the executive only the responsibility to make factual findings? Does it set forth the facts that the executive must consider and the criteria against which to measure them? And most importantly, did Congress, and not the Executive Branch, make the policy judgments? Only then can we fairly say that a statute contains the kind of intelligible principle the Constitution demands.

139 S. Ct. at 2141.

Justice Gorsuch’s opinion raises constitutional principle above agency self-interest, political expediency, congressional inconvenience, and unwarranted and risky deference to a select cohort of agency “experts.” (Anyone familiar with the “dueling experts” of litigation, with conflict among experts during debates in other public forums, or with history, especially recent history, must regard with skepticism the consistency, reliability, and independence of experts.)

Justice Gorsuch prefers to rely on the constitutional framework, informed and advised by both experts and others, to resolve the main lines of public policy and the overall management of the nation, which presents issues that require balancing both expert opinion and other irreplaceable components, including public opinion, public risk, public cost and public benefit, constitutional norms, and other national values over which an expert or an administrator or an agency staff has no greater power to decide correctly than the informed opinion of the people’s elected representatives, including the president, who is one of only two officeholders (along with the vice-president) elected by the nation as a whole.

The intractable confusion resulting from phrases such as “common understanding,” “intelligible principle,” and the others, is such that capable and

reputable modern scholars can maintain simultaneously that the “non-delegation doctrine” is unjustified by, and unknown to, the Constitution, *see, e.g.*, Eric A. Posner and Adrian Vermeule, *Interring the Non-Delegation Doctrine*, 61 U. CHI. L. REV. 1721 (2002), while others maintain equally staunchly that the whole of legislative delegation and the resulting administrative state is ahistorical and unconstitutional, *see, e.g.*, PHILIP HAMBURGER, *IS ADMINISTRATIVE LAW UNLAWFUL?* (Univ. of Chicago Press, 2014).

But more specifically, in the few years between *Butterfield* and the present, the law of the United States on non-delegation has changed — by a series of small increments justified by increasingly attenuated inferences — from a lively argument about whether Congress can bestow on an executive agent the power, for example, to forfeit, as a prohibited cargo, low “cup quality” teas, such as “Country green teas,” to an argument in the present about whether Congress, based on an ambiguous sentence or two in a statute, can bestow on an executive agent the power indefinitely to halt the operation of, and perhaps destroy, an entire industry or several industries or perhaps the industries of the entire nation, destroy businesses and lives dependent on industry, halt the movement of citizens within the nation, halt anyone’s entering or exiting the nation or entering or exiting any or all of the states, halt public gatherings, including religious services, regardless of purpose, or otherwise alter the course, history, prosperity, and health of the nation and the balance of governmental authority — legislative and executive, federal and state, state and local — throughout the nation.

During the scores of years of litigation about non-delegation, the Constitution, that is, the organic grant of power from the sovereign people and the sovereign states to the federal government, has changed in no manner pertinent to non-delegation, but the rulings of the Supreme Court and the lower federal courts, themselves components of the federal government and immediately dependent on Congress for support and continuity, have changed relentlessly and have allowed a more encompassing and increasingly amorphous delegation to the administrative state of the power to command and coerce the citizenry. Courts have allowed an increasing hegemony to the unelected, electorally unaccountable, and largely anonymous executive agents, comfortably housed in one of many formidable edifices in Washington, D.C., or in a regional office, and doing who knows what, for who knows what reason, and at who knows whose instigation — but always answering to no one (at least, no one that the citizenry can perceive) and always reliably defended in their pronouncements by a legion of lawyers, staff, consultants, experts, and others, as well as litigious special interest entities.

From *The Brig Aurora* to now, no court has failed to affirm the apparently self-evident proposition that Congress cannot delegate the power to legislate, but at the same time no court, excepting for a moment in the 1930s, has detected the forbidden but always elusive unconstitutional delegation of legislative authority, regardless of the ambiguity or expanse of the grant of authority. As a result, the power of the executive agencies has expanded exponentially. The federal courts have stood by

quiescently as the structure and theory of government that is explicit in the Constitution has mutated and deformed.

In a letter to Nathaniel Macon on October 20, 1821, Thomas Jefferson wrote:

Our government is now taking so steady a course as to show by what road it will pass to destruction, to wit, by consolidation first; and then corruption, it's necessary consequence. The engine of consolidation will be the Federal judiciary; the two other branches the corrupting and corrupted instruments.

Jefferson is not yet proven wrong.

The question remains as to the best means to determine whether legislation has exceeded the permissible boundary of delegation. Perhaps a few elemental questions, in concert with those identified by Justice Gorsuch, point toward an answer. For example, can Congress, the president, and the court ascertain from the statute at the time of enactment (1) the scope of the regulatory power granted to the agency, including the range of activity subject to regulation; (2) the circumstances in which an activity becomes subject to regulation and for how long; (3) the extent to which and the duration for which the agency — without congressional approval — can constrain liberty and alter human conduct and industry; and (4) the extent of any remedial authority, including the power to suspend, terminate, prohibit, enjoin, or compel an activity or to fine, imprison, or otherwise coerce any person? Also, can the Congress, the president, and a court ascertain whether any stated activity or person is definitely outside the statute and beyond the scope of the grant of regulatory power to the agency, that is, whether a stated activity or actor is not subject to regulation, remedy, and punishment by the agency?

These questions are essential because, in practice, law is force, a legitimate and formalized means of command and coercion, both of which are organically and structurally bounded in a constitutional republic. If Congress cannot specify what force — what power to command and coerce — is invested in an agency by a statute, Congress perforce has bestowed on an agency the power to decide for itself, unbound by legislative directive, the nature and scope of the agency's power to deploy force, that is, to command and coerce. Forbidding that sort of delegation seems the least that is required by, and the least that is unmistakably implicit in, the Constitution's bestowing the entire legislative power on the legislative branch. Again, the legislative power is the government's power to command and coerce; the party, however denominated or arrayed, who determines the scope and extent of the power to command and coerce is the party who exercises the legislative power.

Without the elemental distinctions, including the separation of powers, prescribed in the Constitution, what remains is neither constitutional nor a republic. The administrative state is nowhere expressed or adumbrated in the Constitution, which grants the entire legislative power to elected representatives, whom the Constitution contemplates will govern in fact and for their governing remain electorally accountable to those who selected and empowered them. Unaccountable administrative law, unbounded by ascertainable directives from the legislative branch, is not the product of an ascendant and robust constitutional republic.

John Hart Ely in *Democracy and Distrust* (Harvard University Press 1980), discussed overly broad delegations to the executive:

Now this is wrong, not because it isn't "the way it was meant to be" — in some circumstances there may be little objection to institutions trading jobs — but rather because it is undemocratic, in the quite obvious sense that by refusing to legislate, our legislators are escaping the sort of accountability that is crucial to the intelligible functioning of a democratic republic.

. . . .

There can be little point in worrying about the distribution of the franchise and other personal political rights unless the important policy choices are being made by elected officials. Courts thus should ensure not only that administrators follow those legislative policy directions that do exist — on that proposition there is little disagreement — but also that such directions are given.

Ely explained succinctly the nature of unbounded administrative lawmaking and the danger of elected legislators avoiding focused work on policy (to focus on spending) and avoiding accountability by diverting responsibility to the administrative agencies. Ely dismissed the transparent excuse that regulatory subjects are too varied, technical, and complex to permit "detailed legislative instructions." Ely's answer is the obvious fact that Congress can summon the same or more resources than an agency, including the agency's staff, experts, and the like. Of course, many arrangements are available other than the false and insidious dichotomy of (1) no administrative agencies or (2) unbounded delegation to an administrative agency. As Ely states, "Policy direction is all that was ever required, and policy direction is what is lacking in much contemporary legislation."

If Section 264(a) conveys to the director of CDC the authority that CDC claims in this action to support the conditional sailing order and the implementing requirements, Section 264(a) fails the "intelligible principle" test and unconstitu-

tionally delegates legislative authority to the director of CDC. The better interpretation is the narrow interpretation advanced by Florida; failing that, the statute goes too far.

B. Count II and Count III

Florida argues that the conditional sailing order is arbitrary and capricious and that CDC failed to provide notice and comment.³⁹ CDC insists that the conditional sailing order exhibits “reasoned decisionmaking” that reflects “public health judgments made in the midst of a deadly global pandemic.” (Doc. 31 at 32) Also, CDC insists that CDC was “not required to conduct notice-and-comment rulemaking to condition a license or enter an order under existing regulations during the pendency of a global public health emergency.” (Doc. 31 at 4) Resolution of these issues requires a preliminary characterization of the conditional sailing order.

1. Whether the Conditional Sailing Order Qualifies as a Rule

CDC maintains that “the challenged agency action is an order, not a rule,” and the conditional sailing order disclaims status as “a rule within the meaning of the APA.” (Doc. 31 at 40; Doc. 1-3 at 19) Instead, CDC identifies the conditional sailing order as “a declaratory order conditioning free pratique, which is a license.” By contrast, Florida argues that the conditional sailing order “is a legislative rule because it creates new legal duties.” (Doc. 56 at 13)

³⁹ Because this order holds that the conditional sailing order exceeds CDC’s authority, Florida’s other APA arguments will receive abbreviated treatment.

“Rule” is defined in 5 U.S.C. § 551(4) as “the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law.” Decisional authority lends clarity to the statutory definition. To constitute a final rule, an agency’s action “must mark the consummation of the agency’s decisionmaking process” and the action must either determine “rights or obligations” or constitute action from which “legal consequences will flow.” *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997) (quoting *Port of Bos. Marine Terminal Ass’n v. Rederiaktiebolaget Transatlantic*, 400 U.S. 62, 71 (1970)).

Franklin v. Massachusetts, 505 U.S. 788, 798 (1992), for example, finds no agency action when the Secretary of Commerce presents a report to the President because the report both imposes “no direct consequences” and functions “more like a tentative recommendation.” By contrast, in *Nat’l Ass’n of Home Builders v. U.S. Army Corps of Engineers*, 417 F.3d 1272 (D.C. Cir. 2005), several trade associations contested the Army Corps of Engineers’ issuance of nationwide permits. The Corps attempted to disclaim the disputed permit as rulemaking action “because it fit[] the APA’s definition of adjudication as the formulation of an ‘order,’” which “includes a ‘licensing’ disposition.” 417 F.3d at 1284. Nonetheless, the permits constituted final agency rules subject to judicial review because the permits “carr[ied] easily-identifiable legal consequences” and because the permits “create[d] legal rights and impose[d] binding obligations.” 417 F.3d at 1279.

Here, the conditional sailing order “creates new law, rights, or duties,” *Warshauer v. Solis*, 577 F.3d 1330, 1337 (11th Cir. 2009), including the duty to build

on-board laboratories for testing; the duty to comply with frequent reporting requirements; the duty to test crew and passengers; the duty to enter into agreements with ports, housing facilities, and medical care facilities; the duty either to complete a simulated voyage under extensive regulation or to mandate near-total vaccination of crew and passengers; the duty to implement testing and outbreak protocols; and the duty to apply for, and maintain, a conditional sailing certificate. (Doc. 31 at 30) A vessel operator must satisfy each of these requirements as a prerequisite to restricted sailing,⁴⁰ and if a vessel operator fails to satisfy the conditional sailing order's obligations or violates — even unintentionally — a mandate of the conditional sailing order, the conditional sailing order carries identifiable legal consequences, such as the prospect of criminal penalties, substantial fines, and suspension of sailing. (Doc. 1-3 at 20) The conditional sailing order serves as neither a tentative recommendation nor a suggested guideline nor a declaratory “final disposition”; the conditional sailing order carries the force of law and bears all of the qualities of a legislative rule.

Further, the conditional sailing order causes a “future effect” rather than a “retroactive effect,” *Safari Club Int’l v. Zinke*, 878 F.3d 316, 333 (D.C. Cir. 2017), and the conditional sailing order generally applies to cruise vessels as a class rather than to an individual vessel only. *Heckler v. Ringer*, 466 U.S. 602, 614 (1984) (emphasizing that the respondents “challenge [the Secretary’s] decision to issue a generally

⁴⁰ In this sense, the conditional sailing order “gives rise to legal rights.” *Manufactured Hous. Inst. v. U.S. Env’t Prot. Agency*, 467 F.3d 391, 398 (4th Cir. 2006).

applicable rule rather than to allow individual adjudication[.]”); *United States v. Fla. E. Coast Ry. Co.*, 410 U.S. 224, 246 (1973) (highlighting that the challenged portions of a tentative order “were applicable across the board to all of the common carriers[.]”); *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 219 (1988) (Scalia, J., concurring) (observing that the Attorney General interprets a rule to contain “future effect” and “general applicability”). Accordingly, the conditional sailing order’s prospective, generalized application invites the conclusion that the order is a “rule.”

Finally, CDC’s conduct demonstrates that CDC recognized that the conditional sailing order is a rule. CDC published in the federal register a proposal to issue a regulatory framework, invited and (ostensibly) considered comments, promulgated the conditional sailing order with some explanation of CDC’s decision, and noted the category of rule — a major rule — under which the conditional sailing order would fall if the conditional sailing order qualified as a rule. Each of these actions, taken together, suggests that CDC “set out with a lawmaking pretense.” *United States v. Mead Corp.*, 533 U.S. 218, 233 (2001).

