## 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.

# <u>DEFENDANTS' MEMORANDUM IN OPPOSITION TO PLAINTIFF'S</u> <u>MOTION FOR A PRELIMINARY INJUNCTION</u>

#### **INTRODUCTION**

The State of Florida, having failed to challenge the Order at issue here for six months, and related orders for another six months before that, now asks this Court—on an emergency basis and without the benefit of full briefing on an administrative record—to invalidate the Centers for Disease Control and Prevention's ("CDC") Conditional Sailing Order, and to authorize the unconditional resumption of cruise ship operations, without enforceable restrictions to prevent the spread of COVID-19. The Court should decline the invitation.

Despite recent gains, the United States remains in the midst of a once-in-acentury pandemic that has killed over half a million Americans and three million people worldwide. Early in the pandemic, several deadly outbreaks were clustered on cruise ships, like the *Diamond Princess* in Japan, and the *Grand Princess* in the San Francisco Bay. These outbreaks required vast expenditures of government resources to evacuate, quarantine, isolate, house, and treat passengers. These experiences demonstrated that cruise ships are uniquely suited to spread COVID-19, likely due to their close quarters for passengers and crew for prolonged periods, and other factors. As a result of these outbreaks, on March 13, 2020, the cruise ship industry's principal trade group, the Cruise Line International Association ("CLIA"), voluntarily suspended passenger operations, and repeatedly extended that voluntary suspension. Not all cruise operators, however, are members of CLIA, and accordingly, many countries, including the United States, paused operations of these high-risk ships while their operators completed plans to ensure a safe environment for travel.

In the United States, the "No Sail Orders" of last year have been superseded by a framework for re-opening known as the "Conditional Sailing Order," or "CSO," which sets reasonable conditions for the operation of cruise ships based on the best available scientific evidence. The CSO provides for a phased re-opening whereby ship operators (1) test crew and develop on-board testing capacity for future crew and passengers, (2) conduct simulated voyages, and then (3) apply for and obtain Conditional Sailing Certificates. Now that CLIA is willing to resume safe sailing, this framework is necessary to ensure the safe re-opening of cruise operations in the United States, and it is based on CDC's plain authority to regulate ships in U.S. waters to prevent the spread of disease.

CDC is working in partnership with the cruise lines—which have not joined Plaintiff's challenge—to expeditiously move through the CSO framework. Currently, the industry is in Phase 2(a), in which cruise ship operators build additional testing capacity and negotiate agreements with port and local health authorities in each jurisdiction in which they intend to dock to ensure that these local authorities agree that any outbreaks can be safely managed. And today, the CDC issued new guidance for cruise ship operators to test their COVID-19 protocols in U.S. waters through simulated voyages and submit an application for a Conditional Sailing Certificate to resume passenger operations.

Plaintiff's proposed injunction would not maintain the status quo so that the Court has time to rule on the underlying issues—it would upend it. The Court should reject this demand for multiple independent reasons. First, Plaintiff lacks standing to bring suit in the first place. The CSO regulates cruise lines, not states. And Plaintiff cannot save its claim to standing by asserting the alleged injuries of its residents as *parens patriae*, or by relying on indirect declines in general tax revenues.

Second, Plaintiff sat on its supposed rights for well over a year while cruise ship operations were restricted. It cannot now establish that irreparable harm would be prevented by letting cruise ships resume operations slightly more quickly than CDC believes is necessary to protect the public's health.

Third, Plaintiff cannot establish a likelihood of success on the merits of their claims. To start, even if the State of Florida were within the zone of interests of the relevant statute—and it is not—the CDC has acted lawfully and reasonably in setting

conditions on the operation of cruise ships, pursuant to clear authority to regulate vessels intending to operate in U.S. ports. The administrative record will show that the agency considered relevant factors, engaged in reasoned decision-making, and came to reasonable conclusions, especially given the extraordinary deference due to Defendants during the ongoing public health emergency. Moreover, in order to bring an "unreasonable delay" claim like the one here, Plaintiff must identify a specific, mandatory agency action that has been delayed; it cannot do so, and the CDC acted reasonably because, under current guidance, cruise ship operators may conduct simulated voyages and commence restricted passenger voyages by mid-summer. Next, Defendants are 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; and Defendants in any event have demonstrated good cause because they did in fact solicit, receive and consider public comments. Finally, Plaintiff has failed to state a claim under the "nondelegation" doctrine because Congress has provided the CDC with manageable standards to apply.

Finally, the balance of equities tips sharply in Defendants' favor, as the threat of further COVID-19 outbreaks on board cruise lines decisively outweighs any economic injury to Plaintiff. For any or all of these reasons, the Court should deny the motion for a preliminary injunction.

#### **BACKGROUND**

<u>Statutory and Regulatory Authority</u>. The federal government has a long history of acting to combat the spread of communicable disease, including the

regulation of vessels in interstate and international travel. Congress enacted the first federal quarantine law in 1796 in response to a yellow fever outbreak, authorizing the President to direct federal officials to help states enforce quarantine laws. Act of May 27, 1796, 4 Cong. Ch. 31, 1 Stat. 474 (1796) (repealed 1799); *see Smith v. Turner*, 48 U.S. 283, 300 (1849). Following a subsequent yellow fever outbreak, Congress replaced this Act with a federal inspection system for maritime quarantines. Act of Feb. 25, 1799, 5 Cong. Ch. 12, 1 Stat. 619 (1799). And in 1893, Congress authorized the Secretary of the Treasury to adopt additional regulations to prevent the introduction of disease into the United States or across state lines where the Secretary considered state or local regulation inadequate. Act of Feb. 15, 1893, 52 Cong. Ch. 114, 27 Stat. 449 (1893).

Section 361 of the Public Health Service Act ("PHSA") consolidates and codifies the federal government's "basic authority to make regulations to prevent the spread of [communicable] disease into this country or between the States[.]" H.R. Rep. No. 78-1364, at 24 (1944). The statute authorizes Defendants "to make and enforce such regulations as in [the Secretary's] 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." 42 U.S.C. § 264(a).<sup>1</sup>

<sup>&</sup>lt;sup>1</sup> Although the statute assigns this authority to the Surgeon General, Reorganization Plan No. 3 of 1966 transferred all statutory powers and functions of the Surgeon General to the Secretary of Health, Education, and Welfare, now the Secretary of Health and Human Services, 31 Fed. Reg. 8855, 80 Stat. 1610 (June 25, 1966), *see also* An Act to Establish a Dep't of Educ., Pub. L. No. 96-88,

The CDC Director implements this authority through regulations at 42 C.F.R. parts 70 and 71. See Control of Communicable Diseases, 82 Fed. Reg. 6890, 6892 (Jan. 17, 2017). Under these regulations, vessels (including cruise ships) are extensively regulated to prevent the introduction, transmission, and spread of communicable diseases from foreign countries into the United States and from one U.S. State or territory into another. For example, "[w]henever the Director has reason to believe that any arriving carrier . . . is or may be infected . . . with a communicable disease, he/she may require detention, disinfection, . . . or other related measures respecting the carrier or article or thing as he/she considers necessary to prevent the introduction, transmission, or spread of communicable diseases." 42 C.F.R. § 71.32(b). The CDC "may require detention of a carrier until the completion of the measures outlined in this part that are necessary to prevent the introduction or spread of a communicable disease." Id. § 71.31(b). It also "may issue a controlled free pratique [i.e., permission for a carrier to enter a U.S. port, disembark, and begin operations under certain stipulated conditions] to the carrier stipulating what measures are to be met." *Id.*; see also id. § 71.1(b). Moreover, the regulations provide that whenever the CDC Director determines that the measures taken by State authorities "are insufficient to prevent the spread of any of the communicable diseases from such State or possession to any other State or

<sup>§ 509, 93</sup> Stat. 695 (October 17, 1979) (codified at 20 U.S.C. 3508(b)). Although the Office of the Surgeon General was later re-established, the Secretary retains these authorities.

possession, he/she may take such measures to prevent such spread of the diseases as he/she deems reasonably necessary[.]" *Id.* § 70.2.

The No Sail Order and Extensions. Pursuant to these authorities, on March 14, 2020, the CDC issued an order entitled "No Sail Order and Suspension of Further Embarkation." See 85 Fed. Reg. 16628-03 (Mar. 24, 2020) ("NSO"). The NSO contains extensive findings about the spread of COVID-19 on board cruise ships, including information about the deadly outbreaks on board specific ships in the early months of the pandemic, and describes the voluntary suspension of operations by CLIA members. *Id.* at 16630-31.<sup>2</sup> The NSO was intended to provide "the necessary pause in operations to develop and implement an appropriate and robust plan to prevent and mitigate the spread of COVID-19[.]" *Id.* at 16631. The NSO contains several requirements for cruise ships that operate in U.S. waters or intend to arrive in U.S. waters during the effective period of the NSO; most relevant here, the NSO required all disembarkation of passengers to be undertaken in coordination with relevant agencies, and prevented any embarkation or operations except as specifically permitted in consultation with the CDC. Id. at 16631.

The CDC extended the NSO three times, and made additional data-based findings in each extension about the continued transmission of COVID-19 on board cruise ships, and the continued need for federal action in light of the inadequacy of

<sup>&</sup>lt;sup>2</sup> The cruise ship response efforts by the CDC in early 2020 were immense and resource-intensive for the CDC and for all levels of government. *See* Treffiletti Decl. ¶¶ 8-23.

local control.<sup>3</sup> The last extension of the NSO, through Oct. 31, 2020, found that, despite the continuing voluntary suspension of operations, and the cooperation of the industry, "[c]ruise ships continue to be an unsafe environment" and were the location of multiple outbreaks and deaths during the period of voluntary suspension. 85 Fed. Reg. at 62732, 62735-36. This extension described the dangers of premature re-opening, found a need for additional precautions and additional assessment of proposals for re-opening, and imposed additional conditions on the granting of controlled free pratique. *Id.* at 62735-38.

