

**UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF FLORIDA**

NORWEGIAN CRUISE LINE HOLDINGS LTD., a Bermuda Company; **NCL (BAHAMAS) LTD.**, d/b/a NORWEGIAN CRUISE LINE, a Bermuda Company; **SEVEN SEAS CRUISES S. DE R.L.**, d/b/a REGENT SEVEN SEAS CRUISES, a Panama Limited Liability Company; **OCEANIA CRUISES S. DE R.L.**, d/b/a OCEANIA CRUISES, a Panama Limited Liability Company;

Plaintiffs,

v.

SCOTT A. RIVKEES, M.D., State Surgeon General and Head of the Florida Department of Health, in his official capacity;

Defendant.

Case No. 1:21-cv-22492-KMW

**PLAINTIFFS' EXPEDITED MOTION FOR A PRELIMINARY INJUNCTION AND
INCORPORATED MEMORANDUM OF LAW**

TABLE OF CONTENTS

Table of Authorities.....	iii
Introduction	1
Background.....	2
Legal Standard	8
Argument.....	8
I. NCLH Is Likely To Prevail On The Merits	8
A. Florida’s Ban Is Preempted By Federal Law.	9
1. Florida’s Ban Conflicts With The Conditional Sailing Order’s Technical Instructions.....	10
2. Florida’s Ban Conflicts With The Conditional Sailing Order’s Operations Manual.	12
B. Florida’s Ban Violates The First Amendment.	12
1. As Applied To NCLH, Florida’s Ban Is An Unconstitutional, Content-Based Restriction On Noncommercial Speech.	12
2. Even If The Ban Were A Restriction On Commercial Speech, It Is Constitutionally Infirm As Applied To NCLH.....	14
C. Florida’s Ban Violates The Dormant Commerce Clause.	15
II. Absent An Injunction, NCLH Will Suffer Irreparable Harm.....	17
III. The Balance Of Equities And Public Interest Weigh Heavily In Favor Of Enjoining Florida’s Ban	19
Conclusion.....	20
Request For Hearing	21

TABLE OF AUTHORITIES

Cases

<i>ABC Charters, Inc. v. Bronson</i> , 591 F. Supp. 2d 1272 (S.D. Fla. 2008)	18
<i>Alliance for the Wild Rockies v. Cottrell</i> , 632 F.3d 1127 (9th Cir. 2011)	20
<i>Alsop v. DeSantis</i> , 2020 WL 4927592 (M.D. Fla. Aug. 21, 2020).....	20
<i>American Booksellers Foundation v. Dean</i> , 342 F.3d 96 (2d Cir. 2003)	16, 17
<i>American Insurance Association v. Garamendi</i> , 539 U.S. 396 (2003)	9, 11
<i>Bainbridge v. Turner</i> , 311 F.3d 110 (11th Cir. 2002).....	15, 16
<i>Bolger v. Young Drug Products Corp.</i> , 463 U.S. 60 (1983)	14
<i>Brown v. Entertainment Merchants Association</i> , 564 U.S. 786 (2011).....	14
<i>Brown-Forman Distillers Corporation v. New York State Liquor Authority</i> , 476 U.S. 573 (1986)	16, 17
<i>California v. ARC America Corporation</i> , 490 U.S. 93 (1989)	9
<i>Charles H. Wesley Education Foundation, Inc. v. Cox</i> , 324 F. Supp. 2d 1358 (N.D. Ga. 2004).....	19
<i>Dennis v. Higgins</i> , 498 U.S. 439 (1991)	15
<i>Ferrellgas Partners, L.P. v. Barrow</i> , 143 F. App'x 180 (11th Cir. 2005).....	18
<i>Fidelity Federal Savings & Loan Association. v. de La Cuesta</i> , 458 U.S. 141 (1982)	9, 11, 12
<i>Florida Transportation Services, Inc. v. Miami-Dade County</i> , 703 F.3d 1230 (11th Cir. 2012)	17