In plain words, if it reads like a rule, is filed like a rule, is treated like a rule, and imposes the consequences of a rule, it’s probably a rule. *N. Carolina Growers’ Ass’n, Inc. v. United Farm Workers*, 702 F.3d 755, 765 (4th Cir. 2012) (finding an agency’s action to constitute rulemaking because “[s]imilar attempts by an agency ‘to comply with APA notice-and-comment procedures suggest that the agency believed them to be applicable,’ and support the conclusion that ‘those procedures were applicable.’”) (quoting *Manufactured Housing Inst. v. EPA*, 467 F.3d 391, 399 (4th Cir.

2006)). Because the conditional sailing order is a rule, CDC was obligated to follow the procedures applying to the promulgation of a rule (unless an exception applied), and the standards guiding review of the conditional sailing order derive from the reservoir of authority addressing legislative rules.

2. Whether the Conditional Sailing Order is Arbitrary and Capricious

Florida asserts that the conditional sailing order is arbitrary and capricious. (Doc. 9 at 14) To this end, Florida argues that CDC “ignored important aspects of the problem,” including development of vaccines and the success of foreign cruise companies, and Florida argues that CDC has provided no realistic opportunity for the cruising fleet to timely complete the four-phase “framework” described in the order. (Doc. 9 at 14–15)

CDC responds that no vaccines had received FDA approval when CDC issued the conditional sailing order, and in any event, CDC “has considered the availability of vaccines in devising and issuing its technical instructions and guidance to implement the [conditional sailing order.]” (Doc. 31 at 33–4) Further, CDC argues that, despite Florida’s grievances about actions “post-dating the conditional sailing order, they cannot be considered in evaluating the reasonableness of the [conditional sailing order].” (Doc. 31 at 34)

The APA empowers a district court to “hold unlawful and set aside agency action, findings, and conclusions found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C. § 706(2)(A). Although an agency’s action receives deference and a district judge enjoys no

authority to “substitute its judgment for that of the agency,” an agency’s action is characterized as “arbitrary and capricious if the agency . . . entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.” *Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

Both Florida and CDC attempt to cite post-conditional-sailing-order developments to undermine or support the validity of the conditional sailing order. But, as both parties acknowledge (Docs. 31 at 34; 56 at 3), “[i]t is a ‘foundational principle of administrative law’ that judicial review of agency action is limited to ‘the grounds that the agency invoked when it took the action.’” *Dep’t of Homeland Sec. v. Regents of the Univ. of California*, 140 S. Ct. 1891, 1907 (2020) (quoting *Michigan v. E.P.A.*, 576 U.S. 743, 758 (2015)). Thus, a proper review of the conditional sailing order’s “reasonableness” must disregard a change in circumstances occurring after the conditional sailing order’s announcement.

On this record (and disregarding later developments), Florida's likelihood of success on the merits of Counts II and III remains unclear.⁴¹ However, two features of the conditional sailing order suggest that the order is arbitrary and capricious.

⁴¹ For example, CDC's allowance of foreign travel and cruising, although a seemingly inconsistent oversight, fails to render the conditional sailing order arbitrary and capricious. *Mobil Oil Expl. & Producing Se. Inc. v. United Distribution Companies*, 498 U.S. 211, 214 (1991) (“[A]n agency need not solve every problem before it in the same proceeding.”); *Heckler v. Chaney*, 470 U.S. 821, 831–32 (1985). Further, the availability of vaccines is an example of a post-conditional-sailing-order development that appears to lack effect on the reasonableness of the conditional sailing order. The astounding and unprecedented rapidity with which vaccines were researched, developed, approved, and administered during 2020 has affected agency action afterward. But, when CDC issued the conditional sailing order on October 30, 2020, the U.S. Food and Drug Administration had yet to authorize a vaccine. (Doc. 1-3 at 8) Citing a September 2020 quote from then-CDC Director Robert Redfield, which acknowledges that vaccines were expected to receive approval by the end of the year, Florida argues that CDC failed to “consider the fact that vaccines would be available long before the Order expires in November 2021.” (Doc. 25 at 14) But the authorization and efficacy of vaccines remained uncertain when CDC issued the conditional sailing order, and the FDA did not authorize for emergency use any vaccine until December 11, 2020. 86 Fed Reg. 5200 (Jan. 19, 2021). Although CDC responded remarkably slowly to the availability and prevalence of vaccines, that tardiness is immaterial to the reasonableness of the conditional sailing order when issued. *Baltimore Gas & Elec. Co. v. Nat. Res. Def. Council, Inc.*, 462 U.S. 87, 103 (1983) (finding that when an agency makes “predictions, within its area of special expertise, at the frontiers of science . . . a reviewing court must generally be at its most deferential.”). Therefore, the conditional sailing order appears to be neither arbitrary nor capricious for failing to consider the presumably forthcoming availability of vaccines. *Auer v. Robbins*, 519 U.S. 452, 459 (1997).

Florida appears to face other temporal obstacles. For instance, Florida argues that CDC's “continuing to lock down the industry” fails to rationally comport with the conditional sailing order's finding that the “benefits of opening the cruise industry outweigh the costs of not allowing cruise ships to sail.” (Doc. 25 at 15) (internal quotation marks omitted). Further, Florida argues that the conditional sailing order employs an “all-or-nothing approach.” (Doc. 25 at 16) But again, attention to the timing of the conditional sailing order's promulgation is instructive. The conditional sailing order purports to provide a “framework” comprising four phases to resume sailing. The soundness of the reasoning in the conditional sailing order is unaffected by CDC's later delay or omission. At most, Florida appears to complain about CDC's months of inaction after issuance of the conditional sailing order; based on this, Florida can advance at most an unreasonable delay claim but not an “arbitrary and capricious” claim.

Finally, Florida's argument that CDC “rel[ies] on stale information from the beginning of the pandemic” is more persuasive. (Doc. 25 at 14–15) But the conditional sailing order incorporates by reference findings and evidence from the initial no-sail order, and the conditional sailing order cites research and data not appearing in the orders. For example, the conditional sailing order

(continued...)

First, the conditional sailing order imposes vague and indefinite rules subject to change. Throughout the conditional sailing order, CDC reserves the authority to “enforce any of the provisions of this framework through additional orders . . . and [to] issue additional technical instructions as needed,” which CDC regularly creates. (Doc. 1-3 at 21, 23, 25, 35; Doc. 72-1 at 3–4) Several of CDC’s subsequent “technical instructions” have “imposed new duties” and have “had ‘palpable effects’ upon the regulated industry and the public in general,” and, consequently, carry the force of law. *Council of S. Mountains, Inc. v. Donovan*, 653 F.2d 573, 580 (D.C. Cir. 1981) (quoting *National Helium Corp. v. Federal Energy Administration*, 569 F.2d 1137, 1146 (Temp. Em. App. 1977)). Imposing on the cruise industry exhaustive, indeterminate, inconsistent, and unclear requirements (each of which threatens substantial penalty), the conditional sailing order likely is by definition capricious. *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 541 (2009) (Stevens, J., dissenting) (remarking about “the FCC’s shifting and impermissibly vague indecency policy”); *Arizona Cattle Growers’ Ass’n v. U.S. Fish & Wildlife, Bureau of Land Mgmt.*, 273 F.3d 1229, 1233 (9th Cir. 2001) (holding that “it was arbitrary and capricious for the Fish and Wildlife Service to issue terms and conditions so vague as to preclude compliance therewith”).

observes that EDC reports “[a]s of October 30, 2020,” confirm (1) that 4% of polymerase chain reaction COVID-19 tests were positive, (2) that twenty-four people had been hospitalized, and (3) that fifteen medical evacuations had occurred. (Doc. 1-3 at 11) Moreover, the conditional sailing order discusses relatively recent academic literature. (Doc. 1-3 at 12–13); see *Miccosukee Tribe of Indians v. United States*, 566 F.3d 1257, 1265 (11th Cir. 2009) (“The general view is that the agency decides which data and studies are the ‘best available’ because that decision is itself a scientific determination.”). Thus, Florida’s likelihood of success on the merits of these arguments remains unclear.

Second, the parties dispute whether CDC's alleged failure to consider the adequacy of measures by state and local governments was arbitrary and capricious. According to Florida, the order relies on a generic, global generalization that all non-federal measures are inherently inadequate to ensure public health and safety in the cruise industry, a conclusion reached without investigation into the measures adopted by the states, the local governments, or the cruise industry. (Doc. 9 at 16)

In response, CDC insists that "CDC reasonably found that state and local governments cannot adequately regulate a ship whose operations are international and interstate in nature." (Doc. 31 at 35) CDC further observes that the conditional sailing order explicitly addresses and implements some of the measures proposed by the cruise industry's Healthy Sail Panel. (Doc. 31 at 35) And according to CDC, Florida identifies no regime adopted by the state or by the cruise industry that adequately protects public health and safety in the cruise industry. (Doc. 31 at 36)

"[A]n agency's exercise of discretion must be both reasonable and reasonably explained." *Multicultural Media, Telecom & Internet Council v. Fed. Commc'ns Comm'n*, 873 F.3d 932, 937 (D.C. Cir. 2017). In other words, an agency must provide some reasoned basis — not agency doctrine — to explain and sustain an action. *See Int'l Union, United Auto, Aerospace & Agr. Implement Workers of Am., UAW v. Pendergrass*, 878 F.2d 389, 392 (D.C. Cir. 1989) ("While our deference to the agency is at a peak for its choices among scientific predictions, we must still look for some articulation of reasons for those choices.").

Because CDC enjoys heightened authority if regulating vessels arriving from abroad, as discussed above, Section 70.2 obligates the director to make a determination “that the measures taken by health authorities of any State . . . are insufficient to prevent the spread of any of the communicable diseases[.]” Section 70.2, which emphasizes local health authorities, is intended to bridle the federal government and to encourage federalism.

The conditional sailing order discusses cruise operators’ “steps to improve their public health response to COVID-19,” but the conditional sailing order finds that “transmission has not been controlled sufficiently by the cruise ship industry.” (Doc. 1-3 at 13, 17–18) Further, the conditional sailing order explains that under Section 70.2 the director determines that state and local measures are “inadequate” because “cruise ships by their very nature travel interstate and internationally and can move beyond the jurisdictional boundaries of any single state or local health authority.” (Doc. 1-3 at 19)

But the conditional sailing order’s global dismissal of state and local health measures fails to offer the type of reasoned finding required by Section 70.2. The conditional sailing order says absolutely nothing evaluative about any “measure taken by health authorities of any State.” Instead, the conditional sailing order determines that all non-federal measures are inherently “inadequate” because cruise ships travel interstate and internationally, a determination that falls far short of conducting a reasoned finding that the measures “taken by health authorities of any State” are insufficient to prevent contagion. *Pendergrass*, 878 F.2d at 392. In fact,

under CDC's rationale, if a state implemented measures more severe and extensive than those of CDC in the conditional sailing order, CDC could still invoke the finding necessary under Section 70.2.

The APA imposes an obligation to “overturn agency actions which do not scrupulously follow the regulations and procedures promulgated by the agency itself.” *Simmons v. Block*, 782 F.2d 1545, 1550 (11th Cir. 1986). CDC's attempt — not at all a scrupulous attempt and, apparently, no attempt at all in this instance — to follow regulations relies on only a conclusory and dubious but self-serving generalization that non-federal measures are inherently insufficient to protect public health and safety. *Am. Fed'n of Lab. & Cong. of Indus. Organizations v. Occupational Safety & Health Admin., U.S. Dep't of Lab.*, 965 F.2d 962, 976 (11th Cir. 1992) (“Mere conclusory statements, such as those made throughout the Air Contaminants Standard, are simply inadequate to support a finding of significant risk of material health impairment.”).

Because CDC neither evaluates nor even mentions measures undertaken or planned by the local health authorities of any state but, nevertheless, finds the measures inherently and inescapably insufficient, the conditional sailing order lacks a reasoned explanation of the insufficiency of those measures. *See Am. Fed'n of Lab.*, 965 F.2d at 977 (holding that “[i]t is not unreasonable to require that the agency explain how it arrived at [a] determination” if the agency is legally obligated to do so). In a word, the conditional sailing order's global and peremptory dismissal of state and local health measures is arbitrary and capricious. *Sierra Club v. U.S. Army*

Corps of Engineers, 464 F. Supp. 2d 1171, 1183 (M.D. Fla. 2006), *aff'd*, 508 F.3d 1332 (11th Cir. 2007) (“An agency decision issued without adherence to its own regulations must be overturned as arbitrary and capricious.”).⁴²

To recapitulate, although several of Florida’s arguments remain unpersuasive on this record, the conditional sailing order is arbitrary and capricious because the order imposes vague and shifting (but binding) legal requirements and because the order fails to offer any reasoned explanation about the inadequacy of local measures.

C. Count IV

Florida’s next challenges pertain to CDC’s alleged procedural failures under the APA. According to Florida, the conditional sailing order (1) encumbers individual rights and obligations, (2) constitutes a “major rule with at least a \$100 million dollar impact,” (3) fails to provide notice and comment, and (4) improperly employs the “good cause” exception. CDC denies any need to provide notice and comment because the conditional sailing order “is an order, not a rule”; because the

⁴² In this circumstance, “due account” of the rule of prejudicial error might suggest that CDC’s mistake “ha[d] no bearing on the ultimate decision.” *Sierra Club v. Slater*, 120 F.3d 623, 637 (6th Cir. 1997). That is, CDC’s failure to furnish a reasoned explanation was arguably immaterial and might have been unlikely to alter the agency’s decision. Although addressed below, this finding is not required to resolve the motion for preliminary injunction in light of CDC’s employment of a measure exceeding its authority. Thus, no further analysis of this issue is merited here.