Conditional Sailing Order. On Oct. 30, 2020, the CDC issued the Framework for Conditional Sailing and Initial Phase COVID—19 Testing Requirements for Protection of Crew, 85 Fed. Reg. 70153-01 (Nov. 4, 2020). The CSO announced that "[a]fter expiration of CDC's [NSO] on October 31, 2020, CDC will take a phased approach to resuming cruise ship passenger operations in U.S. waters." *Id.* The CDC reviewed the NSO extensions and the evidence gathered to date regarding mitigation of risk on board cruise ships, including the results of scientific studies of onboard transmission, progress made by cruise lines, and public comments received in response to a request for information. *Id.* at 70154-57. \*See also Treffiletti Decl. ¶¶ 33-45.

<sup>&</sup>lt;sup>3</sup> See No Sail Order and Suspension of Further Embarkation: Notice of Modification and Extension and Other Measures Related to Operations, 85 Fed. Reg. 21004 (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. 44085-01 (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. 62732-01 (Oct. 5, 2020).

<sup>&</sup>lt;sup>4</sup> See also CDC Regulations.gov, RFI Cruise Ship Planning, Comments (July 21, 2020), available at https://www.regulations.gov/document/CDC-2020-0087-0001/comment (last visited around May 5, 2021) (around 13000 comments received); Treffiletti Decl. Ex. A (selected comments).

Based on this record, the CDC determined that a phased approach to granting controlled free pratique was appropriate:

- Phase 1: Crew testing. Ship operators to conduct shoreside testing of crew, develop on-board testing capacity, begin testing crew weekly, and submit results to the CDC.<sup>5</sup>
- Phase 2: Simulated voyages. These are designed to test ship operators' protocols for mitigating COVID–19 onboard, and require them to "document the approval of all U.S. port and local health authorities where the ship intends to dock or make port," including adequate agreements to deal with housing and medical care in event of an outbreak.
- Phase 3: Certification. After successfully completing simulated voyages, ship operators may apply for a Conditional Sailing Certificate.
- Phase 4: Return to passenger voyages, in a manner that mitigates the risk of COVID-19 spread.

85 Fed. Reg. at 70153, 70158-59; Treffiletti Decl. ¶ 33.

Although Phase 1 was originally planned to last 60 days, ship operators reported that supply issues prevented them from procuring onboard laboratory equipment, and the CDC extended the time for compliance. *See* Treffiletti Decl. ¶¶ 46-49. As of April 26, 2021, 95% of cruise ships covered by the CSO (56 out of 59 ships in U.S. waters) have performed the required mass screening testing of all crew, and 80% (47 of 59 ships) have fully completed Phase 1. *Id.* ¶ 49.

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<sup>&</sup>lt;sup>5</sup> Given the briefing schedule for a preliminary injunction, Defendants have not had time to compile the voluminous administrative record for the CSO (which incorporated the findings of the NSO and extensions). Defendants will produce the administrative record when they move for summary judgment. The Declaration of Captain Aimee Treffiletti is submitted herewith to provide additional background about the process for developing the CSO, information about the current state of reopening, and an explanation of the likely consequences of the requested injunction.

Meanwhile, on April 2, 2021, the CDC announced the guidance for the next phase. In Phase 2(a), ship operators are preparing to conduct simulated voyages, including by complying with new technical instructions for crew testing and negotiating agreements with port and local health authorities. 6 In developing these requirements, the CDC consulted extensively with state, local, and international health authorities. See id. ¶¶ 50-55. On April 28, 2021, following multiple meetings with industry representatives, the CDC sent a letter to cruise ship operators, emphasizing the agency's commitment to the phased resumption of passenger operations around mid-summer, and clarifying several aspects of the Phase 2(a) guidance. *Id.* ¶ 52 & Ex. B. Among other things, that letter explains that the CDC will respond to an application within five business days, clarifies that multiport agreements are acceptable, updates the vaccination and testing requirements, and provides that "[i]n lieu of conducting a simulated voyage," ship operators may attest "that 98 percent of crew are fully vaccinated" and that "95 percent of passengers" will be "verified by the cruise ship operator as fully vaccinated prior to sailing."<sup>7</sup>

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<sup>&</sup>lt;sup>6</sup> See CDC, Technical Instructions for Mitigation of COVID-19 Among Cruise Ship Crew, available at <a href="https://www.cdc.gov/quarantine/cruise/management/technical-instructions-for-cruise-ships.html">https://www.cdc.gov/quarantine/cruise/management/technical-instructions-for-cruise-ships.html</a>; CDC, Technical Instructions for a Cruise Ship Operator's Agreement with Port and Local Health Authorities under CDC's Framework for Conditional Sailing Order, available at <a href="https://www.cdc.gov/quarantine/cruise/instructions-local-agreements.html">https://www.cdc.gov/quarantine/cruise/instructions-local-agreements.html</a>.

<sup>&</sup>lt;sup>7</sup> The Governor of Florida has issued an Executive Order stating that "[b]usinesses in Florida are prohibited from requiring patrons or customers to provide any documentation certifying COVID-19 vaccination." Fl. Exec. Order No. 21-81, § 2 (Apr. 2, 2021); see also Orlando Sentinel, DeSantis' ban of vaccine passports could lead to showdown with businesses in Florida, <a href="https://www.orlandosentinel.com/politics/os-ne-prem-ne-vaccination-passports-florida-20210415-p5ih3mwtjrervlnnufbe3mijgi-story.html">https://www.orlandosentinel.com/politics/os-ne-prem-ne-vaccination-passports-florida-20210415-p5ih3mwtjrervlnnufbe3mijgi-story.html</a>. It is unclear whether the Governor's order will delay cruise ships from resuming operations in Florida.

On May 5, 2021, the CDC released guidance regarding simulated voyages, 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. Treffiletti Decl. ¶ 58 & Exs. C, D. While the CDC may adjust these recommendations based on public health considerations and other factors, cruise ship operators now have all the necessary instructions they need to conduct simulated voyages, apply for a COVID-19 conditional sailing certificate, and ultimately begin restricted passenger voyages as they are able to meet the various requirements. *Id.* The CDC anticipates that such voyages could begin by mid-summer. *Id.* ¶ 74.

Cruise lines have advocated for faster re-opening, or lifting of the CSO, but they continue to work with the CDC and have not, to date, challenged the CSO in court. *See* Treffiletti Decl. ¶ 74 (describing ongoing engagement with industry). CLIA is publicly advocating for a "phased resumption" of cruising to begin in early July, which is consistent with current CDC guidance and the April 28 letter.<sup>8</sup>

**This Litigation**. The State of Florida filed suit, raising five counts against Defendants, and seeking, *inter alia*, a permanent injunction against the CSO in its entirety. Compl., ECF No. 1. The present motion seeks the same injunction as a preliminary matter.

<sup>&</sup>lt;sup>8</sup> See CLIA, Cruise Industry COVID-19 Facts and Resources, <a href="https://cruising.org/en/cruise-industry-covid-19-facts-and-resources">https://cruising.org/en/cruise-industry-covid-19-facts-and-resources</a>.

#### STANDARDS FOR A PRELIMINARY INJUNCTION

"A preliminary injunction is an extraordinary remedy never awarded as of right." Winter v. Nat. Res. Def. Council, Inc., 555 U.S. 7, 24 (2008). "In order to obtain [a preliminary injunction], a party must establish four separate requirements namely, that (1) it has a substantial likelihood of success on the merits; (2) irreparable injury will be suffered unless the injunction issues; (3) the threatened injury to the movant outweighs whatever damage the proposed injunction may cause the opposing party; and (4) if issued, the injunction would not be adverse to the public interest." Swain v. Junior, 961 F.3d 1276, 1284–85 (11th Cir. 2020) (citation omitted). "[F]ailure to meet even one dooms" Plaintiff's motion. Wreal, LLC v. Amazon.com, 840 F.3d 2144, 1248 (11th Cir. 2016). Plaintiff here has an even higher burden. 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." Ne. Fla. Chapter of Ass'n of Gen. Contractors of Am. v. City of Jacksonville, 896 F.2d 1283, 1284 (11th Cir. 1990). "Mandatory preliminary relief,]" which changes the status quo, "is particularly disfavored, and should not be issued unless the facts and law clearly favor the moving party." Powers v. Sec'y, Fla. Dep't of Corr., 691 F. App'x 581, 583 (11th Cir. 2017) (citation omitted).

## **ARGUMENT**

#### I. PLAINTIFF LACKS STANDING.

Plaintiff lacks standing. The CSO regulates cruise lines, not states. Florida may not invoke the interests of its residents to support standing in a suit against the federal government, and Florida's attempt to invoke the indirect effect of federal policy on its general tax revenues is effectively a generalized grievance. Even if lower general tax revenues were a legally cognizable injury, Florida can only speculate that any harm will in fact occur or that its injury is fairly traceable to the CDC Order, given the effect of the independent decisions of third parties and the course of the virus on Florida's finances.

The CSO does not require Plaintiff to do or refrain from doing anything—it regulates cruise ships, none of whom have challenged it in court. *See Massachusetts v. Mellon*, 262 U.S. 447, 482 (1923) ("Nor does the statute require the states to do or to yield anything."). Because Plaintiff is not "the object of the [challenged] government action[,]" its standing is "substantially more difficult" to establish. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 562 (1992); *see also Wilderness Soc. v. Griles*, 824 F.2d 4, 10-12 (D.C. Cir. 1987) (addressing threatened injuries in standing law).