<i>Friedenberg v. School Board of Palm Beach County</i> , 911 F.3d 1084 (11th Cir. 2018).....	8
<i>Galvin v. New York Racing Association, Inc.</i> , 70 F. Supp. 2d 163 (E.D.N.Y. 1998).....	18
<i>Gayle v. Meade</i> , 2020 WL 3041326 (S.D. Fla. June 6, 2020)	18, 19
<i>Geier v. American Honda Motor Company, Inc.</i> , 529 U.S. 861 (2000)	9, 11
<i>Gonzalez v. Governor of Georgia</i> , 978 F.3d 1266 (11th Cir. 2020)	19
<i>Healy v. Beer Institute, Inc.</i> , 491 U.S. 324 (1989)	16
<i>Japan Line, Ltd. v. Los Angeles County</i> , 441 U.S. 434 (1979)	15
<i>JB Weld Co. v. Gorilla Glue Co.</i> , 978 F.3d 778 (11th Cir. 2020)	10
<i>Jolly v. Coughlin</i> , 76 F.3d 468 (2d Cir. 1996)	18
<i>Kassel v. Consolidated Freightways Corporation of Delaware</i> , 450 U.S. 662 (1981)	15
<i>Lebamoff Enterprises Inc. v. Whitmer</i> , 956 F.3d 863 (6th Cir. 2020)	16
<i>Legato Vapors, LLC v. Cook</i> , 847 F.3d 825 (7th Cir. 2017)	16
<i>Martin v. Medtronic, Inc.</i> , 254 F.3d 573 (5th Cir. 2001)	11
<i>McCall v. California</i> , 136 U.S. 104 (1890)	15
<i>Mitchell v. Cuomo</i> , 748 F.2d 804 (2d Cir. 1984)	18
<i>Nantahala Power & Light Co. v. Thornburg</i> , 476 U.S. 953 (1986)	11

<i>Odebrecht Construction, Inc. v. Secretary, Florida Department of Transportation</i> , 715 F.3d 1268 (11th Cir. 2013)	18
<i>Oneok, Inc. v. Learjet, Inc.</i> , 575 U.S. 373 (2015)	9, 11, 12
<i>Otto v. City of Boca Raton</i> , 981 F.3d 854 (11th Cir. 2020)	12, 13, 14
<i>Phelps–Roper v. Nixon</i> , 545 F.3d 685 (8th Cir. 2008)	19
<i>R.A.V. v. City of St. Paul</i> , 505 U.S. 377 (1992)	12
<i>Reed v. Town of Gilbert</i> , 576 U.S. 155 (2015)	13, 14
<i>Sam Francis Foundation v. Christies, Inc.</i> , 784 F.3d 1320 (9th Cir. 2015)	16
<i>Siegel v. LePore</i> , 234 F.3d 1163 (11th Cir. 2000).....	18
<i>Sorrell v. IMS Health, Inc.</i> , 564 U.S. 552 (2011).....	13, 14, 15
<i>Strawser v. Strange</i> , 44 F. Supp. 3d 1206 (S.D. Ala. 2015).....	19
<i>Swain v. Junior</i> , 961 F.3d 1276 (11th Cir. 2020)	19
<i>Sylvan Learning Inc. v. Learning Solutions, Inc.</i> , 795 F. Supp. 2d 1284 (S.D. Ala. 2011).....	18
<i>Tim Hortons USA, Inc. v. Tims Milner LLC</i> , 2019 WL 2515006 (S.D. Fla. June 17, 2019)	18
<i>Tobinick v. Novella</i> , 848 F.3d 935 (11th Cir. 2017)	14
<i>Trailer Marine Transport Corp. v. Rivera Vazquez</i> , 977 F.2d 1 (1st Cir. 1992)	16
<i>Turner Broadcasting System, Inc. v. FCC</i> , 512 U.S. 622 (1994)	13

<i>United States v. Alvarez</i> , 567 U.S. 709 (2012)	14
<i>United States v. Playboy Entertainment Group</i> , 529 U.S. 803 (2000)	14
<i>University of Texas v. Camenisch</i> , 451 U.S. 390 (1981)	10
<i>Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.</i> , 425 U.S. 748 (1976)	13
<i>Walgreen Co. v. Rullan</i> , 405 F.3d 50 (1st Cir. 2005)	16
<i>Wollschlaeger v. Governor of Florida</i> , 848 F.3d 1293 (11th Cir. 2017)	12, 13, 14, 15
<i>Young v. Coloma-Agaran</i> , 2001 WL 1677259 (D. Haw. Dec. 27, 2001)	17

U.S. Constitution and Federal Statutes

U.S. Const. art. I.....	15
U.S. Const. art. VI.....	9
42 U.S.C. § 264.....	9

State Statutes

Florida Statute § 381.00316.....	1, 5, 10, 13
----------------------------------	--------------

Regulations

85 Fed. Reg. 16628-03 (Mar. 24, 2020).....	2
85 Fed. Reg. 62732-01 (Oct. 5, 2020).....	2
85 Fed. Reg. 70153-01 (Nov. 4, 2020).....	3, 16

Plaintiffs Norwegian Cruise Line Holdings Ltd., NCL (Bahamas) Ltd., Seven Seas Cruises S. de R.L., and Oceania Cruises S. de R.L. (together, “NCLH”) hereby respectfully move for a preliminary injunction under Federal Rule of Civil Procedure 65(a) for the reasons set forth below.