Similarly immaterial is Florida’s “unreasonable delay” argument, which Florida advances in only a few lines of the preliminary injunction motion and only as an alternative argument. (Doc. 25 at 17) Although CDC’s advancement from phase one to phase two was glacial given the conditional sailing order’s incremental timeline and although an agency’s own “regulations that have the force of law” can impose the obligation for a “discrete agency action,” *Norton v. S. Utah Wilderness All.*, 542 U.S. 55, 65 (2004), this order’s holding that the conditional sailing order exceeds CDC’s authority and is capricious precludes any need to thoroughly analyze Florida’s alternative “unreasonable delay” argument.

conditional sailing order meets the “good cause” standard; and because Florida suffered no prejudicial error. (Doc. 31 at 40–41)

Although CDC attempts to frame the conditional sailing order as the “conditioning of a license,” the conditional sailing order imposes in the first instance a license requirement (among a litany of other requirements), which attaches to a cruise vessel before leaving a U.S. port. Violation of the conditional sailing order triggers a serious consequence, as discussed earlier. The conditional sailing order is a rule and, moreover, the conditional sailing order acknowledges that, if the conditional sailing order is a rule, “it would be a major rule.” (Doc. 1-3 at 19) The APA therefore obligates CDC to treat the conditional sailing order as a rule and to provide notice and comment. 5 U.S.C. § 553(b).

CDC published the request for information on July 20, 2020, and received 13,000 comments. 85 Fed. Reg. 44083. The conditional sailing order mentions the subject of some comments and states that CDC “carefully considered these comments in drafting” the conditional sailing order. (Doc. 1-3 at 15) Yet the conditional sailing order fails to address which measures CDC “carefully considered,” the conditional sailing order fails to evaluate and respond to any comment, and the conditional sailing order pronounces that the “CDC bases its public health determinations on the best available science and not on public opinion.” (Doc. 1-3 at 15) Attempting to justify CDC’s omission, the conditional sailing order insists that notice and comment “are not required because CDC has already obtained public comment and good cause exists.” (Doc. 1-3 at 19) And the

conditional sailing order cites “the public health emergency caused by COVID-19” as supplying the “good cause” to forgo notice and comment. Also, in support of the “good cause” exception, the conditional sailing order explains that “it would be impracticable and contrary to the public’s health” to follow notice and comment procedures. (Doc. 1-3 at 19)

To satisfy its notice-and-comment obligations under the APA, “an agency must consider and respond to significant comments received during the period for public comment.” *Perez v. Mortg. Bankers Ass’n*, 575 U.S. 92, 96 (2015). Therefore, the conditional sailing order violates the APA unless an exception applies.⁴³

5 U.S.C. § 553(b)(3)(B).

The “good cause” exception, “narrowly construed and only reluctantly countenanced,”⁴⁴ *Mack Trucks, Inc. v. EPA*, 682 F.3d 87, 93 (D.C. Cir. 2012) (quoting

⁴³ Additionally, although the APA imposes no duty to entitle a document “notice of proposed rulemaking,” *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S. Ct. 2367, 2385 (2020), sufficient notice requires publishing in the Federal Register “the terms or substance of the proposed rule or a description of the subjects . . . [such that] the affected party ‘should have anticipated’ the agency’s final course in light of the initial notice.” *Nat’l Lifeline Ass’n v. Fed. Commc’ns Comm’n*, 921 F.3d 1102, 1115 (D.C. Cir. 2019). Further, sufficient notice requires “the notice of proposed rulemaking contain ‘reference to the legal authority under which the rule is proposed.’” *Little Sisters of the Poor*, 140 S. Ct. at 2384. CDC’s July 21, 2020 request for information observes that the requested information “may be used to inform future public health guidance and preventative measures relating to travel on cruise ships.” 85 Fed. Reg. 44083. But the request makes no “reference to legal authority” and is insufficient to apprise an affected party of the extensive regulatory framework appearing in both the conditional sailing order and the technical instructions. That is, the request for information provides notice of the subject matter (the resumption of sailing); but CDC only tentatively and vaguely notes that the request “may be used to inform public health guidance.” The conditional sailing order otherwise fails to provide notice of the burdensome regulatory framework.

⁴⁴ Precedent demonstrates how infrequently the exception should receive acceptance. *See, e.g., Am. Fed’n of Gov’t Emp., AFL-CIO v. Block*, 655 F.2d 1153, 1158 (D.C. Cir. 1981) (“[A]dministrative agencies should remain conscious that such emergency situations are indeed rare.”); *N. Carolina Growers’ Ass’n, Inc. v. United Farm Workers*, 702 F.3d 755, 767 (4th Cir. 2012) (explaining that the circumstances permitting reliance on the “good cause” exception are exceedingly “rare”).

Util. Solid Waste Activities Grp. v. EPA, 236 F.3d 749, 754 (D.C. Cir. 2001)), excuses the APA’s notice-and-comment procedures in an “emergency situation.” *Jifry v. FAA*, 370 F.3d 1174, 1179 (D.C. Cir. 2004). For example, if the “impracticability” of notice and comment poses “a possible imminent hazard to aircraft, persons, and property within the United States,” *Jifry*, 370 F.3d at 1179, or if a rule is of “life-saving importance” to an industry, an agency might lawfully bypass notice and comment for “good cause.” *See, e.g., Council of the S. Mountains, Inc. v. Donovan*, 653 F.2d 573, 581 (D.C. Cir. 1981) (applying the exception to prevent deaths in the mining industry); *Hawaii Helicopter Operators Ass’n v. FAA*, 51 F.3d 212, 214 (9th Cir. 1995) (permitting the exception in the wake of several helicopter fatalities); *see Util. Solid Waste Activities Grp. v. EPA*, 236 F.3d 749, 754–55 (D.C. Cir. 2001) (discussing the standards for “good cause” but ultimately rejecting the agency’s invocation of the exception).

Also, an agency may employ the “good cause” exception “when the agency for good cause finds . . . that notice and public procedure thereon are . . . contrary to the public interest.” 5 U.S.C. § 553(b)(B).⁴⁵ But this exception typically applies to financial regulations effectively thwarted by notice and comment,⁴⁶ and CDC’s

⁴⁵ Other exceptions not relevant here also apply — for example, “good cause” might exist if notice and comment are entirely “unnecessary” because the rule is ministerial or perfunctory. 5 U.S.C. § 553(b)(B).

⁴⁶ *See, e.g., Mobil Oil Corp. v. Dep’t of Energy*, 728 F.2d 1477, 1492–93 (Temp. Em. Ct. App. 1983) (finding good cause because the drastic economic harm of price discrimination and market dislocation which a price control rule sought to prevent was likely to result if notice of price controls were given in advance).

burden in issuing CDC's findings of good cause is to "demonstrate why notice and comment would be *detrimental* to the public interest." *Ass'n of Cmty. Cancer Centers v. Azar*, 2020 WL 7640818, at *7 (D. Md. Dec. 23, 2020).

Typically, the facts and context of each instance dictate whether "good cause" existed during enactment. *See Mid-Tex Elec. Coop. v. FERC*, 822 F.2d 1123, 1132 (D.C. Cir. 1987) (describing the "good cause" inquiry as "inevitably fact- or context-dependent"). For instance, "good cause" exists to bypass notice and comment amid an imminent threat of "terrorist acts involving aircraft in the aftermath of September 11, 2001," *Jifry*, 370 F.3d at 1179, and "good cause" exists in cases attempting to avert financial manipulation or market distortions. *DeRieux v. Five Smiths, Inc.*, 499 F.2d 1321 (Temp. Emer. Ct. App. 1974), *cert. denied*, 419 U.S. 896 (1974). But no "good cause" exists if the agency's "emergency" action does nothing to "stave off an[] imminent threat to the environment or safety or national security" or otherwise remedy the emergency allegedly justifying the action. *Mack Trucks*, 682 F.3d at 93. Nor does "good cause" exist if the agency's own delay caused the alleged "emergency" situation. *Nat. Res. Def. Council v. Nat'l Highway Traffic Safety Admin.*, 894 F.3d 95, 114 (2d Cir. 2018) ("Good cause cannot arise as a result of the agency's own delay.").

CDC lacked "good cause" to evade the statutory duty of notice and comment. First, almost no one doubts that COVID-19 presents a legitimate health concern, and almost no one doubts that the uncertainty was much greater in October 2020. HHS declared COVID-19 a public health emergency early in 2020 and suspended cruises

beginning in March 2020 through October 2020 under a series of no-sail orders. And even the Cruise Line International Association, the cruise industry's leading trade group, which includes ninety-five percent of cruise vessels, voluntarily suspended U.S. operations from April 2020 until October 31, 2020.⁴⁷ Press Release, CLIA, *Cruise Lines Int'l Ass'n, CLIA and Its Ocean-Going Cruise Line Members Announce Third Voluntary Suspension of U.S. Operations* (Aug. 5, 2020). Therefore, COVID-19 might have constituted an acute health threat in October 2020, but the no-longer-new COVID-19 pandemic is insufficient for "good cause" in October 2020, two-hundred-and-thirty-two days after cruising ceased. *Regeneron Pharms., Inc. v. United States Dep't of Health & Hum. Servs.*, 2020 WL 7778037, at *13 (S.D.N.Y. 2020). If the existence of a communicable disease alone permitted CDC to find "good cause," CDC would seldom, if ever, need to comply with the statutory requirement for "good cause" to dispense with notice and comment.

Exhibiting the same pattern of evasion, CDC published the request for information more than three months before issuing the conditional sailing order. 85 Fed. Reg. 44083 (Jul. 2020). By September 21, 2020, CDC received roughly 13,000 comments. During that time, CDC had ample time to effect notice and comment. *Regeneron Pharms.*, 2020 WL at *12 ("CMS could have announced a NPRM in April, when these effects were at their worst. It could have done the same

⁴⁷ The Cruise Line International Association voluntarily extended the suspension further until December 31, 2020. Press Release, CLIA, *Cruise Lines Int'l Ass'n, Reaffirming Commitment to Stringent Protocols - Voluntarily Extend Suspension of U.S. Operations* (Nov. 3, 2020).

in July 2020, when . . . COVID cases increased Delays after the MFN Order suggest a lack of urgency, including the two months between the executive order being announced and publicly issued[.]”). CDC might have justifiably attempted to invoke the “good cause” exception in the original no-sail order (and perhaps even in an extension), but by October 2020, after the cruise industry had been shut down for seven months, a claim of “good cause” to avoid notice and comment must fail. *Nat. Res. Def. Council*, 894 F.3d at 114 (holding that an agency cannot justify “good cause” if the agency’s delay caused the putative emergency); *United States v. Gavrilovic*, 551 F.2d 1099, 1105 (8th Cir. 1977) (holding that the agency’s “finding of good cause was not based on an acute and immediate threat to public health . . . , but rather on the specific threat posed by defendants’ operation.”).

Next, the stated purpose of the conditional sailing order undermines CDC’s suspension of notice and comment under “the [COVID-19] public health emergency.” (Doc. 1-3 at 19) The conditional sailing order purports to establish a “framework” to re-open sailing because “[t]he benefits of this framework outweigh the costs of not allowing cruise ships to sail.” (Doc. 1-3 at 16) But unlike the no-sail orders, the conditional sailing order contemplates a trade-off that invites more risk than the no-sail orders, which contemplated a zero-risk — no sailing. Accordingly, CDC cannot justify the “good cause” exception by citing an emergency that the conditional sailing order is not directly tailored to “remedy.” *Mack Trucks, Inc. v. EPA*, 682 F.3d 87, 93 (D.C. Cir. 2012) (finding no good cause because the regulation

that was issued without notice and comment failed to directly address the alleged “imminent threat”).

Finally, rulemaking is the business of trade-offs, and public health is one among many considerations that should contribute to balancing competing interests. Eliminating notice and comment from an agency’s rulemaking “invariably detracts from the fairness, wisdom, and political legitimacy of a rule.” HICKMAN & PIERCE, ADMINISTRATIVE LAW TREATISE § 5.10 (6th ed. 2020). “The more expansive the regulatory reach of these rules, of course, the greater the necessity for public comment.”⁴⁸ *Am. Fed’n of Gov’t Emp., AFL-CIO v. Block*, 655 F.2d 1153, 1156 (D.C. Cir. 1981). This is especially true if an agency imposes criminal penalties for violation of its rule. *See United States v. Gavrilovic*, 551 F.2d 1099, 1105 (8th Cir.1977) (“When the consequence of agency rule making is to make previously lawful conduct unlawful and to impose criminal sanctions, the balance of these competing policies imposes a heavy burden upon the agency to show public necessity.”).

The conditional sailing order purports to expansively regulate an entire industry and has a dramatic impact on the economy — and on a few states especially. (Doc. 1-3) (acknowledging that the Office of Information and Regulatory Affairs characterizes the conditional sailing order as a “major rule”). CDC cannot

⁴⁸ This is to say nothing of the additional requirements imposed if an agency’s action qualifies as a “major rule,” as here. *See* HICKMAN AND PIERCE, ADMINISTRATIVE LAW TREATISE § 11.1 (6th ed. 2020) (describing the requirements for a major rule); Executive Order 13132 (1999) (requiring an agency to confer with state and local officials if the agency’s rulemaking “ha[s] substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government”).

reasonably assert that the conditional sailing order, which touches billions of dollars in the economy and hundreds of thousands of people, is “inconsequential to the industry and to the public.” *Mack Trucks*, 682 F.3d at 94. And given the economic importance and expansive reach of the regulation, the importance of participation from the industry and public becomes more pronounced. CDC explains that the conditional sailing order “is based, in part, on extensive interaction with the cruise industry and States[.]” (Doc. 31 at 41) But the cruise industry, including state ports, has objected to the conditional sailing order for several months, and Florida initiated this action in resistance to the conditional sailing order. 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.