To start, Plaintiff is mistaken to suggest that it has standing in its *parens patriae* capacity to invoke the well-being of its residents. *See* Pl.'s Mot. for Prelim. Inj. ("Pl.'s Mot."), ECF No. 9 at 21-22. While a state may in some circumstances be able to sue as *parens patriae* for its citizens, "it is no part of its duty or power to enforce their rights in respect of their relations with the federal government. In that field[,] it is the

United States, and not the state, which represents them as parens patriae." *Mellon*, 262 U.S. at 485-86; see also Alfred L. Snapp & Son, Inc. v. Puerto Rico, 458 U.S. 592, 610 n. 16 (1982); Gov't of Manitoba v. Bernhardt, 923 F.3d 173, 179-83 (D.C. Cir. 2019); Graham v. Schweiker, 545 F. Supp. 625, 627 (S.D. Fla. 1982).

For its own part, Florida has not demonstrated a legally cognizable Article III injury to itself. To obtain the prospective relief it seeks, Plaintiff bears the burden of showing that it "is immediately in danger of sustaining some direct injury" and that the "threat of injury must be both 'real and immediate,' not 'conjectural' or 'hypothetical.'" *City of Los Angeles v. Lyons*, 461 U.S. 95, 102 (1983) (citation omitted).

Plaintiff claims that it "is likely to continue to suffer . . . economic harm" as a result of lower general tax revenues. Pl.'s Mot. at 22.9 But "loss of general tax revenues as an indirect result of federal policy is not a cognizable injury in fact." *El Paso Cty., Texas v. Trump*, 982 F.3d 332, 339 (5th Cir. 2020); *see also see Arias v. DynCorp*, 752 F.3d 1011, 1055 (D.C. Cir. 2014) (same); *Iowa ex rel. Miller v. Block*, 771 F.2d 347, 353 (8th Cir. 1985) (same). The reality is that "'virtually all federal policies' will have 'unavoidable economic repercussions." *El Paso*, 982 F.3d at 339 (quoting *Pennsylvania v. Kleppe*, 533 F.2d 668, 672 (D.C. Cir. 1976)). Accordingly, complaints

<sup>&</sup>lt;sup>9</sup> Plaintiff also gestures at a procedural injury, claiming CDC deprived Florida of the opportunity to comment on the challenged order. Pl.'s Mot. at 21 n.10. Leaving aside the fact that the CDC provided opportunity for comment on the safe resumption of passenger operations, *see* 85 Fed. Reg. at 44083-85; *Spokeo, Inc. v. Robin*, 136 S. Ct. 1540, 1548-49 (2016). Plaintiff "cannot satisfy the demands of Article III by alleging a bare procedural violation." *Spokeo, Inc.*, 136 S. Ct. at 1550; *see also Summers v. Earth Island Inst.*, 555 U.S. 488, 496 (2009) (rejecting claim that plaintiffs have standing because "they have been denied the ability to file comments" and explaining that "a procedural right *in vacuo*—is insufficient to create Article III standing").

about such losses typically amount to "the sort of generalized grievance about the conduct of government, so distantly related to the wrong for which relief is sought, as not to be cognizable for purposes of standing." *Kleppe*, 533 F.2d at 672.

Even if Plaintiff's alleged economic injury were cognizable, its injury is premised on "continued closure of the cruise industry[,]" Johnston Decl., ECF No. 9-25, ¶ 5, as "the important summer cruising season is fast approaching," Pl.'s Mot. at 22. However, Plaintiff "present[s] no concrete evidence to substantiate [its] fears" that the cruise operations will not imminently resume under the challenged policy, "but instead rest[s] on mere conjecture about possible governmental actions." See Clapper v. Amnesty Int'l, 568 U.S. 398, 420 (2013). Contrary to Plaintiff's fears, the CSO—unlike the NSOs—establishes a "framework for a phased resumption of cruise ship passenger operations," 85 Fed. Reg. at 70,153, in order to effectuate "a return to passenger voyages in a manner that mitigates the risk of COVID-19," id. at 70157. Indeed, Plaintiff's own "evidence" speculates that guidelines "vital for the cruise lines" to resume operations under the challenged order "[c]ould be just days away," Pl.'s Ex. 7 at 5; see also Pl.'s Ex. 28 at 3 ("possibility of a summer restart of service"), consistent with the CSO's goal of resuming safe voyages by mid-summer. And that speculation is confirmed by today's release of guidance for the next phases of the CSO. Treffiletti Decl. ¶ 58. It is therefore likely that many cruises can operate on the schedule currently planned by the industry. Even if Plaintiff had established "an objectively reasonable likelihood that" the cruise industry would continue to be shut down through the summer in the United States under the challenged order, an

"'objectively reasonable likelihood' . . . is inconsistent with [the] requirement that 'threatened injury must be certainly impending to constitute injury in fact.'" *Clapper*, 568 U.S. at 410 (quoting *Whitmore v. Arkansas*, 495 U.S. 149, 158 (1990)). <sup>10</sup>

Plaintiff also fails to demonstrate causation or redressability. Here, Plaintiff provides nothing but speculation to support its theory that any lost general tax revenues are fairly traceable to the CDC's order, as opposed to the independent decisions of third parties, like cruise lines and passengers. Plaintiff provides evidence of past tax revenue purportedly associated with cruise ships from before the COVID-19 pandemic. See Johnston Decl. ¶ 4; see also Pl.'s Ex. 20 at 44; Pl.'s Ex. 21 at 29; Pl.'s Ex. 22 at 10; Pl.'s Ex. 23 at 36; Pl.'s Ex. 24 at 27; Pl.'s Ex. 25 at 3. And Plaintiff's primary declarant merely "[a]ssum[es] . . . that the cruise industry would return to 2019 numbers" if the challenged order is vacated. See Johnston Decl. ¶ 5 (emphasis added). But a state's impaired tax revenues during an ongoing pandemic "is driven by countless variables, from the performance of the broader economy" to whether or not a resurgence of COVID-19 will occur, as well as independent decisions of cruise ship operators, tourists, airlines, and businesses in the state. See XY Planning Network LLC v. SEC, 963 F.3d 244, 253 (2d Cir. 2020); see also Clapper, 568 U.S. at 413

<sup>&</sup>lt;sup>10</sup> In "cases in which the plaintiff alleges that governmental action will be taken directly against him[,] . . . the Court has assessed the likelihood that the clash between the government and the plaintiff will in fact occur." *Griles*, 824 F.2d at 11. A plaintiff may establish a sufficiently imminent injury in that setting "if the threatened injury is 'certainly impending' or there is a 'substantial risk' that the harm will occur." *Susan B. Anthony List v. Dreihaus*, 573 U.S. 149, 158 (2014) (citation omitted). Plaintiff does not claim a threat of injury emanating directly from government conduct in this case, however. *See* Pl.'s Mot. at 22. Here, the CDC is "act[ing] directly against a third party"—the cruise ship industry—"whose expected response in turn will [purportedly] injure the plaintiff." *Griles*, 824 F.2d at 11.

(refusing to "endorse standing theories that require guesswork as to how independent decision-makers will exercise their judgment"); *Simon v. E. Kentucky Welfare Rights*Org., 426 U.S. 26, 42-43 (1976). Plaintiff's submissions do not attempt to estimate what revenues would be absent CDC action – i.e., if cruising were legally permitted to resume without federal public health oversight and against CDC advice.

Additionally, Plaintiff's injury is premised on speculation that either (1) no ship-borne outbreak of COVID-19 (including a variant) would occur, or (2) if a ship-borne outbreak did occur, the weighty costs of addressing the emergency would not be placed on the State. *See XY Planning Network*, 963 F.3d at 253 (concluding that State's theory "assumes away the potential downsides of" their preferred approach). Without adequate planning and regulation to mitigate COVID-19 risks, cruise ship operations during the pandemic may result in "State and local public health officials" facing major "burden[s] supporting cruise ships attempting to make port with ill passengers or crew and struggl[ing] to repatriate passengers and crew while also protecting the limited medical assets" available in their community. 85 Fed. Reg. at 44087; *see also* Treffiletti Decl. ¶¶ 37, 51-55.

The CDC has concluded that without adequate precautions, a cruise ship outbreak exacerbating and amplifying the spread of the virus is quite likely given the unique characteristics of cruise ships. *See* Treffiletti Decl. ¶ 75; 85 Fed. Reg. at 44090-91. Plaintiff does not evaluate the impact of such outbreaks on the cruise economy or its overall tax revenue. And Plaintiff makes no effort to address the economic implications of would-be cruise passengers forgoing a cruise in the absence of the

assurances of safety that accompany federal regulation during the ongoing pandemic.<sup>11</sup> All these what-ifs and could-bes highlight Plaintiff's speculation in asserting an imminent injury caused by the challenged actions. Because the supposed injuries, at most, arise from the kind of "unavoidable economic repercussions of virtually all federal policies[,]" they do not support standing. *XY Planning Network*, 963 F.3d at 252 (quoting *Kleppe*, 533 F.2d at 672).

#### II. FLORIDA HAS NOT DEMONSTRATED IRREPARABLE HARM.

"A delay in seeking a preliminary injunction of even only a few months . . . militates against a finding of irreparable harm." Wreal, LLC, 840 F.3d at 1248. "Indeed, the very idea of a preliminary injunction is premised on the need for speedy and urgent action to protect a plaintiff's rights before a case can be resolved on its merits." Id. Here, Plaintiff seeks to "preliminarily enjoin Defendants from enforcing, or giving any effect to, the [CSO,]" ECF No. 9-30, but offers no explanation why it waited nearly six months after the temporary emergency order was issued to seek judicial review—let alone stay or preliminarily enjoin it. Plaintiff's "unexplained delay undercuts any sense of urgency and, therefore, Plaintiff has failed to demonstrate sufficient need for a preliminary injunction." Seiko Kabushiki Kaisha v. Swiss Watch Int'l, Inc., 188 F. Supp. 2d 1350, 1356 (S.D. Fla. 2002).