INTRODUCTION

Since March 2020, concerns about COVID-19 have led to a debilitating, total shutdown of the cruise industry generally and NCLH specifically. That shutdown has inflicted incalculable, irrecoverable losses not only upon NCLH but upon all those whose interests ride with it—including NCLH’s many employees and passengers as well as a surrounding ecosystem (vendors, manufacturers, wholesalers, hotels, restaurants, airlines, travel agents, *etc.*). Now, after months of Herculean efforts, NCLH is at last set to resume sailing August 15, 2021 from Miami, Florida, in a way that will be safe, sound, and consistent with governing law, particularly the Conditional Sailing Order issued by the Centers for Disease Control and Prevention (“CDC”). Yet one anomalous, misguided intrusion threatens to spoil NCLH’s careful planning and force it to cancel or hobble upcoming cruises, thereby imperiling and impairing passengers’ experiences and inflicting irreparable harm of vast dimensions.

While NCLH would require documentation confirming that its passengers have been vaccinated (per experts’ consensus, passengers’ desires, and NCLH’s commitments to CDC), the State of Florida has enacted a law—Florida Statute § 381.00316—that expressly ***prohibits*** NCLH from requiring such documentation. The upshot places NCLH in an impossible dilemma as it prepares to set sail from Florida: NCLH will find itself either on the wrong side of health and safety and the operative federal legal framework, or else on the wrong side of Florida law. Because neither is acceptable, NCLH must respectfully turn to this Court seeking essential, preliminary relief. Only with the benefit of an injunction suspending § 381.00316 as applied to NCLH can NCLH’s passenger cruises from Florida proceed as planned starting August 15.

For the reasons set forth herein and in supporting declarations, this Court has overwhelming justification to grant a preliminary injunction suspending § 381.00316 as applied to NCLH. NCLH’s instant challenge is likely to succeed on multiple, independent grounds under federal law: Florida’s prohibition conflicts with federal statutes and regulations and is therefore preempted; it interferes with communications between a business and its customers, in violation of the First Amendment (as applicable to States under the Fourteenth Amendment); it profoundly disrupts the proper flow of interstate and international commerce without advancing any

substantial state interest, in violation of the Dormant Commerce Clause; and it precludes this business from protecting the health and safety of its employees and customers against the extraordinary backdrop of a deadly pandemic, in violation of substantive due process as protected by the Fourteenth Amendment.

Moreover, absent relief, the specter of irreparable harm is obvious and imminent. As attested by Frank Del Rio, NCLH's CEO, NCLH is duty-bound to protect the health and safety of its personnel and passengers, as it can and will by requiring proof of vaccinations, yet it cannot afford to expose itself to prosecution by Florida and crushing penalties of up to \$5,000 per passenger, as it would by requiring vaccine documentation in the present posture. Absent a preliminary injunction, therefore, NCLH will not be able to sail as it has assured its passengers (who overwhelmingly support vaccination and documentation of same) it is poised to do. The result would be a devastating, unrecoverable loss for everyone—not only for NCLH's business but also for tens of thousands of passengers, employees, and stakeholders who all benefit from NCLH resuming safe operations as planned. In contrast, nothing appreciable weighs on the other side of the equitable scales. Whereas Florida should be glad to see NCLH resuming safe operations and generating valuable economic returns, no one will suffer from passengers simply confirming that they have been vaccinated, as agreed, while this case proceeds expeditiously to final judgment.

BACKGROUND

From the onset of the COVID-19 pandemic, outbreaks aboard cruise ships were fueled by compressed environments and challenges maintaining decontamination and social distancing. The experiences of ships like the Diamond Princess and Grand Princess at the start of 2020 vividly demonstrated the potential speed and sweep of transmission onboard cruises. 85 Fed. Reg. 16628-03, 16629–30 (Mar. 24, 2020). In response, NCLH and other members of the leading trade group, Cruise Lines International Association, voluntarily suspended passenger operations on March 13, 2020. 85 Fed. Reg. at 16631; Decl. of Frank J. Del Rio ("Del Rio Decl.") ¶ 7.