The conditional sailing order states dismissively that “CDC bases its public health determinations on the best available science and not on public opinion.” (Doc. 1-3 at 15) Although CDC certainly should base scientific determinations on “the best available science,” the conditional sailing order and the series of “orders” that followed “imposed new duties” on an entire industry. *Nat’l Nutritional Foods Ass’n v. Kennedy*, 572 F.2d 377, 385 (2d Cir. 1978). Therefore, the APA requires notice and comment. *See Nat’l Nutritional Foods Ass’n*, 572 F.2d at 385 (rejecting the FDA commissioner’s arguments that “public participation was unnecessary” and that “there was nothing more for the public to say”). Proper APA proceedings

would not have prevented reliance on “the best available science,” and APA proceedings would have afforded the regulated parties an opportunity to participate in rulemaking in light of the best available science and other pertinent considerations. CDC’s vague invocation of “the public interest” is insufficient to eclipse CDC’s administrative duty. *Nat’l Nutritional Foods Ass’n*, 572 F.2d at 385.

Finally, CDC has still initiated no notice and comment for either the conditional sailing order or the series of orders that followed. CDC’s continued failure presents at least three problems. First, if “good cause” was lacking in October 2020, “good cause” is certainly lacking now. *Kollett v. Harris*, 619 F.2d 134 (1st Cir. 1980) (rejecting a “good cause” rationale because the agency delayed fourteen months). Second, “[c]ommon sense suggests that any administrative action taken in a rare ‘emergency’ situation . . . need only be temporary, pending public notice-and-comment procedures.” *Am. Fed’n of Gov’t Emp.*, 655 F.2d at 1157. Third, because several of CDC’s subsequent “technical instructions” have “imposed new duties” and have “had ‘palpable effects’ upon” the cruise industry and public, the technical instructions likely demand notice and comment. *Council of S. Mountains, Inc. v. Donovan*, 653 F.2d 573, 580 (D.C. Cir. 1981) (quoting *National Helium Corp. v. Federal Energy Administration*, 569 F.2d 1137, 1146 (Temp. Em. App. 1977)). The

continually shifting standards in the open-ended “technical instructions”⁴⁹ demonstrate the deficiencies both in the conditional sailing order and in CDC’s sustained failure to provide notice and comment. *Am. Fed’n of Gov’t Emp.*, 655 F.2d at 1158 (“[O]nce the interim rules were published, notice and public procedure would [not] have been ‘impracticable, unnecessary, or contrary to the public interest’ in the formulation of the final regulations governing inspection standards[.]”).

To excuse its oversights, CDC offers a gloss on the conditional sailing order with a *post hoc* appeal to the doctrine of “harmless error.” (Doc. 31 at 42); 5 U.S.C. § 706 (“[D]ue account shall be taken of the rule of prejudicial error.”). Yet CDC’s oversights are anything but harmless. If CDC’s “harmless error” argument attempts to suggest that the conditional sailing order was unimportant or minor in impact, that position already met with rejection. To the extent that CDC argues that Florida suffered no prejudice, that argument is equally unavailing. Florida’s evidence persuasively demonstrates injury to cruise companies, port authorities, states, and the public. CDC’s failure to comply with Section 553 of the APA, which might have

⁴⁹ Also, the technical instructions say woefully little about how the proposed measures relate to scientific data about preventing transmission. For example, to bypass a simulated voyage, a vessel operator must attest that 98% of crew and 95% of passengers are vaccinated. But CDC fails to explain why the vaccination rate is so much higher than the rate it deems sufficient to obtain so-called “herd immunity.” To the extent the conditional sailing order’s cited literature could explain the effect of the technical instructions’ measures, CDC relies on scientific literature that, by April and May 2021, was stale.

On the subject of scientific data, the conditional sailing order also cites scientific evidence supporting the *need* for measures to prevent COVID-19 (for example, high rates of COVID-19 infection and heightened transmission for a cruise vessel), but the conditional sailing order cites no evidence supporting the efficacy of the measures imposed.

avoided or mitigated some of the deficiencies in the conditional sailing order and later “technical instructions,” constitutes prejudicial error.

IRREPARABLE INJURY

Although likely to succeed on the merits, Florida must establish that without a preliminary injunction Florida faces a substantial likelihood of an irreparable injury. *Siegel v. LePore*, 234 F.3d 1163, 1176 (11th Cir. 2000) (“A showing of irreparable injury is “the *sine qua non* of injunctive relief.”). An injury qualifies as “irreparable” if a monetary remedy cannot offer relief. *Sampson v. Murray*, 415 U.S. 61, 88 (1974). Further, Florida must face an actual and imminent injury, not a speculative or remote injury. *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7 (2008); *Northeastern Fla. Chapter of the Ass’n of Gen. Contractors v. City of Jacksonville*, 896 F.2d 1283, 1285 (11th Cir. 1990). And if adequate compensation or other corrective relief will become available, Florida will avoid an irreparable injury and cannot justify a preliminary injunction. *Sampson v. Murray*, 415 U.S. 61, 90 (1974). CDC argues that Florida cannot establish an irreparable injury because Florida delayed beginning the action, because Florida alleges an insignificant injury, and because Florida speculates about its future injury.

First, CDC argues that Florida waited too long to begin the present action. CDC contends that Florida’s “unexplained delay undercuts any sense of urgency, and therefore, [Florida] fails to demonstrate a sufficient need for a preliminary injunction.” (Doc. 31 at 18) (citing *Seiko Kabushiki Kaisha v. Swiss Watch Int’l, Inc.*, 188 F. Supp. 2d 1350, 1356 (S.D. Fla. 2002) (Lenard, J.)). In other words, CDC

concludes that if Florida sued shortly after the conditional sailing order became effective (nearly eight months ago), Florida would not need a preliminary injunction to save the summer cruise season. Accordingly, CDC recommends a “strong presumption” against a preliminary injunction. (Doc. 31 at 18–19)

Although “a delay in seeking a preliminary injunction of even only a few months — though not necessarily fatal — militates against a finding of irreparable harm,” Florida offers a reasonable explanation that satisfactorily explains Florida’s timing of this action. *Wreal, LLC v. Amazon.com, Inc.*, 840 F.3d 1244, 1248 (11th Cir. 2016). For months after the initial no-sail order in early 2020, both the cruise industry and Florida relied on CDC’s assurance that soon sailing could expeditiously resume. But between issuance of the conditional sailing order and April 2021, the industry awaited from CDC the necessary implementing manuals, guidance, and instruction. When the guidance finally arrived in April 2021, Florida sued immediately. In sum, Florida not only behaved reasonably by relying on CDC until April 2021 but also acted expeditiously after April 2021 and after the cruise season became conclusively threatened. *Wreal, LLC*, 840 F.3d at 1248 (discerning “any justification for delay.”); *NRDC v. Pena*, 147 F.3d 1012, 1026 (D.C. Cir. 1998).

Next, CDC argues that Florida’s financial injury cannot qualify as an irreparable injury. (Doc. 31 at 19) CDC correctly notes that a financial injury is usually compensable by a payment of money and is, therefore, not irreparable. *Snook v. Tr. Co. of Georgia Bank of Savannah*, 909 F.2d 480, 487 (11th Cir. 1990) (citing *Sampson v. Murray*, 415 U.S. 61, 90 (1974)). But in an APA action sovereign

immunity bars the recovery of monetary damages from the federal government. Florida’s financial injury — amounting to at least millions of dollars — becomes irreparable. 5 U.S.C. § 702 (authorizing actions “seeking relief other than money damages”); *Odebrecht Const., Inc. v. Sec’y, Fla. Dep’t of Transp.*, 715 F.3d 1268, 1289 (11th Cir. 2013) (“In the context of preliminary injunctions, numerous courts have held that the inability to recover monetary damages because of sovereign immunity renders the harm suffered irreparable.”); *Idaho v. Coeur d’Alene Tribe*, 794 F.3d 1039, 1046 (9th Cir. 2015); *Kentucky v. U.S. ex rel. Hagel*, 759 F.3d 588, 599 (6th Cir. 2014); *Chamber of Commerce v. Edmondson*, 594 F.3d 742, 770–71 (10th Cir. 2010); *Iowa Utilities Bd. v. FCC*, 109 F.3d 418, 426 (8th Cir. 1996); *United States v. State of N.Y.*, 708 F.2d 92, 93 (2d Cir. 1983); *Georgia v. Pruitt*, 326 F. Supp. 3d 1356, 1367 (S.D. Ga. 2018) (Wood, J.). Also, by alleging in Count IV that CDC failed to provide notice and comment, Florida arguably establishes irreparable injury. *California v. Azar*, 911 F.3d 558, 581 (9th Cir. 2018) (citation omitted) (reaffirming that “the harm flowing from a procedural violation can be irreparable.”); *ITServe All. Inc. v Scalia*, 2020 WL 7074391, at *10 (D.NJ. 2020) (“Many courts have found that a preliminary injunction may be issued solely on the grounds that a regulation was promulgated in a procedurally defective manner.”)

Relying mostly on non-binding precedent, almost all of which is outside the Eleventh Circuit, CDC responds by arguing that Florida’s injury must arise to a “significant” amount to qualify as irreparable. (Doc. 31 at 19–20) (citing *Air Transp. Ass’n of Am., Inc. v. Exp.-Imp. Bank of the U.S.*, 840 F. Supp. 2d 327, 335 (D.D.C.

2012)). But, even if needing to prove a “significant” injury, Florida plausibly alleges an encompassing and cumbersome financial injury. Florida attaches economic reports and declarations detailing millions of dollars in lost revenue if cruises cannot sail. (Docs. 45-20; 45-21; 45-22; 45-23; 45-24; 45-25) CDC attempts to trivialize (Doc. 31 at 20) Florida’s injury by comparing the lost revenue to Florida’s annual budget (under that logic, a billion dollar loss is not “significant” to the federal government). But Florida attaches economic reports — uncontested by CDC — that describe the cruise industry’s enormous financial effect, which reaches into most sectors of Florida’s economy. *Odebrecht Const., Inc.*, 715 F. 3d at 1288 (remarking about “the substantial nature of the . . . harm” when considering whether an injury is “actual and imminent.”). For example, Florida attaches a study summarizing the cruise industry’s “economic impact”:

As a result of the activity of the cruise industry, Florida businesses received just over \$9.0 billion, or 36 percent of the direct expenditures generated by the cruise industry in the United States. Due to the absolute scale of the industry, direct expenditures in Florida impacted just about all segments of the economy, including recreation and amusement establishments, wholesalers of products purchased by cruise lines, manufacturers of communications and navigation equipment, producers of machinery and equipment such as engine parts, boilers, laundry equipment and computers, manufacturers of fabricated metal products such as locks and security equipment and business service providers such as interior designers and computer services consultants these direct expenditures generated total economic impacts of almost 159,000 jobs and \$8.1 billion in income throughout the Florida during 2019.

(Doc. 45-1 at 45–46) A “fact-finding investigation” by the Federal Maritime Commission confirms that Florida’s economy has lost more than \$22 billion and 169,000 jobs since cruises and cargo ships have been unable to sail. (Doc. 45-2 at 28;

Doc. 45-27) As long as some cruises remain unable to sail, at least a portion of this financial loss will reduce state revenue, the effects of which compound owing to the cruise industry's ubiquitous footprint on Florida's economy. Further, every day the cruise industry faces uncertainty about when cruises can unequivocally resume sailing, Florida faces an imminent and increasingly likely threat that at least part of the cruise industry will abandon Florida's ports, which would perpetuate the economic harm resulting from CDC's regulatory regime. *V.N.A. of Greater Tift Cty., Inc. v. Heckler*, 711 F.2d 1020, 1034 (11th Cir. 1983) (considering the loss of a business); *Pizza Fusion Holdings, Inc. v. Burton Holdings LLC*, 2015 WL 11197817, at *1 (S.D. Fla. 2015) (Martinez, J.) ("Notably, impending loss or financial ruin of business constitutes irreparable injury"). In sum, Florida plausibly alleges a "significant" irreparable injury.

Finally, CDC argues that Florida cannot establish irreparable injury because the cruise industry steadily progresses through the conditional sailing order's four phases. (Doc. 67 at 3; Doc. 72 at 4) Reporting the approval (as of June 4, 2021) of port agreements for twenty-two vessels and two conditional sailing certificates, CDC argues that Florida speculates about irreparable injury because sailing "is set to resume as planned." (Doc. 67 at 3; Doc. 72) As explained in the analysis of standing, Florida's injury is not speculative; Florida's injury "is sufficiently concrete [and] supported by the record," and directly caused, at least in part, by the conditional sailing order, which prevents some cruises from sailing or sailing

profitably — an outcome that derivatively harms Florida’s revenue and economy.