Indeed, Plaintiff says that the "extraordinary and drastic remedy" of a preliminary injunction, see All Care Nursing, Inc. v. Bethesda Mem. Hosp., Inc., 887 F.2d

<sup>&</sup>lt;sup>11</sup> Commenters overwhelmingly supported regulatory policies that would mitigate the risk of COVID-19 transmission. *See* 85 Fed. Reg. at 70,156; Treffiletti Decl. ¶ 38.

1535, 1537 (11th Cir. 1989), is warranted because "the important summer cruising season is fast approaching," Pl.'s Mot. at 22. But if Plaintiff had timely petitioned for judicial review, its "claim [w]ould have been brought at such a time as to allow consideration of the merits" long before the summer "without requiring entry of a" preliminary injunction. *See Hill v. McDonough*, 547 U.S. 573, 584 (2006) (quoting *Nelson v. Campbell*, 541 U.S. 637, 650 (2004)). Accordingly, this Court must "apply 'a strong presumption against the grant of a'" preliminary injunction. *See id.* (quoting *Nelson*, 541 U.S. at 650); *see also Lanvin Inc. v. Colonia, Inc.*, 739 F. Supp. 182, 192-93 (S.D.N.Y. 1990) ("A movant for extraordinary relief cannot mask an ongoing failure on its part to mitigate its damages as an ongoing instance of irreparable harm.").

Plaintiff's attempt to demonstrate irreparable harm falls short for an additional reason: the injury it alleges is insufficient. "Even if denial of injunctive relief would present some monetary injury to the plaintiff[], . . . not finding *irreparable* injury" would be proper. *Snook v. Trust Co. of Georgia Bank of Savannah, N.A.*, 909 F.2d 480, 487 (11th Cir. 1990) (emphasis in original). "Financial damage alone is insufficient to warrant injunctive relief." *Seiko Kabushiki Kaisha*, 188 F. Supp. 2d at 1355.

Although a threat to a plaintiff's existence or continued operations may constitute irreparable harm, Florida presents no evidence that its purported cruise ship tax revenue is needed to keep the state in financial operation pending judicial review of the challenged order. *See Alsop v. Desantis*, No. 8:20-cv-1052, 2020 WL 4927592, at \*4 (M.D. Fla. Aug. 21, 2020) (Merryday, J.)); *Cal. Ass'n of Private Postsecondary Schs. v. DeVos*, 344 F. Supp. 3d 158, 170-71 (D.D.C. 2018); *see also Odebrecht Const., Inc. v.* 

Sec'y, Fla. Dep't of Transp., 715 F.3d 1268, 1288 (11th Cir. 2013) (finding irreparable the "substantial nature of the . . . harm" that constituted approximately "100% of [plaintiff's] revenues"); cf. VNA of Greater Tift Cty., Inc. v. Heckler, 711 F.2d 1020, 1034 (11th Cir. 1983) (considering allegation of "being forced out of business").

Here, Florida speculates that lost tax revenue associated with cruise ship operations might be \$82 million. Johnston Decl. ¶ 5. 12 But in a state with a Chief Executive that has recommended a Fiscal Year 2021-2022 budget of \$96.6 billion, 13 the amount at issue is roughly 0.085% of the state's budget. Plaintiff's suggestion that "any damages," no matter how slight, "in a suit against a defendant with sovereign immunity are irreparable per se" surely "stretches too far," Air Transp. Ass'n of Am. Inc. v. Export-Import Bank of the United States, 840 F. Supp. 2d 327, 335 (D.D.C. 2012), and "is inconsistent with [the] characterization of injunctive relief as an extraordinary remedy[,] Winter, 555 U.S. at 22. Moreover, "[t]here are several possible means by which [Florida] could recover" its less-than-hoped-for tax revenues other than a suit against Defendants because the state, like a public utility, has captive taxpayers and any losses are "recoverable [by adjustments] in the [state]'s

<sup>&</sup>lt;sup>12</sup> The corrected Fitz-Patrick Declaration estimates total revenue losses during the pandemic for some local ports. *See* ECF No. 25-26. Even assuming that Florida could assert these losses on behalf of the ports, which is unlikely, the declaration makes no attempt to connect those losses to CDC action or even to cruise lines.

<sup>&</sup>lt;sup>13</sup> Governor Ron DeSantis Announces His "Florida Leads" Budget Proposal for FY 2021-2022, https://www.flgov.com/2021/01/28/governor-ron-desantis-announces-his-florida-leads-budget-proposal-for-fy-2021-2022/ (last visited May 5, 2021).

[tax] rates." Cf. Wisc. Gas Co. v. FERC, 758 F.2d 669, 675 (D.C. Cir. 1985); see also Florida v. Mellon, 273 U.S. 12, 18 (1927). 14

Given the speculative nature of the "injuries" here, *see* Part I, *supra*, issuing a preliminary injunction here would be inconsistent with the Eleventh Circuit's emphasis that "the asserted irreparable injury must be neither remote nor speculative," *Swain*, 961 F.3d at 1292 (citation omitted), to be awarded only "upon a clear showing that the plaintiff is entitled to such relief," *Winter*, 555 U.S. at 22.<sup>15</sup>

## III. PLAINTIFF CANNOT DEMONSTRATE A LIKELIHOOD OF SUCCESS ON THE MERITS.

## A. Plaintiff Lacks Statutory Standing.

Counts 1-4 raise claims under the APA, and Plaintiff lacks statutory standing to raise such claims. The APA's grant of standing to persons "adversely affected or aggrieved by agency action within the meaning of a relevant statute," 5 U.S.C. § 702, does not extend to the full reach of Article III, and is satisfied only if the plaintiff's interests are "arguably within the zone of interests to be protected or regulated by the

<sup>&</sup>lt;sup>14</sup> Plaintiff also asserts that it provided \$20 million in unemployment benefits to cruise industry employees since March 1, 2020. *See* Heckman Decl., ECF No. 9-19, ¶ 3. But Plaintiff provides only speculation that any of those individuals—let alone a substantial number of them—would leave the unemployment rolls and resume working in the cruise industry if the CSO were enjoined, especially as "[c]ruise ship crew are primarily foreign nationals" meaning ships are not primarily hiring in Florida. Treffiletti Decl. ¶ 69. And as the State reopens, it is just as likely that these individuals will leave unemployment and find work elsewhere. Moreover, Plaintiff fails to account for federal reimbursement of state unemployment spending. *See* American Rescue Plan of 2021, Pub. L. No. 117-2, 135 Stat. 4 (Mar. 11, 2021). Plaintiff has not "shown that the alleged loss is unrecoverable[.]" *Wisc. Gas*, 758 F.2d at 675.

<sup>&</sup>lt;sup>15</sup> Plaintiff also relies on *California v. Azar*, 911 F.3d 558, 581 (9th Cir. 2018). *See* Pl.'s Mot. at 22 n.11. But that case only highlights how Plaintiff's evidence of irreparable injury "does not measure up to the kind of detailed . . . analysis about the expected impact of an agency regulation that courts have relied on to find standing[,]" let alone irreparable harm. *Washington v. HHS*, 482 F. Supp. 3d 1104, 1117 (W.D. Wash. 2020) (citing *Azar*, 911 F.3d at 572).

statute" that the plaintiff says was violated. *See Ass'n of Data Processing Serv. Orgs., Inc. v. Camp*, 397 U.S. 150, 153 (1970); *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 129-30 (2014). Thus, even if Florida could establish Article III standing as result of supposed injuries to its tax revenues, that injury is not within the zone of interests of the applicable statute or regulation. It cannot reasonably be assumed that, in "[t]he particular language of" Section 264(a), "Congress intended to protect" a State government's general tax revenue. *See Air Courier Conference of Am. v. Am. Postal Workers Union AFL-CIO*, 498 U.S. 517, 524-25 (1991). The regulations are aimed at public health conditions on board vessels. And while the CSO explicitly takes into account the public health burden on state and local governments, it is not designed to protect, or even consider, state tax revenues. Plaintiff thus cannot establish a likelihood of success on any APA claim. <sup>16</sup>

## B. The CSO Does Not Exceed the CDC's Authority.

1. The CSO's restriction of cruise operations pending the implementation of reasonable COVID-19 health and safety protocols falls comfortably within the CDC's authority to prevent the introduction, transmission, and spread of

<sup>&</sup>lt;sup>16</sup> The Eleventh Circuit has recognized a carve-out for some *ultra vires* actions where the plaintiff is alleging that the agency acted clearly outside its statutory authority. *Chiles v. Thornburgh*, 865 F.2d 1197, 1210-11 (11th Cir. 1989). The question of whether an plaintiff can evade the zone of interests requirement by asserting an equitable *ultra vires* cause of action is pending before the Supreme Court in *Biden v. Sierra Club*, No. 20-138 (cert. granted Oct. 19, 2020). Here, it is not clear that Plaintiff has even raised such a claim. And to the extent this reasoning means that Florida need not establish statutory standing for the Count 1 argument that the CDC was acting outside statutory authority, Florida would still need to demonstrate statutory standing for the argument that the CDC acted outside its *regulatory* authority and must show that Florida is within the zone of interests of the relevant statute to challenge the CDC's application of its own regulations.

communicable disease into and within the United States. The PHSA vests the Secretary with broad authority "to make and enforce such regulations as in his judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases" from abroad or among the states. 42 U.S.C. § 264(a). The plain text of the statute thus evinces a legislative determination to defer to the "judgment" of public health authorities about what measures they deem "necessary" to prevent contagion, see id.—a determination made in the light of history and experience, given the death toll caused by past epidemics like yellow fever, see supra at p.5. And the examples Congress gave of specific measures the Secretary may take to control communicable diseases—which are illustrative, not exhaustive underscore the breadth of this authority, showing that it may infringe on personal liberties or property rights to protect the public health, including the "detention" of individuals, 42 U.S.C. § 264(b)–(d), and even the "destruction" of property, id. § 264(a).