California v. Azar, 911 F.3d 558, 581 (9th Cir. 2018)

The likelihood of Florida’s irreparable injury is not materially affected by the fact that some cruises are undertaking to comply with the conditional sailing order. As of June 4, 2021, CDC lists only eleven cruise ships ready to begin phase two (of four phases) simulated voyages. CDC has scheduled these voyages to begin no earlier than June 20, 2021, and several begin in August 2021. (Doc. 72-1 at 2–4) Even under CDC’s timeline, few cruise ships, if any, appear poised to qualify by late summer to sail with a satisfactory complement of passengers. For all other ships, the summer season remains almost assuredly lost. The conditional sailing order not only impedes immediate cruising, but the conditional sailing order threatens the economic feasibility of scheduling cruises under restricted sailing. Ships obtaining a conditional sailing certificate remain subject to “restricted passenger voyages,” which, among other things, prevent a cruise ship from offering an “itinerary longer than [seven] days.” (Doc. 1-3 at 33) The restrictions burden the cruise industry’s capacity for profitable sailing. (Doc. 56 at 4–5) In sum, Florida plausibly alleges that the conditional sailing order cripples the cruise industry’s ability to begin sailing and to sail in a manner that avoids economic loss as a result of sailing. (Doc. 25 at 22) Owing to a disabled cruise industry, both obstacles impose an imminent and irreparable financial injury on Florida.

The Cruise Lines International Association states:

“the effect of these new mandates is that nearly half a million Americans — from longshoremen and ground transportation operators to hotel, restaurant, and retail workers, travel agents, and tens of thousands of businesses that service cruise ships, are continuing to financially suffer with no reasonable timeline provided for the safe return of cruising.”

(Doc. 49- 9 at 2) Florida establishes an imminent, actual, and irreparable injury.

BALANCING OF THE EQUITIES AND THE PUBLIC INTEREST

Because Florida requests an injunction against an agency of the federal government, the analysis of the balance of equities and the analysis of the public interest merge. *Nken v. Holder*, 556 U.S. 418, 435 (2009); *Swain v. Junior*, 958 F.3d 1081, 1091 (11th Cir. 2020). Arguing that the prospective injury to the public’s health exceeds the ongoing financial injury to Florida and the economic injury to Florida’s economy, CDC claims that absent the requirements imposed by the conditional sailing order, cruises “would likely exacerbate and amplify the spread” of COVID-19. (Doc. 31 at 44; Doc. 46-1 at 33) CDC not only fails to substantiate this supposition with persuasive evidence, but CDC discounts the retreat of COVID-19, the success of other similar industries, and the mitigation on measures that would exist without the conditional sailing order.

States, including Florida, have crafted and implemented measured re-opening plans that address both the public health risk and the economic damage associated with COVID-19. And since early 2021, highly effective vaccines are available across the United States. More than forty percent of United States residents (minors included) are fully vaccinated.

As of June 11, 2021, about sixty-four percent of adults have received at least one dose of a vaccine. Fifty-three percent of adults are fully vaccinated.⁵⁰ In an effort to achieve “herd immunity,” which approaches steadily, states administer more than a million vaccines a day. Recognizing the effectiveness of vaccines, CDC admits that persons “do not need to self-quarantine after cruise travel” because “fully vaccinated people can travel at low risk to themselves.” (Doc. 45-8 at 2; Doc. 45-15 at 2) Even New York has “re-opened.” Governor Cuomo announced that, because 70% of New York adults are vaccinated, the longstanding “closing” of New York can end.

CDC’s regulation of comparable industries confirms the success combating COVID-19. Rather than shutting down other industries catering to large groups of people, CDC offers voluntary “recommendations” and “considerations” (which CDC could offer cruises) to promote the safe operation of hospitality and leisure industries. For example, “to slow the spread of COVID-19” (Doc. 45-4, Doc. 45-5, Doc. 45-6), CDC publishes guidance about the safe operation of a hotel, a casino, and a sporting arena or stadium — each a venue permitted to accommodate hundreds of, or thousands of, people for an extended time. Further, CDC offers guidance to prevent the spread of COVID-19 on an airplane, which safely transports thousands of people each day. (Doc. 45-11) The safe operation of comparable

⁵⁰ <https://covid.cdc.gov/covid-data-tracker/#vaccinations>.

industries strongly counsels against finding that moderating the conditional sailing order would endanger the public health.

CDC responds by arguing that cruise ships “present a unique setting that is particularly conducive to transmission of the virus.” (Doc. 31-1 at 33) In light of the proliferation of vaccines, CDC’s own data weakens this conclusion. CDC reports that “if passengers originate from a community with a medium prevalence of COVID-19 and 50% of those passengers are fully vaccinated . . . modeling data estimates that the passengers’ risk of introducing COVID-19 onto the ship has only been reduced by 62.8%.” (Doc. 31-1 at 28) But the presence of COVID-19 in the community decreases daily, and vaccinations continue to rise. A passenger’s risk of introducing COVID-19 onto a ship decreases as COVID-19 abates. CDC relies on in-house “modeling data,” which is unpublished, unrefereed, and undisclosed by CDC and which reportedly offer only conclusory, modeling-based comparisons to other “densely populated” living configurations, which currently thrive without the same restrictions imposed on cruises. (One supposes that if this data were convincing, CDC in recent months might have revealed the study, the model, the results, the methodology, and the researchers.)

Even absent the conditional sailing order, the cruise industry appears poised to implement strong and proven safety measures for combating COVID-19. (Doc. 56 at 18–21; Doc. 1-3 at 13–14; Doc. 45-10 at 7) The cruise industry not only maintains a self-interest in offering safe cruises, but the cruise industry “ha[s] worked together to develop layers of protection,” including precautions the cruise industry proposed

to CDC. (Doc. 25-10 at 7) Before the conditional sailing order, the industry formed a “Healthy Sail Panel” of public health experts to design “practical, adaptable, and science-based solutions for mitigating and living with COVID-19.” (Doc. 1-3 at 13–14) The Cruise Line International Association established mandatory COVID-19 protocols, which include testing, masks, distancing, and ventilation. (Doc. 56 at 19) And in Florida, ports offer vaccination programs to support the cruise industry. (Doc. 56 at 20) In sum, even as COVID-19 subsides, precautions persist and will continue to contain COVID-19’s (diminishing) spread.

The success containing COVID-19 in 2021 confirms CDC’s initial finding that the benefits of sailing “outweigh the costs of not allowing cruise ships to sail.” (Doc. 1-3 at 16) Cruises now safely sail all over the world with protocols designed to minimize the spread of COVID-19. Since July 2020, more than 400,000 people have sailed on cruises abroad. (Doc. 45-9; Doc. 45-10) In Europe, thousands sail on cruises without debilitating infections of COVID-19. (Doc. 25-29 at 13) Although citing examples of localized infection (or, at least, “positive” test results) among persons on cruise ships abroad, CDC fails to persuasively show that the infections are not successfully confined or that the infections otherwise endanger a broadly vaccinated group of passengers and the public. (Doc. 31-1 at 80) The availability of vaccines and testing and the comparatively trivial incidence of infection on foreign cruises — all quickly identified and confined — commends optimism about the safe operation of sailing in the United States, which enjoys high rates of vaccination and greatly enhanced, on-board containment mechanisms.

With the advent of highly effective vaccines, with more than half of adults fully vaccinated, with infection plummeting, with death from COVID-19 asymptotically approaching zero; with the benefit of effective therapeutics for COVID-19; with masks, safe distancing, and sanitation; and with the successful and safe re-opening of business, including airlines, sporting events, and other high capacity venues, COVID-19 no longer threatens the public's health to the same extent presented at the start of the pandemic or when CDC issued the conditional sailing order. In fact, CDC's conditional sailing order relies on stale data obtained to justify the no-sail orders when the danger posed by COVID-19 was qualitatively and quantitatively different from today. (Doc. 1-3 at 8-19; Doc. 31-1 at 15, 17)

Conversely, Florida's injury and the injury to Florida's economy grows by the day. In 2019, more than thirteen million cruise passengers and crew embarked and disembarked in Florida and patronized Florida's businesses. (Doc. 45 at 14) Even if a fraction of 2019's demand for sailing exists in 2021, as long as sailing remains restricted or reduced, Florida suffers a derivative injury to revenue and to the economy. Without the expeditious resumption of sailing, Florida's injury threatens to become permanent owing to the cruise industry's credible threat (Docs. 45-10; 28; 29) of leaving Florida. *All. for the Wild Rockies v. Cottrell*, 632 F.3d 1127, 1138 (9th Cir. 2011) ("[T]he effect on the health of the local economy is a proper consideration in the public interest analysis."). And Florida's high likelihood of success on the merits ensures that a preliminary injunction would serve the public interest. After all, "[t]here is generally no public interest in the perpetuation

of unlawful agency action.” *League of Women Voters of United States v. Newby*, 838 F.3d 1, 12 (D.C. Cir. 2016); *Gordon v. Holder*, 721 F.3d 638, 653 (D.C. Cir. 2013) (“[E]nforcement of an unconstitutional law is always contrary to the public interest.”); *United States v. Alabama*, 691 F.3d 1269, 1301 (11th Cir. 2012) (“[f]rustration of federal statutes and prerogatives are not in the public interest, and we discern no harm from the state’s nonenforcement of invalid legislation.”); *Washington v. Reno*, 35 F.3d 1093, 1103 (6th Cir. 1994) (finding a “greater public interest in having governmental agencies abide by the federal laws that govern their existence and operations.”). The balance of harm and the public interest favors Florida.

CONCLUSION

This order resolves Florida’s motion for a preliminary injunction. In brief, this order confirms Florida’s constitutional and statutory standing to assert the claims in the complaint. This order finds that Florida is highly likely to prevail on the merits of the claim that CDC’s conditional sailing order and the implementing orders exceed the authority delegated to CDC under Section 264(a). Alternatively, this order (1) finds that, if Section 264(a) includes the comprehensive authority claimed by CDC to promulgate and enforce regulations, Section 264(a) likely constitutes an unconstitutional delegation of legislative power to CDC because the delegation fails to convey any “intelligible principle” to guide CDC’s exercise of authority and (2) finds that the Supreme Court seems likely to impose soon a more demanding standard, which Section 264(a), as interpreted by CDC, is even more likely to fail.

Additionally, this order determines that Florida is likely to prevail on at least one, but perhaps not all, of the several other claims based on the APA.

Because of (1) Florida's probability of success on the merits, (2) the imminent threat of irreparable injury to Florida, (3) the comparative injury depending on whether an injunction issues, and (4) the imminent and material threat to the public interest, Florida's motion for preliminary injunction is **GRANTED**, and CDC is **PRELIMINARILY ENJOINED** from enforcing against a cruise ship arriving in, within, or departing from a port in Florida the conditional sailing order and the later measures (technical guidelines, manuals, and the like). However, the preliminary injunction is **STAYED until 12:01 a.m. EDT on JULY 18, 2021**, at which time the conditional sailing order and the measures promulgated under the conditional sailing order will persist as only a non-binding "consideration," "recommendation" or "guideline," the same tools used by CDC when addressing the practices in other similarly situated industries, such as airlines, railroads, hotels, casinos, sports venues, buses, subways, and others. (Docs. 45-4; 45-5; 45-6; 46-4)

However, to further safeguard the public's health while this action pends, CDC may propose not later than **JULY 2, 2021**, a narrower injunction both permitting cruise ships to sail timely and remaining within CDC's authority as interpreted in this order. The motion for the proposed injunction must support the proposed terms with current scientific evidence and fully disclose — if unavailable to the public — scientific evidence, including methodology, raw data, analysis, and the like and the names and qualifications of the scientists participating in the study,

modeling, or the like. If CDC moves under this paragraph, Florida must respond within seven days. A hearing will occur immediately after Florida's response. Additionally, if circumstances materially change at any time, either party can request a hearing to modify this injunction, a hearing will occur immediately (within twenty-four hours, if necessary), and an order resolving the motion will issue immediately.

The parties are ordered to return to mediation before Magistrate Judge Anthony Porcelli at a time and place ordered by Judge Porcelli and in accord with the terms (including confidentiality) of the earlier mediation order (Doc. 51).

ORDERED in Tampa, Florida, on June 18, 2021.



STEVEN D. MERRYDAY
UNITED STATES DISTRICT JUDGE

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

STATE OF FLORIDA,

Plaintiff

v.

Case No. 8:21-cv-839-SDM-AAS

XAVIER BECERRA, Secretary of the
Dep't of Health and Human Services,
et al.,

Defendant.

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

I, Aimee Treffiletti, declare as follows:

1) I currently hold the position of Program Chief of the Centers for Disease Control and Prevention's (CDC) Vessel Sanitation Program (VSP) and have served in this position since 2016. VSP is an applied environmental health program with a mission to help the cruise ship industry prevent and control the introduction, transmission, and spread of gastrointestinal illness on board cruise ships in U.S. waters. CDC is an agency within the U.S. Department of Health and Human Services (HHS).

2) Prior to assuming my current position, I served as an Environmental Health Officer and as Assistant Deputy Program Chief in the VSP. Between 2008 and early 2020, I conducted almost 700 cruise ship public health inspections and trained over 4,000 cruise ship managers and supervisors on maritime public health principles. Based this experience, I am familiar with the cruise ship industry's policies and practices to mitigate onboard illnesses and their response when outbreaks of illness occur on board cruise ships.

3) I have been leading the CDC Maritime Unit in support of CDC's COVID-19 response on cruise ships since April 15, 2020. I oversee a staff of between 25 and 30 CDC personnel who compose the Maritime Unit's various teams, which, among other duties, gather and compile epidemiologic and other data; review laboratory test results and assist cruise ship operators in building capacity to test passengers and crew for COVID-19 and other illnesses; assist cruise ship operators in responding to illnesses onboard; create public health surveillance systems for cruise ship operators to assess whether COVID-19 exists on board; and assist with communications to media, interagency partners, cruise industry, and the public.

Background

4) While cruise ships share similarities with other forms of travel or recreation such as airlines, railroads, buses, subways, hotels, casinos, sports venues, and theme parks, there are several factors that make them a unique environment that facilitates the spread of COVID-19.

- Cruises bring travelers together from different countries.

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

5) As explained in the Framework for Conditional Sailing Order (85 Fed. Reg. 70153) (hereinafter, the “CSO”), multiple studies confirm that transmission rates on board ship are in fact much higher than in other settings.¹ While overall public health

¹ Kordsmeyer, A.-C.; Mojtahedzadeh, N.; Heidrich, J.; Militzer, K.; von Münster, T.; Belz, L.; Jensen, H.-J.; Bakir, S.; Henning, E.; Heuser, J.; et al. *Systematic Review on Outbreaks of SARS-CoV-2 on Cruise, Navy and Cargo Ships*. Int. J. Environ. Res. Public Health 2021, 18, 5195. <https://doi.org/10.3390/ijerph18105195>; Rocklöv J, Sjödin H, Wilder-Smith A. *COVID-19 Outbreak on the Diamond Princess Cruise Ship: Estimating the Epidemic Potential and Effectiveness of Public Health Countermeasures*. J. Travel Med. 2020; 18;27(3):taaa030. <https://doi.org/10.1093/jtm/taaa030>; Payne DC, Smith-Jeffcoat SE, Nowak G, et al. *SARS-CoV-2 Infections and Serologic Responses from a Sample of U.S. Navy Service Members—USS Theodore Roosevelt*, April 2020. MMWR Morb Mortal Wkly Rep 2020;69:714–721. DOI: <http://dx.doi.org/10.15585/mmwr.mm6923e4>.

outlooks in the U.S. have improved, the factors described above and the studies regarding transmission rates, lead the CDC to conclude that transmission rates on board cruise ships will continue to be higher than elsewhere.

6) While cruising will never be a zero-risk activity for spread of COVID-19, CDC has worked with cruise ship operators to manage this risk and allow cruise ship operators to resume passenger operations in a way that protects crew members, passengers, port personnel, and communities.

7) Nearly all cruise ships are foreign flagged, operate on roundtrip itineraries, and, per 46 U.S.C. § 55103, may not travel between U.S. ports without making a stop at a foreign port. Out of the 65 cruise ships² currently operating under the CSO, only one cruise ship, the *Pride of America*, operated by NCL America, a division of Norwegian Cruise Lines, is registered in the United States and operates exclusively between U.S. ports in Hawaii. All cruise ships operating out of Florida and subject to the CSO are foreign flagged; these ships must stop at one or more foreign ports during each voyage.

8) Individual state and local health departments have not traditionally regulated cruise ship operations. Depending on the jurisdiction, state and local health departments typically lack the legal authority, staffing, training, and public health resources, to conduct illness surveillance and take other actions to manage communicable disease risk on board cruise ships. Moreover, such health departments

² Silverseas Cruises' *Silver Muse* entered U.S. waters on July 4, 2021, and is now operating under the CSO, raising the total number of ships operating under the CSO to 65.

have been strained by the current pandemic and have devoted public health resources to other areas of concern, such as elder care facilities, schools, and local businesses.

9) Based upon information and belief, neither the Florida Department of Health nor any local health departments in Florida have any health and safety protocols specific to preventing COVID-19 onboard cruise ships and rely on the CDC to oversee this public health activity. In submissions to the CDC in response to a request for information, Florida ports requested CDC oversight in this area. ECF No. 31-2, at pdf pp. 14, 18, 20.

The Conditional Sailing Order's Requirements

10) On October 30, 2020, CDC issued the CSO, which resumes cruise ship passenger operations in U.S. waters through a phased approach. There are four phases to the CSO: mass crew testing and acquiring onboard laboratory testing equipment (Phase 1); preparing for simulated and revenue voyages (e.g., identifying locations through port agreements to provide for the quarantine or isolation, respectively, of exposed and ill passengers) (Phase 2A) and simulated voyages to test onboard health and safety protocols (Phase 2B);³ applying for a COVID-19 Conditional Sailing Certificate (Phase 3); and passenger revenue voyages with public health precautions (Phase 4). Cruise ship operators that choose to sail with 95%

³ Simulated voyages are short test sailings with volunteer passengers, designed to practice and test insofar as practicable the cruise ship operator's ability to mitigate COVID-19 onboard prior to beginning passenger revenue voyages.

vaccinated crew and 95% vaccinated passengers do not have to conduct a simulated voyage prior to applying for a COVID-19 Conditional Sailing Certificate.

11) The CSO employs traditional public health tools to manage COVID-19 risk on board cruise ships, including: public health surveillance (i.e., the ongoing collection, analysis and dissemination of health-related data to provide information to mitigate potential outbreaks); testing, disease reporting, requiring the cruise ship operator to arrange for the isolation of ill persons and quarantine of exposed persons and their contacts; and non-pharmaceutical interventions such as masks⁴ and physical distancing; and vaccinations.

12) The CSO does not require cruise ships to build onboard laboratories. Rather, cruise ship operators must procure an onboard testing unit about the size of a desktop printer that easily fits within their existing medical centers. This equipment allows cruise ship operators to more easily test for the virus that causes COVID-19, can be operated with rudimentary training, and does not require a professional laboratorian. Moreover, cruise ships' pre-existing medical centers typically already have different types of laboratory testing equipment on board for diagnosing illness.

13) The CSO does not require cruise ship operators to revamp a ship's ventilation system. Rather, CDC's technical instructions only require that cruise ship operators ensure that existing ventilation systems, such as toilet room exhaust fans, operate

⁴ <https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/masking-science-sars-cov2.html>

properly and that sufficient negative air pressure (i.e., air blows in, not out) exists in medical centers and in cabins designated for isolation and quarantine.

14) The CSO also does not operate to “detain” cruise ships. Rather, the CSO functions as “controlled free pratique,” meaning that it sets forth the minimum public health and safety measures that cruise ship operators must observe as a condition of operating in U.S. waters. Cruise ship operators that choose to not follow these health and safety standards may depart U.S. waters. Those remaining in U.S. waters are not “detained” and are free to move around.

Cruise Ships are Satisfying CSO Requirements and Restarting Passenger Voyages

15) As of July 5, 2021, out of the 65 ships covered by the CSO, 53 have completed mass crew testing and 59 have acquired the onboard laboratory testing equipment required by the Order.

16) As of July 5, 2021, cruise ship operators representing 11 brands—Bahamas Paradise Cruise Line, Carnival Cruise Lines, Celebrity Cruises, Disney Cruise Line, Holland America Line, MSC Cruises, Norwegian Cruise Line, Oceania Cruises, Princess Cruises, Regent Seven Seas Cruises, and Royal Caribbean International—have submitted port agreements to CDC’s Maritime Unit. Additionally, CDC’s Maritime Unit has been in discussions with cruise ship operators representing 3 additional brands—American Queen Steamboat Company, Crystal Cruises, and Virgin Voyages—with specific plans to operate ships under the CSO beginning in July-September.

17) These port agreements collectively cover 47 vessels at 11 ports of call: Port of Palm Beach, Port Everglades, Port of Miami, Port Canaveral, Port of Galveston, Port of Seattle, Cape Liberty Cruise Port (New Jersey), and four Alaska ports. CDC's Maritime Unit has approved port agreements for all 47 vessels. Twelve vessels have been approved for more than one port.

18) As of July 5, 2021, CDC's Maritime Unit has received and granted 13 requests from cruise ship operators to conduct simulated voyages under the CSO. The Maritime Unit has communicated to Royal Caribbean International that it must confirm that it has installed its laboratory testing equipment and tested its crew prior to conducting a simulated voyage onboard the *Ovation of the Seas*. The other requests for simulated voyages have been or were approved for the following ships and dates:

- *Freedom of the Seas* sailed out of Port Miami on June 20, 2021
- *Serenade of the Seas* planned out of Port of Seattle on July 7, 2021
- *MSC Meraviglia* planned out of Port Miami on July 17, 2021
- *Allure of the Seas* planned out of Port Canaveral on July 27, 2021
- *Disney Fantasy* planned out of Port Canaveral on July 28-30, 2021
- *Independence of the Seas* planned out of Port of Galveston on August 1, 2021
- *Symphony of the Seas* planned out of Port Miami on August 1, 2021
- *Mariner of the Seas* planned out of Port Canaveral on August 11, 2021

- *Oasis of the Seas* planned out of Cape Liberty Cruise Port on August 22-28, 2021
- *Disney Dream* planned out of Port Canaveral (Disney Cruise Lines to provide sailing dates)
- *Grand Classica* planned out of Port of Palm Beach (Bahamas Paradise Cruise Line to provide sailing dates)
- *Odyssey of the Seas* planned out of Port Everglades (Royal Caribbean International to provide sailing dates)

Upon information and belief, most of these ships plan to commence passenger operations within two weeks of completing their simulated voyage.

19) As of July 5, 2021, CDC's Maritime Unit has received and granted COVID-19 Conditional Sailing Certificates to conduct revenue passenger voyages to 12 ships operating under the CSO.

20) The Maritime Unit has communicated to Celebrity Cruises that the *Celebrity Millennium* must confirm that the ship has submitted 14 days of surveillance reporting prior to entering U.S. waters. The Maritime Unit has communicated to Norwegian Cruise Line that the *Norwegian Encore* and *Norwegian Gem* must confirm that all crew have been tested prior to resuming passenger revenue voyages.

21) Cruise ship operators granted a COVID-19 Conditional Sailing Certificate began or have indicated they plan to begin passenger revenue voyages on the following dates:

- *Celebrity Edge* out of Port Everglades began on June 26
- *Freedom of the Seas* out of Port Miami began on July 2
- *Carnival Vista* out of Port of Galveston began on July 3
- *Carnival Horizon* out of Port Miami began on July 4
- *Carnival Breeze* out of Port of Galveston beginning on July 15
- *Celebrity Millennium* out of Port of Seattle beginning on July 23
- *Nieuw Amsterdam* out of Port of Seattle beginning on July 24
- *Celebrity Equinox* out of Port Everglades beginning on July 25
- *Majestic Princess* out of Port of Seattle beginning on July 25
- *Carnival Miracle* out of Port of Seattle beginning on July 27
- *Norwegian Encore* out of Port of Seattle beginning on August 1
- *Norwegian Gem* out of Port of Miami beginning on August 10

Upon information and belief, all these ships have already booked passengers for these voyages and will continue sailing on back-to-back voyages, i.e., embark new passengers on the same day as they disembark passengers from a previous voyage.

CDC Collaboration with Cruise Lines

22) The CDC has been working collaboratively with cruise lines to ensure a safe restart of sailing. Since November 30, 2020, CDC, and often senior leadership from other relevant federal agencies, have engaged in regularly scheduled calls with cruise industry representatives to discuss their restart plans. This includes the following types of meetings:

- high-level executive meetings with cruise line CEOs to engage in dialogue and exchange information regarding the impact of vaccines and other scientific developments since the CSO was issued,
- technical assistance calls with cruise line personnel representing operations, medical, and public health, to discuss operational questions about the CSO and technical instructions, and
- ad hoc meetings with individual cruise lines to discuss questions related to their specific operations.

23) During these calls, and in subsequent email communications, cruise industry representatives have expressed their desire to rebuild passenger confidence, prove COVID-19 can be successfully managed on board cruise ships sailing in U.S. waters, and avoid a repeat of cruise ship humanitarian crises (e.g., *Diamond Princess*, *Grand Princess*, *Costa Luminosa*, *Zaandam*) that occurred in the early days of the pandemic. Cruise industry representatives have also expressed concern that a large scale COVID-19 outbreak onboard one cruise ship could jeopardize their restart plans and the future of the entire industry.

Ongoing Public Health Risks Due to COVID-19 Require Continued CDC Oversight

24) Because cruise ship operators are restarting operations mostly on ships that have not carried passengers since March 2020, and with new crew implementing new health and safety protocols, shortfalls in training or in fully implementing protocols are to be expected. It is particularly important that any lapses in training or

in implementing protocols be identified and quickly remedied, especially if the ship plans to sail with less than 95% vaccinated passengers. CDC oversight is essential to ensuring that such lapses are identified and promptly addressed.

25) For example, on June 20–22, 2021, a cruise ship operator conducted the first simulated voyage under the CSO onboard a cruise ship sailing out of the Port of Miami. Five CDC personnel were present to inspect the vessel; three of these inspectors sailed with the cruise ship until the end of the simulated voyage on June 22.

26) During and at the close of this inspection, CDC inspectors shared and discussed their observations with cruise ship personnel. The inspectors identified the following areas needing improvement prior to the ship's first passenger revenue voyage:

- Staff training deficiencies in operating laboratory testing equipment, failures to properly use personal protective equipment, and lapses in identifying unvaccinated passengers required to wear masks and physically distance.
- Incomplete documentation of procedures relating to COVID-19 laboratory testing equipment, which could lead to inconsistent and unreliable COVID-19 test results.
- Unvaccinated passengers needing COVID-19 testing mixed with other passengers, and passengers with positive test results were not physically distanced from other passengers cleared for embarkation.

- Inconsistent signage to remind passengers to physically distance, such as limiting capacity in elevators.

After discussing these observations with the cruise ship operator and based on the operator's submission of an "after-action" report, on June 28, CDC issued the operator a COVID-19 Conditional Sailing Certificate to conduct passenger revenue voyages.

27) On June 26, 2021, a cruise ship operator conducted the first revenue passenger voyage in U.S. waters since the start of the pandemic. Four CDC personnel were present to inspect the vessel but did not sail with the ship. The inspectors identified the following areas needing improvement:

- Unvaccinated passengers mixed with other embarking passengers during the check-in process prior to receiving the results of their pre-embarkation COVID-19 test results.
- Cruise line employees screening and directing embarking passengers in the terminal seemed unsure of the process for unvaccinated passengers.
- Another employee conducting embarkation screening of passengers was unsure on the route to send unvaccinated passengers to be tested.