The Secretary has delegated this authority to the public health experts at the CDC, and 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. For example, Section 71.32(b) provides that when "any arriving carrier" "is or may be infected or contaminated with a communicable disease," the CDC Director "may require [its] detention, disinfection, . . . or other related measures . . . as he/she considers necessary to prevent the introduction, transmission, or spread of

communicable disease." 42 C.F.R. § 71.32(b). Likewise, Section 71.31(b) authorizes the CDC to "require detention of a carrier until the completion of the measures outlined in this part that are necessary to prevent the introduction or spread of a communicable disease." *Id.* § 71.31(b). And the CDC "may issue a controlled free pratique to the carrier stipulating what measures are to be met," *id.*, as a condition of receiving "permission to enter a U.S. port, disembark, and begin operation," *id.* § 71.1.

Notably, Plaintiff does not contend that these regulations exceed the CDC's statutory authority—indeed, it concedes that, "[p]roperly read, these regulations make sense as an outflow of § 264," Pl.'s Mot. at 13. The CSO falls squarely within these regulations, and that alone resolves Plaintiff's claim that the order exceeds CDC's authority. In essence, the CSO requires that, "as a condition of obtaining or retaining controlled free pratique," 85 Fed. Reg. at 70158, arriving ships show that they have implemented reasonable COVID-19 preventive measures, have adequate testing capacity and can operate with risk mitigation measures, and will not burden already-strapped federal, state, and local resources if infections arise.

Requiring that ships take such reasonable protective measures as a condition of obtaining controlled free pratique falls well within the agency's authority and is amply supported by the available evidence. The CSO applies to cruise ships that currently operate in (or intend to enter) U.S. waters, *see* 85 Fed. Reg. at 70153, and therefore applies to "arriving carrier[s]" within the meaning of 42 C.F.R. § 71.32(b). It is premised on explicit findings about the risk of transmission of COVID-19 on

cruise ships, explaining that many operators have struggled to follow CDC guidance and prevent outbreaks even without passengers on board, *see* 85 Fed. Reg. at 70156, and thus establishes that the CDC has reason to believe that such carriers "[are] or may be infected or contaminated with a communicable disease," 42 C.F.R. § 71.32(b), or "present a threat of introduction of communicable diseases into the United States," *id.* § 71.31(a). <sup>17</sup> And as a condition of obtaining "controlled free pratique," *id.* § 71.31(b), it requires that ships take now-commonplace "related measures"—like infection precautions, testing, and emergency planning—that the CDC has found are necessary to prevent the spread of COVID-19, *see id.* §§ 71.31(b), 71.32(b); 85 Fed. Reg. at 70158-63. <sup>18</sup>

If there were any gap between the CDC's authority in Part 71 and the CSO—and there is not—it would be amply filled by 42 C.F.R. 70.2. The CSO, like the earlier NSO and its extensions, finds that State and local measures are inadequate to control the threat of the disease on board cruise ships. *See* 85 Fed. Reg. at 16631, 21006, 44091, 62736-37, 70157. For example, the CSO states that "[c]ruise ships by

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<sup>&</sup>lt;sup>17</sup> Plaintiff suggests that any "detention" of a ship under these regulations is necessarily time-limited. Pl.'s Mot. at 12-13. The CSO primarily imposes specific conditions on the granting of controlled free pratique. But even if the CSO were viewed as requiring "detention," it would still be authorized. The regulations do not impose a specific time limit on detention, and the CDC may require "completion of the measures outlined in this part that are necessary to prevent the introduction or spread of a communicable disease," 42 C.F.R. 71.31(b), and/or "other related measures respecting the carrier or article or thing as he/she considers necessary to prevent the introduction, transmission, or spread of communicable diseases."

<sup>&</sup>lt;sup>18</sup> Indeed, the regulations themselves contemplate such "[p]ublic health prevention measures," including the "review of travel documents, records review, and other non-invasive means, to determine [an] individual's health status and potential public health risk to others," including "physical examination" and the "collection of human biological samples for laboratory testing as may be needed to diagnose the presence or extent of infection with a quarantinable communicate disease." 42 C.F.R. § 71.1.

their very nature travel interstate and internationally and can move beyond the jurisdictional boundaries of any single state or local health authority," and that "local transmission of COVID-19 onboard a cruise ship can escalate quickly into additional interstate and international transmission when infected persons travel." Id. at 70157. Cruise ships are, by purpose and operation, conveyances of international and interstate travel, and single cruise ships have been responsible for outbreaks affecting multiple countries. See generally CSO; see also Alaska. Br., ECF No. 19-1 at 3 (describing Alaska as a "destination" for ships, not the point of embarkation). The CSO also explains in great detail that the orders are reasonably necessary to prevent the further transmission and spread of the pandemic, and finds that "this pandemic is inherently and necessarily a problem that is international and interstate in nature, and such transmission has not been controlled sufficiently by the cruise ship industry or individual State or local health authorities." 85 Fed. Reg. at 70157. This evidencebased conclusion is both reasonable and obvious—local authorities cannot adequately control conditions on cruise ships that move between multiple jurisdictions because they cannot inspect and enforce conditions on their operation outside the local jurisdiction in question. Indeed, while Plaintiff criticizes the CDC for allegedly "refus[ing] to consider measures by Florida," Pl.'s Mot. at 12, it never explains what those supposed measures are, much less how they are "[]sufficient" to prevent contagion," 42 C.F.R. § 70.2.

**2.** Plaintiff's contention that the CSO nevertheless exceeds the CDC's statutory authority—despite falling firmly within its regulations—thus appears to rest

on the notion that the order "shut[s] down the cruise industry" entirely. Pl.'s Mot. at 13. Indeed, Plaintiff goes so far as to call the CDC order a "'ruse' designed to 'keep the industry docked,'" and to question whether the agency is dealing with "the cruise industry in good faith." *Id.* at 7 (citation omitted). In fact, the CDC has for months worked closely with cruise operators—none of which have joined this suit—to move toward the resumption of passenger operations, which it hopes to do by midsummer. Treffiletti Decl. ¶ 52. In the meantime, 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.

As noted above, the plain text of the statute confers broad authority on the Secretary to exercise his "judgment" to take action that he deems "necessary" to avert the international and interstate spread of contagion. 42 U.S.C. § 264(a); see Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837, 843 (1984) (where the text is clear, courts "must give effect to the unambiguously expressed intent of Congress"). Congress's choice of such broad language must be given effect, as "Congress knows to speak in plain terms when it wishes to circumscribe, and in capacious terms when it wishes to enlarge, agency discretion." City of Arlington, Texas v. FCC, 569 U.S. 290, 296 (2013); see Gonzales v. Oregon, 546 U.S. 243, 258-59 (2006) (characterizing similar language authorizing "necessary" action as granting "an agency broad power to enforce all provisions"). It is commonplace for "legislative options [to] be especially broad" in areas implicating "medical and scientific uncertainties[.]" Marshall v. United States, 414 U.S. 417, 427 (1974).

The statutory language exudes flexibility and deference to the judgment of the public health experts at the CDC, and it logically includes regulation of the conveyances of international and interstate travel, including the temporary imposition of conditions for operation during a pandemic. Cf. Indep. Turtle Farmers of Louisiana, Inc. v. United States, 703 F. Supp. 2d 604, 619 (W.D. La. 2010) (finding PHSA authorized ban on sale of baby turtles in light of findings about spread of disease). "Congress' intent, as evidenced by the plain language of the delegation provision [of Section 264], is clear: Congress gave the Secretary of HHS broad power to issue regulations necessary to prevent the introduction, transmission or spread of communicable diseases." Brown v. Azar, No. 1:20-CV-03702-JPB, 2020 WL 6364310, at \*7 (N.D. Ga. Oct. 29, 2020), appeal docketed, No. 20-14210 (11th Cir.); see also Chambless Enters., LLC v. Redfield, No. 3:20-CV-01455, 2020 WL 7588849, at \*5 (W.D. La. Dec. 22, 2020) (similar), appeal docketed, No. 21-30037 (5th Cir.); Louisiana v. Mathews, 427 F. Supp. 174, 176 (E.D. La. 1977) (similar). 19

That conclusion is buttressed by the findings in the CSO. The CDC determined that its regulations in this area, and the CSO in particular, are necessary to prevent the introduction and spread of COVID-19 in interstate and international

<sup>&</sup>lt;sup>19</sup> Plaintiff inaccurately characterizes the CSO as a "shutdown" of an entire "industry." *See* Pl.'s Mot. at 3, 14. The NSOs of last year temporarily paused operations in the highest risk portion of an industry (large cruise ships) while operations were already broadly voluntarily suspended during a deadly pandemic, an extraordinary situation. The CSO actually lifts the NSO and sets out a framework for re-opening subject to conditions. Regardless, the pause in operations is doubtless temporary now that there is a path to re-opening, and it is well within CDC's authority to prevent interstate and international spread of communicable diseases caused by ships moving in interstate and international travel.

travel. *See, e.g.*, CSO, 85 Fed. Reg. at 70157 ("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."); *see also id.* (finding "evidence to support a reasonable belief that cruise ships are or may be infected or contaminated with a quarantinable communicable disease" based on current data). And the agency has long interpreted this statutory authority to include setting conditions on the operation of ships in U.S. ports. *See supra* pp. 5-7.