While these deficiencies present less of a public health concern because the ship is operating with 95% of crew and 95% of passengers fully vaccinated, CDC has advised the cruise ship operator of these observations so that they can be remedied.

28) While COVID-19 can be a manageable risk on board cruise ships, continued CDC oversight and supervision are needed to protect the public's health. Specifically, CDC is aware of cruise ship operators mislabeling positive COVID-19 test results as negative; improperly engaging in repeat testing of crew to negate the reporting of a positive test result; erroneously interpreting test results; accidentally releasing crew early from quarantine due to an error in transcribing names; and failing to prevent obvious breaches of quarantine by crew.

29) Furthermore, as cruise ship operators have continued to embark new crew in anticipation of passenger revenue voyages in the U.S., cases of COVID-19 among crew have been reported, highlighting the continued need for public health management of cases to mitigate this risk.

- On June 11, 2021, CDC was notified of three positive COVID-19 test results among crew members on a cruise ship (Cruise Ship A) with an additional 12 positive cases subsequently identified in crew. Because this ship will not be sailing as a highly vaccinated ship, the ship was scheduled to conduct a simulated voyage, but postponed the simulation because of these infections.⁵
- On June 17, 2021, CDC was notified of one positive COVID-19 test result for a crew member on another cruise ship (Cruise Ship B). After an investigation, the ship was cleared by CDC to conduct passenger revenue voyages and is sailing as a highly vaccinated ship.

⁵ [Cruise Ship Color Status | CDC](#) Accessed June 27, 2021.

- On June 24, 2021, CDC was notified of five positive COVID-19 test results among crew members on a cruise ship (Cruise Ship C).⁶ Because this ship will not be sailing as a highly vaccinated ship, the ship was scheduled to conduct a simulated voyage, but postponed the simulation because of these infections.⁷
- On June 25, 2021, CDC was notified of three positive COVID-19 test results among crew members on a cruise ship (Cruise Ship D). Because this ship will not be sailing as a highly vaccinated ship, the ship was scheduled to conduct a simulated voyage, but postponed the simulation because of these infections.⁸

30) Further, CDC recently classified Delta as a virus variant of concern. Variants of concern spread more easily and quickly than other COVID-19 variants, which may lead to more cases, particularly among the unvaccinated. Early evidence shows that the Delta variant spreads 64% more easily than the Alpha variant, which spreads 50% more easily than the original SARS-CoV-2 strain. Preliminary data suggests that the Delta may lead to more severe disease as well.^{9, 10, 11, 12} Due to concern over variants, protective public health measures—such as testing, mask use, and physical distancing—are particularly important for the unvaccinated.

⁶ [Cruise Ship Color Status | CDC](#) Accessed June 27, 2021.

⁷ [Cruise Ship Color Status | CDC](#) Accessed June 27, 2021.

⁸ [Cruise Ship Color Status | CDC](#) Accessed June 27, 2021.

⁹ [SARS-CoV-2 Variant Classifications and Definitions \(cdc.gov\)](#)

¹⁰ [About Variants of the Virus that Causes COVID-19 | CDC](#)

¹¹ [CDC Director Rochelle Walensky On Coronavirus Variants And Vaccinations : NPR](#)

¹² [Increased Household Transmission of COVID-19 Cases Associated with SARS-CoV-2 Variant of Concern B.1.617.2: A national case-control study \(khub net\)](#)

31) Cruise ship voyages from the U.S. will include itineraries to countries that have low vaccination rates but are reopening to international tourism. These countries have limited testing capabilities for their populations, which restricts their ability to identify COVID-19, including variants of concern. Cruise ship travel to these countries may risk introducing variants of concern into the United States. Travelers may be at risk for getting and spreading COVID-19 variants in the following countries where cruise ships that have submitted requests for simulated voyages or applications for revenue passenger voyages intend to sail, per published itineraries: the Bahamas, Mexico, Honduras, Saint Maarten, Dominican Republic, Haiti, Aruba, and Saint Kitts and Nevis.^{13, 14, 15, 16, 17, 18, 19, 20, 21}

32) Removing traditional public protections, as implemented through the CSO—public health surveillance, testing, reporting, requiring the cruise ship operator to rapidly identify and isolate infectious persons and quarantine exposed persons and their contacts, implementing non-pharmaceutical interventions (such as mask wearing and physical distancing), and confirming vaccination status—just as cruising is beginning to restart, places the public at risk, undermines public confidence in the

¹³ [COVID-19 in the Bahamas](#)

¹⁴ [COVID-19 in Mexico](#)

¹⁵ [COVID-19 in Trinidad and Tobago](#)

¹⁶ [COVID-19 in Honduras](#)

¹⁷ [COVID-19 in Sint Maarten](#)

¹⁸ [COVID-19 in the Dominican Republic](#)

¹⁹ [COVID-19 in Haiti](#)

²⁰ [COVID-19 in Aruba](#)

²¹ [COVID-19 in Saint Kitts and Nevis](#)

ability of cruise ship operators to mitigate COVID-19, and jeopardizes cruise industry plans for safe restart.

Vaccinated Cruises and Florida's Vaccine Passport Law

33) CDC and cruise industry representatives have further discussed the importance of high vaccination rates among passengers and crew for the safe restart of cruising. In an April 26, 2021 statement describing the industry's vaccination goals, industry representatives explained that that "the vast majority of our guest bookings will be fully vaccinated before sailing." Similarly, in a May 11 letter, Cruise Line International Association (CLIA), the leading industry trade group, stated that "vaccines are a gamechanger and cruise line requirements will serve to incentivize passengers to become vaccinated." *See* Exhibit A, attached. CDC fully supports the efforts of cruise ship operators to operate highly vaccinated cruises because vaccines provide the best available protection against COVID-19.

34) While CDC and the cruise industry recognize the important role of vaccinations in the safe restart of cruising, the Florida "vaccine passport" law has created uncertainty for cruise ship operators. This law, Senate Bill (SB) 2006, was signed on May 3, 2021. SB 2006 prohibits any business entity operating in Florida from requiring patrons or customers from providing any documentation certifying COVID-19 vaccination to gain access to, entry upon, or service from the business. Cruise ships operating in Florida that attempt to verify vaccination status could therefore face penalties of up to \$5,000 per passenger.

35) CDC is aware of at least one cruise line that initially planned to operate with fully vaccinated travelers but has now changed its plans and opted to conduct a simulated voyage instead because of the risk of exorbitant fines being levied by Florida if they confirm passengers' vaccination status at embarkation. Ships sailing out of Washington and Alaska do not face this uncertainty, and CDC remains committed to working with the cruising industry to resume safer sailing.

36) Accordingly, it is my professional judgment based on all the information available to CDC, that it is necessary to continue the CSO to protect the public's health by mitigating unnecessary risk of COVID-19 transmission onboard cruise ships and into surrounding communities.

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

Signed this 6th day of July 2021.



Aimee Treffiletti, MPH, REHS (CAPT, USPHS)
Maritime Unit
Global Migration Task Force
Centers for Disease Control and Prevention

EXHIBIT A



May 11, 2021

Nathaniel Smith, MD, MPH
Deputy Director for Public Health Service and Implementation Science
Centers for Disease Control and Prevention
U. S. Department of Health and Human Services
1600 Clifton Road NE
Atlanta, GA 30329

Dear Dr. Smith,

The cruise industry greatly appreciates the countless hours you and the Maritime Unit have devoted over the past several months to refining the path to cruise resumption. We are very encouraged by the spirit of cooperation and the clear desire on the part of the Centers for Disease Control and Prevention (CDC) to restore the cruise industry to operating status by this summer.

As you know, we have been working through the detailed technical instructions issued so far under the Framework for Conditional Sailing Order (CSO). On many points of discussion, we have sought clarification; on others we have probed whether alternative approaches might achieve the same intended effect in a more goal-oriented way. We greatly appreciate your willingness to consider our views and we know that over time, by following the current process, we will have our questions answered and the remaining information provided. However, the pace we are on will not allow for sailing to resume in July, which impacts the ability to salvage at least part of the Alaska season. If we are to be able to vaccinate crew members and re-crew ships that have been idle for well over a year, we must have definitive and workable protocols in the next few days. If not, ships cannot be readied by July and the vital economic lifeline cruising provides to that state and its people will have been forfeited for two full years.

To that end, we believe vaccines are a gamechanger and cruise line requirements will serve to incentivize passengers to become vaccinated.

Our key concerns with the CSO and associated technical instructions are the significant restrictions placed on cruises when compared to other forms of travel, leisure, and entertainment, despite the cruise industry's emphasis on vaccinations as a component of U.S. market resumption. The recently issued technical guidance contains no meaningful distinctions between fully vaccinated cruises and those with lesser levels of vaccination. In fact, the guidance seems predicated on a pre-vaccine operating environment and devalues the beneficial protection offered by the vaccines. In our view, this undermines our shared goal of encouraging workers and guests to become vaccinated.

With that in mind, we would like to offer a set of industry commitments for U.S. restart protocols and a framework for how vaccines can be incentivized in the cruise environment. We believe the attached document illustrates the clear benefits to be derived from vaccinated voyages, while also reflecting the reduction of risk on cruises that are open to all, including children not eligible for vaccination.

We agree with the CDC's view that we cannot realistically strive for zero-risk (this is true for very venue and industry) and that risk must be mitigated.

To that end, we believe the attached framework of industry commitments will significantly reduce risk to a level that would compare favorably to other venues. This framework also makes clear that, even with fully vaccinated voyages, additional public health measures would still be required, including testing, sanitation and case management procedures. This approach would meet the levels of protection envisioned by the CSO but would more readily reflect the benefits of vaccines. We would anticipate these measures for initial restart with a reassessment by September 1, 2021.

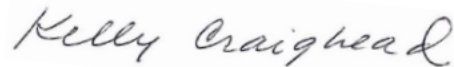
We are prepared to clear our schedules and dedicate as much time as necessary this week to finalize these protocols and enable resumption of cruising from all U.S. ports by July.

Thank you for your consideration.

Sincerely,



Michael Bayley, President & CEO
Royal Caribbean International



Kelly Craighead, President & CEO
Cruise Lines International Association



Gianni Onorato, Chief Executive Officer
MSC Cruises, S.A.



Brian Salerno, SVP, Maritime Policy
Cruise Lines International Association



Josh Weinstein, Chief Operations Officer
Carnival Corporation & plc

Attachment: Industry Commitments Framework

cc: Gary Rasicot, Department of Homeland Security
Joel Szabat, Department of Transportation
Ben Wakana, White House Covid-19 Response Team
Richard Timme, RDML, U.S. Coast Guard



INDUSTRY COMMITMENTS FOR CLIA CRUISE LINE U.S. RESTART PROTOCOLS

OVERVIEW

This proposal is based on the science that is known as of May 10, 2021, and is necessary for the cruise lines to plan and manage the logistics of cruising in July 2021. As the knowledge base of COVID-19 and impact of vaccinations and treatments evolve, these protocols are to be re-evaluated no less than every 60 days as of September 1, 2021, to reflect such developments.

Two types of voyages are specified:

1. **Vaccinated Cruising** that requires $\geq 95\%$ of crew¹ and guests (including children regardless of eligibility for a vaccine) to be vaccinated; and
2. **Cruising Open to All** that requires $\geq 95\%$ of crew¹ to be vaccinated and encourages all passengers to be vaccinated.

TESTING AND SCREENING PROTOCOLS		Vaccinated Cruising Requires $\geq 95\%$ Crew ¹ and Guests ² to Be Vaccinated	Cruising Open to All (Vaccinated and Unvaccinated Guests) Requires $\geq 95\%$ Crew ¹ to Be Vaccinated, and Encourages Guests to be Vaccinated
1a	Vaccinated guest testing	Antigen test no more than 72 hours prior to embarkation; no test required for people with a document of recovery within the last 3 months.	Same as for Vaccinated Cruising
1b	Unvaccinated guest testing	Double testing (viral test) 72 hours prior to travel and Antigen at embarkation; no test required for people with a document of recovery within the last 3 months.	Same as for Vaccinated Cruising
2a	Vaccinated crew embarkation	Multiple testing (PCR 72 hours before travel, antigen at embarkation and antigen testing every other day for the first 7 days onboard).	Same as for Vaccinated Cruising
2b	Unvaccinated crew embarkation	Triple testing (PCR 72 hours before travel, antigen at embarkation, NAAT at the end of 10 day quarantine).	Same as for Vaccinated Cruising
3	Crew vaccinations	Crew deemed to be "vaccinated crew" 14 days after receiving final required dose of FDA / WHO authorized vaccine.	Same as for Vaccinated Cruising
4a	Vaccinated crew testing (surveillance)	All vaccinated crew tested monthly with antigen.	Same as for Vaccinated Cruising
4b	Unvaccinated crew testing (surveillance)	All unvaccinated crew tested weekly with antigen.	Same as for Vaccinated Cruising
5	Embarkation health screening	Health disclosure and symptom screening (temperature check not required)	Same as for Vaccinated Cruising
6	Disembarkation testing	Viral tests for disembarking persons within a 72 hour time period before disembarkation in accordance with the entry test requirements for persons entering the United States generally.	Same as for Vaccinated Cruising
7	Standards of all testing requirements	Devices/tests with emergency use authorization from FDA.	Same as for Vaccinated Cruising

¹ Crew in embarkation quarantine are excluded.

² Includes children regardless of their eligibility for a vaccination.

MASK & SOCIAL DISTANCING PROTOCOLS		Vaccinated Cruising Requires ≥ 95% Crew ¹ and Guests ² to Be Vaccinated	Cruising Open to All (Vaccinated and Unvaccinated Guests) Requires ≥ 95% Crew ¹ to Be Vaccinated, and Encourages Guests to be Vaccinated
8a	Vaccinated guest mask requirements (indoor public spaces)	Not required.	Yes, unless eating or drinking; not required for guests under 2 years old.
8b	Unvaccinated guest mask requirements (indoor public spaces)	Not required.	Yes, unless eating or drinking; not required for guests under 2 years old.
9a	Vaccinated guest mask requirements (outdoors)	Not required.	Not required, unless physical distancing is not possible.
9b	Unvaccinated guest mask requirements (outdoors)	Not required.	Not required, unless physical distancing is not possible; not required for guests under 2 years old
10a	Vaccinated crew mask requirements (indoor spaces excluding personal cabin)	Yes, unless eating or drinking.	Yes, unless eating or drinking.
10b	Unvaccinated crew mask requirements (indoor spaces excluding personal cabin)	Yes, unless eating or drinking.	Yes, unless eating or drinking.
11a	Vaccinated crew mask requirements (outdoors)	Yes, unless eating, drinking or in crew outdoor areas.	Yes, unless eating, drinking or in crew outdoor areas.
11b	Unvaccinated crew mask requirements (outdoors)	Yes, unless eating, drinking or in crew outdoor areas and can maintain appropriate physical distancing.	Yes, unless eating, drinking or in crew outdoor areas and can maintain appropriate physical distancing.
12	Physical distancing	Not required.	3 feet except for families and traveling companions.

QUARANTINE & ISOLATION PROTOCOLS		Vaccinated Cruising Requires ≥ 95% Crew ¹ and Guests ² to Be Vaccinated	Cruising Open to All (Vaccinated and Unvaccinated Guests) Requires ≥ 95% Crew ¹ to Be Vaccinated, and Encourages Guests to be Vaccinated
13	Quarantine of close contacts of a positive case	Guests: Vaccinated guests 7 day quarantine only if symptomatic close contact; unvaccinated close contacts, 10 day quarantine required. Crew: 7-day quarantine required for vaccinated crew only if symptomatic with exit antigen test; unvaccinated crew will quarantine for 10 days with NAAT exit test.	Same as for Vaccinated Cruising
14	Isolation	Required for symptomatic and asymptomatic confirmed COVID-19 cases.	Same as for Vaccinated Cruising

FOOD SERVICE PROTOCOLS		Vaccinated Cruising Requires ≥ 95% Crew ¹ and Guests ² to Be Vaccinated	Cruising Open to All (Vaccinated and Unvaccinated Guests) Requires ≥ 95% Crew ¹ to Be Vaccinated, and Encourages Guests to be Vaccinated
15a	Guest buffet food service	Full self-serve buffet available.	No self-serve buffet.
15b	Crew buffet food service	Full self-serve buffet available.	Same as for Vaccinated Cruising

¹ Crew in embarkation quarantine are excluded.

² Includes children regardless of their eligibility for a vaccination.

INDUSTRY COMMITMENTS FOR U.S. RESTART PROTOCOLS

SHORE EXCURSIONS, CREW VISITS & PRIVATE ISLAND PROTOCOLS		Vaccinated Cruising	Cruising Open to All (Vaccinated and Unvaccinated Guests)
		Requires ≥ 95% Crew ¹ and Guests ² to Be Vaccinated	Requires ≥ 95% Crew ¹ to Be Vaccinated, and Encourages Guests to be Vaccinated
16	Shore excursions	<p>From start of cruising until September 1, 2021 (non-US destinations):</p> <ul style="list-style-type: none"> Guests limited to Company approved indoor and outdoor excursions. Must follow same mask and physical distancing requirements applicable in the Cruising Open to All column. <p>From start of cruising (U.S. destinations only):</p> <ul style="list-style-type: none"> All off-ship activities permitted as allowed by local authorities. <p>After September 1, 2021 (non-U.S. destinations):</p> <ul style="list-style-type: none"> All off-ship activities as allowed by local authorities. 	<p>Vaccinated Guests</p> <p>From start of cruising until September 1, 2021 (non-US destinations):</p> <ul style="list-style-type: none"> Guests limited to Company-approved indoor and outdoor excursions. Must follow mask and physical distancing requirements noted in items 8a, 9a, & 11 <p>From start of cruising (U.S. destinations only):</p> <ul style="list-style-type: none"> All off-ship activities permitted as allowed by local authorities. <p>After September 1, 2021 (non-U.S. destinations):</p> <ul style="list-style-type: none"> All off-ship activities as allowed by local authorities. <p>Unvaccinated Guests</p> <p>Non-US destinations:</p> <ul style="list-style-type: none"> Company-approved outdoor excursions only. Must follow mask and social distancing requirements noted in items 8b, 9b & 12. <p>U.S. destinations:</p> <ul style="list-style-type: none"> All off ship activities are permitted as allowed by local authorities. Must follow mask and physical distancing requirements noted in items 8b, 9b, & 12.
17	Crew shore visits	<p>Vaccinated crew: Only for company approved indoor and outdoor excursions using the same onboard protocols applicable to vaccinated crew.</p> <p>Unvaccinated crew: Only for Company-approved outdoor excursions using the same onboard protocols applicable to unvaccinated crew.</p>	Same as for Vaccinated Cruising
18	Private Islands/private port-controlled area	<p>Guests able to circulate freely within the private island/private port controlled area.</p> <p>For 60 days guests will follow the mask and physical distance requirements as applicable for Cruising Open to All, and thereafter as per requirements of local authorities.</p>	<p>Guests able to circulate freely within the private island/private port-controlled area.</p> <p>Same mask and physical distancing requirements as applicable generally for Cruising Open to All apply on private island/private port-controlled area.</p>

PORT AGREEMENTS, & TEST CRUISE PROTOCOLS		Vaccinated Cruising	Cruising Open to All (Vaccinated and Unvaccinated Guests)
		Requires ≥ 95% Crew ¹ and Guests ² to Be Vaccinated	Requires ≥ 95% Crew ¹ to Be Vaccinated, and Encourages Guests to be Vaccinated
19	Port agreements	As agreed between local port authorities/health authorities and cruise line.	Same as for Vaccinated Cruising
20	Test cruise	Not required.	One per cruise line for its first Cruising Open to All voyage, with cruise lines' third party auditor oversight. Future Cruising Open to All cruise ships will complete tabletop exercises instead.

¹ Crew in embarkation quarantine are excluded.

² Includes children regardless of their eligibility for a vaccination.

VENTILATION, CLEANING & CAPACITY PROTOCOLS		Vaccinated Cruising	Cruising Open to All (Vaccinated and Unvaccinated Guests)
		Requires ≥ 95% Crew ¹ and Guests ² to Be Vaccinated	Requires ≥ 95% Crew ¹ to Be Vaccinated, and Encourages Guests to be Vaccinated
21	Ventilation	HEPA filtration in Medical Center. Appropriate combination of increased fresh air and air filtration throughout the ship, including use of heightened MERV standards where appropriate.	Same as for Vaccinated Cruising
22	Cleaning protocols	Cleaning and disinfection plans for each ship per the CDC Vessel Sanitation Program (VSP) Outbreak Prevention and Response Plan (OPRP).	Same as for Vaccinated Cruising
23	Onboard medical capabilities	Onboard medical capabilities include COVID-19 testing, critical care capabilities and additional equipment, trained medical staff with additional shoreside support as needed, and designated isolation and quarantine facilities	Same as for Vaccinated Cruising
24	Ship capacity	Limited to 70% for first 30 days.	Limited to 50% for first 30 days and thereafter what is needed to maintain physical distancing.

¹ Crew in embarkation quarantine are excluded.

² Includes children regardless of their eligibility for a vaccination.

Proposed Vaccination Goals in support of Cruise Resumption (April 26, 2021)

Purpose

The technical guidance for Phase 2A under the Conditional Sailing order requires “a plan and timeline for vaccination of cruise ship crew prior to resuming passenger operations.” The guidance also requires “presentation of proposals...to incorporate vaccination strategies to maximally protect passengers...and land-based communities.” The following is a high level, proposed approach to addressing these requirements. Industry believes that this approach will significantly reduce risk of COVID-19 transmission, allow for easier modifications of requirements in the CSO that are predicated on pre-vaccine conditions, and would facilitate cruise resumption in the U.S. by Summer 2021.

Guest Vaccinations

We are recommending all guests over the age of 18 be fully vaccinated before sailing. Based upon current market surveys, we believe that the vast majority of our guest bookings will be fully vaccinated before sailing. Children under the age of 18 will be subject to testing protocols. We recognize that a percentage of our guests may be unwilling to accept vaccine for various reasons.

Crew Vaccinations

We are committed to supporting the ability for all of our crewmembers to be vaccinated for cruises as they restart in the United States. We plan on using FDA/WHO approved vaccines. We are advising all crew to receive the vaccine in their home country as guided by their national health department. Any crew member who receives a non FDA/WHO approved vaccine will be regarded as non vaccinated and will be offered the approved vaccine once guidelines from the CDC are available.

Our intention is for all of our crew to be vaccinated. We recognize that a small percentage of crew may be unwilling to be vaccinated for various reasons such as medical or religious reasons, but we are committed to not sailing a vessel commercially out of the US unless at least 90% of our crew working on that vessel are vaccinated. Further, the cruise lines agree to institute strict antigen surveillance testing every three days for any unvaccinated crew members. Each ship will have a vaccination plan, tracking vaccine type, date of inoculation and will maintain all records associated with the crew vaccinations.

Conditions to the above

This crew commitment is dependent upon access to FDA/WHO vaccines which are not currently available commercially to cruise lines and for which government support is required. The cruise lines are in discussion with several Governors' offices in states in which vessels plan to operate, for such states to provide the necessary supply of surplus vaccine, and are working to arrange a mutually agreed path forward. Cruise lines will offer to pay for all vaccine and administration thereof at commercial rates. The foregoing will require the full support of the CDC, Department of Health and Human Services and the other representative agencies of this inter-agency working group.

This proposal is also on the basis that this commitment will be accompanied by (i) the significant relaxation of requirements contained within the CSO that are inconsistent with a largely vaccinated population, and (ii) the acceleration of timelines, streamlining of administrative steps and elimination of CDC stage-gating approvals, all to enable initial restart of commercial cruise operations by 4 July 2021.

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

STATE OF FLORIDA,

Plaintiff,

v.

CASE NO. 8:21-cv-839-T-23AAS

XAVIER BECERRA, et al.,

Defendants.

_____ /

ORDER

CDC moves (Doc. 96) for a stay pending appeal from a preliminary injunction (Doc. 91). CDC designates the motion “time-sensitive.” Assuming either Florida or CDC will move immediately in the Eleventh Circuit for a review of this order and to offer the most time — before the preliminary injunction becomes effective on July 18, 2021 — for the parties to brief and for the Eleventh Circuit to resolve the forthcoming motion, this order promptly addresses CDC’s present motion.

With some marginal elaboration and a new affidavit not otherwise in the record, CDC in the present motion rehearses the arguments advanced unsuccessfully in opposition to Florida’s motion for a preliminary injunction. CDC’s arguments remain unpersuasive. CDC remains dismissive of the requirements of the Administrative Procedure Act, remains dismissive of the manifest disjunction between the statute granting CDC authority and the authority CDC purports to

exercise over the cruise industry, remains dismissive of state and local health regulation and dismissive of the cruise industry's self-regulation (that resulted in a voluntary cessation of cruise ship operation when COVID-19 appeared in early 2020), remains dismissive of successful cruise ship operation elsewhere in the world, and surprisingly remains studiously dismissive of the opportunity, afforded in the preliminary injunction, for CDC to propose an alternative injunction that preserves any part of CDC's cruise ship regulations within CDC's statutory grant of authority and justified by reliable data (that is, data that CDC will disclose, unlike the undisclosed CDC data that speculates about the effect of COVID-19 aboard a cruise ship and on which CDC relies to impose the disputed regulatory regime).

In this instance, CDC's argument fails for the reasons elaborated in the preliminary injunction to show a likelihood of success on appeal, and CDC fails to demonstrate that denial of the stay will injure materially CDC or the United States, any third party, or the public. Although CDC invariably garnishes the argument with dire prospects of "transmission" of COVID-19 aboard a cruise vessel, these dark allusions dismiss state and local health authorities, the industry's self-regulation, and the thorough and costly preparations and accommodations by all concerned to avoid "transmission" and to confine and control the "transmission," if one occurs. In other words, CDC can show no factor that outweighs the need to conclude an unwarranted and unprecedented exercise of governmental power. More to the point, this action is not about what health precautions against COVID-19 are necessary or

helpful aboard a cruise ship; this action is about the use and misuse of governmental power.

The preliminary injunction finds that in the present scheme regulating the cruise ship industry CDC has acted athwart the Administrative Procedure Act and exercised authority not granted to CDC by statute. CDC's motion (Doc. 96) for a stay — a stay that would serve to extend the unwarranted, unprecedented, and injurious exercise of governmental power by one person, the Director of CDC — is **DENIED**.

ORDERED in Tampa, Florida, on July 7, 2021.



STEVEN D. MERRYDAY
UNITED STATES DISTRICT JUDGE