Plaintiff argues that the broad grant of authority in the first sentence of § 264(a) is implicitly narrowed by that provision's second sentence, which indicates that the agency "may provide for such inspection, fumigation, disinfection, sanitation, pest extermination, destruction of [infected or contaminated] animals or articles . . . , and other measures, as in his judgment may be necessary." 42 U.S.C. § 264(a). Plaintiff contends that the enumerated list is effectively exhaustive, but that contention is foreclosed by other subsections of § 264 itself. Those 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. *See, e.g., Independent Turtle Farmers of La., Inc.,* 703 F. Supp. 2d at 619-20 (holding that the second sentence of § 264(a) is illustrative, not exhaustive); *see also Brown*, 2020 WL 6364310, at \*8 (similar).<sup>20</sup>

<sup>&</sup>lt;sup>20</sup> Plaintiff's invocation of various other canons of statutory interpretation, Pl.'s Mot. at 10-11, cannot override the statutory text. The Supreme Court has emphasized that courts should not resort to such rules of thumb when the statute is clear. *See Sebelius v. Cloer*, 569 U.S. 369, 381 (2013).

Even if the first sentence in 264(a) were implicitly narrowed by the second sentence, the CSO is still squarely within the agency's statutory authority. The CSO imposes a set of conditions that is very similar to the types of public health enforcement actions relating to vessels laid out in that language, which include inspection, disinfection, destruction of property, and "other measures." Even on Plaintiff's reading, the statutory list thus contemplates actions with respect to sites, objects, or animals that are, or could be, infected with a disease. The CSO includes just such actions. It requires (for a specific category of high risk ships): on-board testing capacity and regular testing during the duration of the order; agreements with ports as to how to handle potential outbreaks, including housing and medical care; completion of a simulated voyage to demonstrate the adequacy of the ship's hygiene, testing, and outbreak protocols; and an application for a Conditional Sailing Certificate that demonstrates compliance with these requirements. See supra pp. 9. Cruise ship operators now have all the information needed to move into operations. *Id.* These requirements may be onerous or time-consuming from the perspective of the cruise lines, but they are not different in kind than the other types of inspection, hygiene, and safety protocols listed in the statute. Indeed, in some respects they are less intrusive than the examples Congress set out, as the CSO does not require the "detention" or "destruction" of any property. 42 U.S.C. § 264(a). Plaintiff's

contention that the CSO conditions are too onerous goes only to Plaintiff's second count; it does not negate the CDC's authority to act when warranted.<sup>21</sup>

Amicus argues that the requirement for agreements with port and local health authorities is beyond the agency's statutory authority. But the CDC does not, as Alaska suggests, "indirectly regulate the State." Alaska Br. at 9. Rather, a cruise ship operator must document the approval of all U.S. port and local health authorities where the ship intends to dock or make port during one or more simulated voyages or restricted passenger voyages as a condition of receiving or retaining controlled free pratique, including the approval of the ship's plans for medical care and housing. The purpose of this requirement is to ensure that cruise operators have pre-arranged with port authorities how operations and outbreaks will be handled during the pandemic – e.g., that if a cruise line's outbreak plan is to shunt thousands of potentially infected passengers onto a small community in Alaska that does not have housing or medical facilities, the cruise line must have the local authority's consent

regulation and oversight pursuant to the authority described in detail above.

<sup>&</sup>lt;sup>21</sup> Plaintiff relies heavily on recent cases regarding a different CDC order that prohibits certain evictions. *See, e.g., Tiger Lily, LLC v. HUD*, 992 F.3d 518 (6th Cir. 2021) (declining to stay a judgment against the CDC's eviction moratorium); *Skyworks, Ltd. v. CDC*, No. 5:20-cv-2407, 2021 WL 911720 (N.D. Ohio Mar. 10, 2021) (declaring that the eviction order exceeds CDC's statutory authority). Other courts have disagreed and held that the eviction order is authorized, *see, e.g., Brown*, 2020 WL 6364310, at \*7; *Chambless Enters.*, 2020 WL 7588849, at \*5, and the Government respectfully submits that the cases cited by Plaintiff are wrongly decided. Moreover, the eviction cases are inapposite because the courts in those cases were evaluating a readily distinguishable order; they in no way considered CDC's statutory authority to regulate vessels. For example, in declining to enter a stay, the Sixth Circuit motions panel—whose decision is not "strictly binding" even within that Circuit, *Wallace v. FedEx Corp.*, 764 F.3d 571, 583 (6th Cir. 2014)—based its decision in part on its conclusion that "[r]egulation of the landlord-tenant relationship is historically the province of the states." *Tiger Lily*, 992 F.3d at 523. The same is decidedly not true of health conditions on board large ships in interstate and international travel that dock at U.S. ports; this area is clearly subject to federal

to do so and must have made arrangements for adequate housing and care. Nothing in the CSO or technical instructions requires states or local authorities to agree to such plans; nor does the CSO impose any penalties on state and local authorities. Treffiletti Decl. ¶ 53. Nothing about that requirement is an unreasonable condition on a grant of controlled free pratique, nor in excess of the CDC's authority. And to the extent the Court finds the statute ambiguous, the CDC's reasonable interpretation of it merits deference. *See Chevron*, 467 U.S. at 843-44 (agency's interpretation of ambiguous language given "controlling weight" unless "arbitrary, capricious, or manifestly contrary to the statute"). <sup>22</sup>

## C. The CSO Is Not Arbitrary and Capricious.

Plaintiff's contention that the CDC Order was arbitrary and capricious is equally meritless. Under this standard, courts do not ask whether an agency's "decision is the best one possible or even whether it is better than the alternatives," *FERC v. Electric Power Supply Ass'n*, 136 S. Ct. 760, 782 (2016); instead, courts "ensure that the [agency] engaged in reasoned decisionmaking[,]" *id.* at 784. This review is uniquely deferential in the context of public health judgments made in the midst of a deadly global pandemic. As Chief Justice Roberts observed, when public health officials "undertake[] to act in areas fraught with medical and scientific

<sup>&</sup>lt;sup>22</sup> Plaintiff's passing suggestion that the CSO addresses a "major question" that Congress could not have intended to delegate to the CDC, Pl.'s Br. at 2, 10 & nn.4-5, does not withstand scrutiny. If agencies were generally denied the authority to take actions with, for example, an economic effect of \$100 million or more, as Plaintiff argues, *id.* at 10 & n.4 (citing 5 U.S.C. § 804(2)), then the Congressional Review Act—which contemplates that agencies will indeed issue such rules, and gives Congress an opportunity to disapprove of them—would make little sense.

uncertainties,' their latitude 'must be especially broad.'" *S. Bay United Pentecostal Church v. Newsom*, 140 S. Ct. 1613, 1613-14 (2020) (Roberts, C.J., concurring in denial of application for injunctive relief). "Where those broad limits are not exceeded, they should not be subject to second-guessing by an 'unelected federal judiciary,' which lacks the background, competence, and expertise to assess public health and is not accountable to the people." *Id.* (quoting *Garcia v. San Antonio Metro. Transit Auth.*, 469 U.S. 528, 545 (1985)).

As set forth above, the CSO findings are based on extensive experience, specific data, and consideration of public and industry input. See supra pp. 7-9. Plaintiff's assertions of error are meritless. First, Plaintiff argues that that Defendants "ignored important aspects of the problem" by failing to "consider the fact that a vaccine would be available long before the Order expires in November 2021" and by making "inadequate efforts to consider the significant developments on that front since." Pl.'s Mot. at 14-15; see also Alaska Br. at 10 (high vaccination rates). But "[i]t is a foundational principal of administrative law that a reviewing court must review only the information that was before the agency at the time of its decision in assessing whether that decision was permissible." Salmeron-Salmeron v. Spivev, 926 F.3d 1283, 1286 (11th Cir. 2019). The Court cannot invalidate the CSO on these grounds because, at the time of the CSO, no vaccines had been authorized, see 85 Fed. Reg. at 70154, and the CDC was not in a position to consider their availability and efficacy. Even if the Court could consider such an argument, it is incorrect. The CDC has considered the availability of vaccines in devising and issuing its technical

instructions and guidance to implement the CSO—documents that Plaintiff conspicuously does not challenge here. *See, e.g.*, Pl.'s Ex. 14 at 3 (vaccinating crew); Pl.'s Ex. 13 (local agreements include vaccination component); Treffiletti Decl. ¶ 67 & Ex. B (letter permitting certain highly vaccinated cruises without simulated voyages). The Treffiletti Declaration further examines the data and explains why the availability of vaccines does not justify lifting of the CSO. Treffiletti Decl. ¶¶ 59-72.

Second, Plaintiff argues that the "lock down" of the cruise industry is not rationally connected to the facts presented, citing other CDC guidance that recognizes that Americans may travel abroad to board cruise ships, and claiming that the CDC fails to consider measures taken by state and local governments and the cruise industry. Pl.'s Mot. at 15-16. To the extent Plaintiff is pointing to experiences post-dating the CSO, they cannot be considered in evaluating the reasonableness of the CSO. Moreover, while the CDC does not currently prohibit individual Americans from going on foreign cruises, it does strongly advise against it, and recommends testing of all returning passengers and quarantine depending on the circumstances. See Treffiletti Decl. ¶ 77.23 "While CDC does not have data indicating what percentage of airline travelers may choose to go overseas to engage in cruise travel, contrary to CDC's recommendations, experience and common sense suggests that this number is significantly less than those passengers who would choose to cruise from a port in the United States if cruise ship operations were to immediately

<sup>&</sup>lt;sup>23</sup> See also CDC, Covid-19 and Cruise Ship Travel, Level 4 Travel Notice, https://wwwnc.cdc.gov/travel/notices/covid-4/coronavirus-cruise-ship.

resume."  $Id.^{24}$  Nor should the lack of prohibition on foreign cruises be taken as an indication that foreign cruises are perfectly safe. Id. ¶¶ 41, 78-81 (explaining that some foreign cruises have led to significant COVID-19 outbreaks, that others are in a location of low COVID-19 prevalence and operating under conditions similar to the CSO, and that still others are not collecting the necessary data). That the CDC has not attempted in this instance to restrict the personal travel of individual Americans abroad hardly renders its regulation of cruise ships in U.S. waters arbitrary.

Plaintiff's additional argument that CDC failed to consider measures taken by state and local governments or the cruise industry is incorrect. As noted above, the CDC reasonably found that state and local governments cannot adequately regulate a ship whose operations are international and interstate in nature. *See supra* pp. 25-26. Moreover, the CDC explicitly considered the measures proposed by the cruise ship industry and the voluntary measures taken to date. *See* 85 Fed. Reg. at 70156 (describing Healthy Sail Panel ("HSP") and other industry proposals); Treffiletti Decl. ¶¶ 43-45 (describing participation in the HSP). And the CDC has continued

<sup>24</sup> 

<sup>&</sup>lt;sup>24</sup> Amicus adds that the testing requirement for using PCR is uniquely arbitrary because an air traveler returning to America from a cruise abroad would only be required to do an antigen test. Alaska Br. at 10-11. The cruise environment represents a uniquely high-risk setting, and use of the more reliable test was prudent during Phases 1 and 2, but based on the data gathered to date, the CDC is updating the guidance to permit antigen testing during later phases. *See* Treffiletti Decl. ¶¶ 56-57. It was moreover not practicable to require the heightened test only for air travelers returning from cruises abroad because the CDC does not currently track who went on a cruise abroad. *Id.* ¶ 77.

<sup>&</sup>lt;sup>25</sup> Other countries are being more cautious. Canada, for example, has banned cruise ships into 2022. *See, e.g.,* Transport Canada, Government of Canada announces one-year ban for pleasure craft and cruise vessels (Feb. 4, 2021), <a href="https://www.canada.ca/en/transport-canada/news/2021/02/government-of-canada-announces-one-year-ban-for-pleasure-craft-and-cruise-vessels.html">https://www.canada.ca/en/transport-canada/news/2021/02/government-of-canada-announces-one-year-ban-for-pleasure-craft-and-cruise-vessels.html</a>.

engaging with the industry. *See* Treffiletti Decl. ¶ 74. The CDC in fact partially adopted recommendations of the HSP, including the use of a phased approach and the requirement for emergency plans. *Id.* ¶ 45. The CDC's conclusion is further underscored by the difficulty that cruise lines had implementing safety measures and controlling COVID-19 among crew during the period of suspension, and by outbreaks on foreign voyages. 85 Fed. Reg. at 70155-56; Treffiletti Decl. ¶ 41.<sup>26</sup> In any event, Florida does not identify or describe the supposedly adequate measures it has imposed on cruise ships that would mitigate the risk of COVID-19.

Third, Plaintiff claims that Defendants "ignored lesser alternatives" such as "imposing safety protocols." Pl.'s Mot. at 16. This is a puzzling contention in light of the fact that the entire purpose of the CSO is to impose health and safety protocols. It sets up a series of protocols as pre-conditions that the cruise lines must meet before resuming operations. *See supra* p. 9. The CSO made explicit findings about the need to implement testing before the next phases. *See* 85 Fed. Reg. at 70156; *see also* Treffiletti Decl. ¶ 56 (explaining specifically the need for PCR testing during early phases). The simulated voyages will allow an opportunity to practice and test the COVID-19 mitigation protocols. *See* 85 Fed. Reg. at 70157; *see also* Treffiletti Decl. ¶ 58. And the certification process reports back the safety measures implemented and

<sup>&</sup>lt;sup>26</sup> The CDC's long experience in dealing with health issues on board cruise ships buttresses this finding as well. The CDC's Vessel Sanitation Program oversees safety protocols for preventing the spread of diseases causing gastroenteritis on board cruise ships, and "even in regard to a well-understood, documented, and researched public health phenomenon on cruise ships, for which the cruise ship industry receives extensive instruction, training, and monitoring, breakdowns in cruise ship operators' health and safety protocols can be expected to occur." Treffiletti Decl ¶¶ 6-7.

the results of the simulated sailing. *See* 85 Fed. Reg. at 70159; *see also* Treffiletti Decl. ¶ 58. Plaintiff's assertion that the CDC did not consider other alternatives seems to be an assertion that the CDC did not choose its apparently preferred alternative—to re-open and hope that the cruise lines will adopt adequate health and safety measures on their own. Re-opening with only voluntary health and safety measures that are unproven and untested in U.S. waters during a pandemic is more likely to risk spreading COVID-19 than a supervised approach and was explicitly considered and rejected by the CDC. *See* 85 Fed. Reg at 70157 (stressing need for oversight); Treffiletti Decl. ¶¶ 40-44.

Fourth, Plaintiff claims that Defendants failed to explain supposedly differential treatment of the cruise industry versus other industries. Pl.'s Mot. at 16-17. Plaintiff may disagree with the CDC's conclusion, but the CDC considered the facts—which show that cruise ships are unique. The CSO found markedly higher transmission rates on board cruise ships than exist in other settings; crew and passengers live onboard for prolonged periods of time in enclosed spaces in which social distancing is challenging at best. *See* 85 Fed. Reg. at 70156 (also citing multiple scientific studies). The Treffiletti Declaration provides additional support, explaining that contract tracing required for cruise passengers in early 2020 was far greater than that for air passengers during the same time frame, and that cruise ships have unique conditions on board that exacerbate transmission. Treffiletti Decl. ¶¶ 21-22, 76. Plaintiff asserts that a cruise ship is like an airplane or a hotel, but offers nothing in

support of that opinion. The data contradicts Plaintiff's unfounded claim, and the agency has engaged in reasoned decisionmaking.

Fifth, Plaintiff complains that the CDC has not provided cruise lines "an opportunity to complete the [CSO] framework," supposedly contradicting its own decision that phased re-opening is appropriate. This is inaccurate, as demonstrated by the April 28 letter and the recently published guidance on simulated voyages. *See supra* pp. 10-11; *see also* Treffiletti Decl. ¶¶ 57-58. It is also not an argument that any particular action the CDC has taken is arbitrary. At most, it is an argument that the CDC unlawfully delayed some unspecified agency action that would permit faster reopening, which fails for the reasons discussed below. *See* Part III.D, *infra*.

## D. There Is No Unreasonable Delay.

Plaintiff has no likelihood of success on its claim that the CDC "unreasonably delayed" action to "allow the cruise industry to safely re-open." Pl.'s Mot. at 17.

Section 706(1) permits judicial review of agency inaction, but only within strict limits. Courts can only compel "discrete agency action that it is required to take."

Norton v. Southern Utah Wilderness Alliance, 542 U.S. 55, 64 (2004) ("SUWA")

(emphasis in original); Yusim v. Dept' of Lab., 645 F. App'x 967, 968 (11th Cir. 2016).

This standard reflects the common-law writ of mandamus, which the APA "carried forward" in Section 706(1). SUWA, 542 U.S. at 63. Thus, Section 706(1) grants judicial review of withheld or delayed agency action only if a federal agency has a "ministerial or non-discretionary" duty amounting to "a specific, unequivocal

command." *Id.* at 63-64. "The limitation to *required* agency action rules out judicial direction of even discrete agency action that is not demanded by law . . . ." *Id.* at 65. Here, Plaintiff has not, and cannot, identify any "specific, unequivocal command" in the statute for the CDC to take any particular action on any particular timeframe; rather, the statute confers broad discretion on the agency to act when necessary. While CDC is committed to a re-opening process, there is no "nondiscretionary duty" requiring that to happen immediately despite an ongoing threat of contagion.

Even if Plaintiff had identified some specific, unequivocal command that could suffice for mandamus, its unreasonable delay claim would fail. See generally Telecomms. Research & Action Ctr. v. FCC, 750 F.2d 70, 79-80 (D.C. Cir. 1984) ("TRAC") (identifying 6 factors to consider). There is nothing unreasonable about the agency not immediately re-opening the cruise lines for unrestricted business. Congress has not imposed a timeline by which the CDC must act, nor provided any standard by which the Court could evaluate the timeframe for agency action. The CDC has explained that full implementation of the CSO has been hindered by delayed compliance in Phase 1, the need to evaluate data and draft the guidance, and consultations with partners, all while getting new agency leadership up to speed in early 2021. Treffiletti Decl. ¶ 50. In light of "the complexity of the task at hand, the significance (and permanence) of the outcome, and the resources available to the agency," Mashpee Wampanoag Tribal Council, Inc. v. Norton, 336 F.3d 1094, 1102 (D.C. Cir. 2003), the agency has acted reasonably. In any event, with the most recent guidance, the cruise lines now have a path to re-opening, and the claim is moot.

## E. Notice-and-Comment Procedures Were Not Required

Plaintiff claims that the CDC failed to provide notice and comment, Pl.'s Mot. at 17-20, but those procedures were not required here for at least three reasons.

First, the challenged agency action is an order, not a rule. See 85 Fed. Reg. at 70,157 (explaining that the "Order is not a rule within the meaning of the [APA], but rather an emergency action taken under the existing authority of [several rules]"). Specifically, the action is a declaratory order conditioning free pratique, which is a license. The APA defines an "order" as "the whole or a part of a final disposition, [including a disposition] declaratory in form, of an agency in a matter other than rule making but including licensing[.]" 5 U.S.C. § 551(6). It defines "licensing," in turn, to "include[] agency process respecting . . . conditioning of a license[.]" *Id*. § 551(9). And a "'license' includes the whole or part of an agency permit, certificate, approval ... or other form of permission[.]" *Id.* § 551(8). The CSO sets forth certain "condition[s] of obtaining or retaining controlled free pratique for operating a cruise ship in U.S. waters." 85 Fed. Reg. at 70,158. "Controlled Free Pratique means permission for a carrier to enter a U.S. port, disembark, and begin operation under certain stipulated conditions." 42 C.F.R. § 71.1. Accordingly, free pratique is a license, and the CSO is an order imposing conditions on free pratique, not a rule.

Second, even if the order were a rule, the APA provides that notice-and-comment rulemaking is not required "when the agency for good cause" determines notice-and comment is "impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. § 553(b)(B). This exception is "an important safety valve to be

used where delay would do real harm." See United States v. Dean, 604 F.3d 1275, 1278-79 (11th Cir. 2010) (citation omitted); see also Jifry v. FAA, 370 F.3d 1174, 1179 (D.C. Cir. 2004); U.S. Steel Corp. v. EPA, 595 F.2d 207, 214 n.15 (5th Cir. 1979) (citing Reeves v. Simon, 507 F.2d 455, 458-59 (Temp. Emer. Ct. App. 1974)). The agency's finding here, which must be reviewed "on the basis of the information available to the agency when it made the decision," see Vt. Yankee Nuclear Power Corp. v. NRDC, 435 U.S. 519, 547 (1978), 27 more than meets that standard; cruise ships could not be allowed to resume normal operations on October 30, 2020, without posing an unreasonable danger to the public. The CSO lasts for a limited period of time<sup>28</sup> and is based, in part, on extensive interaction with the cruise industry and States such as Plaintiff. In this evolving situation, the public health emergency amply justifies the order taking immediate effect without opportunity for notice and comment. See Reeves, 507 F.2d at 459 (finding good cause exemption properly invoked to respond to "a temporary, but highly disruptive, national emergency").

Third, "[e]ven assuming that the APA require[d CDC] to" undergo notice and comment to issue the CSO, "there was no 'prejudicial error" to Florida here. *See Little Sisters of the Poor Saints Peter and Paul Home v. Pennsylvania*, 140 S. Ct. 2367, 2385

<sup>&</sup>lt;sup>27</sup> Even if Plaintiff's suggestion that "the good-cause exemption . . . no longer applies in April 2021" were correct, *see* Pl.'s Mot. at 19, which it is not, the "reviewing court must review only the information that was before the agency at the time of its decision in assessing whether that decision was permissible," *Salmeron-Salmeron*, 926 F.3d at 1286. Plaintiff inappropriately asks the Court to engage in a "sort of Monday morning quarterbacking." *See Vt. Yankee*, 435 U.S. at 547.

<sup>28</sup> The CSO "remain[s] in effect until the earliest of (1) the expiration of the Secretary of [HHS's]

declaration that COVID-19 constitutes a public health emergency; or (2) the CDC Director rescinds or modifies the order based on specific public health or other consideration; or (3) November 1, 2021." 85 Fed. Reg. at 70,163.

(2020) (quoting 5 U.S.C. § 706). Notice and comment "allow an agency to reconsider, and sometimes change, its proposal based on the comments of affected persons." Dean, 604 F.3d at 1278 (quoting Miami-Date Cty. v. EPA, 529 F.3d 1049, 1059 (11th Cir. 2008)). The CDC solicited and considered comments on a detailed request for information that serves the same purpose. See supra p. 8. Moreover, the challenged order sets forth a broad framework for the resumption of cruise ship operations in a manner that mitigates the spread of COVID-19 and explicitly contemplates implementation "though additional orders" and "additional technical instructions." 85 Fed. Reg. at 70,158. The CDC has worked closely with Florida, among other stakeholders, to consider and incorporate its views, even when issuing technical guidance for the phased resumption of cruise ship operations in the months after the CSO was issued. See Treffiletti Decl. ¶¶ 37, 54-55. While conveying its concerns during that time period, Florida "certainly had . . . notice" of the CSO. See Little Sisters, 140 S. Ct. at 2385. Under these circumstances, Florida "do[es] not come close to demonstrating that [it] experienced any harm" from lack of prepromulgation notice of the CSO, "let alone that they have satisfied the harmless error rule"— in this suit six months after issuance. See Little Sisters, 140 S. Ct. at 2385; Treffiletti Decl. ¶¶ 54-55. Indeed, Florida notes that "[a]n agency must consider and respond to significant comments received during the period for public comment," Pl.'s Mot. at 19, but it does not identify the comments it made to the CDC over the past several months, and it does not explain how the CDC allegedly failed to address

those comments in this unique emergency context. *Cf. Air Transp. Ass'n of Am. v. Civil Aeronautics Bd.*, 732 F.2d 219, 224 n.11 (D.C. Cir. 1984).

#### F. The Statute is Constitutional.

Plaintiff has not demonstrated a likelihood of success on its nondelegation claim. Although Plaintiff argues that Section 264 is an unconstitutional delegation of legislative power, Pl.'s Mot. at 20, "Congress does not violate the Constitution merely because it legislates in broad terms," Touby v. United States, 500 U.S. 160, 165 (1991), and the Supreme Court has not invalidated a statute on nondelegation grounds since 1935, see Gundy v. United States, 139 S. Ct. 2116, 2129 (2019). The CDC's authority to promulgate public health regulations necessary to prevent the spread of disease should not be the first. As another district court recently explained, 42 U.S.C. § 264's limitation of agency action to measures that are "necessary" "to prevent the introduction, transmission, or spread of communicable diseases" into the United States or among the states, provides a sufficient intelligible principle, and is analogous to other statutes which had been upheld. See Chambless, 2020 WL 7588849, at \*10-11. Congress has clearly authorized at least direct public health regulation of transport vessels in interstate and international commerce. Plaintiff's nondelegation challenge here easily fails.

#### IV. THE BALANCE OF HARMS FAVORS THE CDC.

As established above, Florida cannot establish an imminent threat of irreparable harm that this Court can redress. Faced with the purely speculative effect of an injunction on the behavior of third parties, the Court must balance the

judgment of public health authorities that the CSO is necessary to contain the spread of COVID-19. *See* 85 Fed. Reg. at 70157 (finding that unrestricted cruising "would place federal partners . . . , healthcare workers, port personnel, and communities at substantial unnecessary risk" and "divert and overburden scarce federal, state, and local, public health and healthcare resources during a pandemic."). The Treffiletti Declaration establishes that, in her "professional judgment, based on nearly 20 years of professional experience and the science gathered regarding SARS-CoV-2 transmission, . . . absent the protections afforded by the CSO's phased approach, allowing cruise ship operators to immediately return to unrestricted passenger travel (i.e., travel subject only to voluntary measures to address the threat of COVID-19) would likely exacerbate and amplify the spread" of the disease. Treffiletti Decl. ¶ 75.

In response, Florida does not present any contrary evidence from any public health authority that supports re-opening under current circumstances. Plaintiff argues only that "the health of the local economy" is part of the analysis. Pl.'s Mot. at 24. Perhaps, but the balance of harms here does not weigh in favor of vacatur. After all, a precipitous re-opening that causes a resurgence of cases or additional outbreaks would harm both the public and Florida's economy. In a matter last year evaluating Florida's own COVID-19 policies, this Court found that "the threatened harms to the public outweigh decisively the injury — if any — to the plaintiffs." *Alsop*, 2020 WL 4927592, at \*4–5 (and collecting cases). The same is true here.

## V. PLAINTIFF'S REQUESTED RELIEF IS OVERBROAD.

Even assuming Plaintiff has established standing to press any claims, it certainly has not established standing to seek relief *outside of Florida*. As the Supreme Court has confirmed, any remedy ordered by a federal court must "be limited to the inadequacy that produced the injury in fact that the plaintiff has established"; a court's "constitutionally prescribed role is to vindicate the individual rights of people appearing before it"; and "[a] plaintiff's remedy must be tailored to redress the plaintiff's particular injury." *Gill v. Whitford*, 138 S. Ct. 1916, 1931-34 (2018). "[W]hen a court goes further than that, ordering the government to take (or not take) some action with respect to those who are strangers to the suit, it is hard to see how the court could be acting in the judicial role of resolving cases and controversies." *DHS v. New York*, 140 S. Ct. 599, 600 (2020) (Gorsuch, J., concurring). Plaintiff has not shown why relief outside Florida is needed to remedy its injuries.

If Florida somehow has standing to seek nationwide relief, issuing a preliminary injunction that is larger in scope than required to provide Florida complete relief would be an abuse of discretion. *See New York v. DHS*, 969 F.3d 42, 88 (2d Cir. 2020); *Azar*, 911 F.3d at 584; *see also Trump v. Hawaii*, 138 S. Ct. 2392, 2428-29 (2018) (Thomas, J., concurring).

#### **CONCLUSION**

The Court should deny Plaintiff's motion for a preliminary injunction.

Dated: May 5, 2021 Respectfully submitted,

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