The next day, CDC issued a "No Sail Order and Suspension of Further Embarkation" ("No Sail Order"), the first of a series of cruise restrictions from CDC. 85 Fed. Reg. at 16631. The No Sail Order required all passenger disembarkation to be undertaken in coordination with relevant agencies, and it prevented any embarkation or operations unless permitted by CDC. *Id.* The No Sail Order was then extended three times before expiring on October 31, 2020. 85 Fed. Reg. 62732-01 (Oct. 5, 2020).

Next came a “Framework for Conditional Sailing and Initial Phase COVID-19 Testing Requirements for Protection of Crew” (“Conditional Sailing Order”), which issued on October 30, 2020 to specify a framework for re-opening. 85 Fed. Reg. 70153-01 (Nov. 4, 2020). The Conditional Sailing Order set out four phases for returning to passenger operations in U.S. waters. *Id.* Phase one obligates cruise operators to build a laboratory aboard each vessel for testing crew. Order, *Florida v. Becerra*, No. 8:21-cv-839-SDM-AAS, at 5 (M.D. Fla. June 18, 2021) (“PI Order”). Phase two has operators undertaking simulated voyages to evaluate each ship’s measures for mitigating COVID-19 on board. *Id.* Even in advance of a simulated voyage, however, the operator must obtain and CDC must approve a “medical care agreement” and a “housing agreement” with healthcare providers and port authorities lining up an appropriate response to any COVID-19 incident. *Id.* at 5–6.

Phase three requires a “Conditional Sailing Certificate” from CDC before undertaking a restricted passenger voyage. *Id.* at 6. The 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.” *Id.* In applying, the operator must attest—under threat of criminal penalties pursuant to 18 U.S.C. § 1001—to full compliance with CDC’s technical instructions and orders. *Id.*

Phase four permits operators with a Conditional Sailing Certificate to undertake “restricted passenger voyages” subject to key strictures, including a seven-day limitation on each voyage. *Id.* The Conditional Sailing Order adds other requirements atop the four phases, and explains that the phases “will be further determined” by both “public health considerations” and an operator’s success in employing specified mitigation measures. *Id.* at 7.

Even after the Conditional Sailing Order outlined a path forward, the absence of concrete implementing instructions left the cruise industry in limbo. New CDC guidance on April 2, 2021, prompted complaints that it would be “unduly burdensome” and “largely unworkable.” *Id.* at 8. Desperate to salvage the summer sailing season, some cruise companies even threatened to leave the U.S. absent “clarity and alignment on what it will take to restart cruising.” *Id.* And the State of Florida sued CDC and sought a preliminary injunction in a purported effort to clear the way for cruise lines to resume passenger operations swiftly and safely. *Id.* at 9.

On April 28, 2021, CDC issued a “Dear Colleague Letter” “commit[ting] to the phased resumption of passenger operations around mid-summer” and addressing “scientific

developments” including the advent of COVID-19 vaccines. *Id.* CDC previewed that operators could obviate simulated voyages by attesting that a certain percentage of crew and passengers have been verified as fully vaccinated prior to sailing. *See* Decl. of Olga Vieira (“Vieira Decl.”) Ex. 1 at 4. On May 14, 2021, CDC then followed through and opened the door for operators to sail, provided they could verify the incidence of vaccinations at the specified rate of 95 percent, per CDC’s “Technical Instructions for Simulated Voyages by Cruise Ship Operators under CDC’s Framework for Conditional Sailing Order” (“Technical Instructions”). Vieira Decl. Ex. 2 at 9.

On May 26, 2021, CDC issued its operative “COVID-19 Operations Manual for Simulated and Restricted Voyages under the Framework for Conditional Sailing Order” (“Operations Manual” or “Manual”). Vieira Decl. Ex. 3. The Operations Manual instructs operators to take systematic account of whether passengers have been fully vaccinated. For instance, operators are to deny boarding to “[p]assengers with signs or symptoms of COVID-19” “if not fully vaccinated without documentation of recovery” but may permit such passengers to “board at [the] operator’s discretion if fully vaccinated.” *Id.* at 6. Similarly, embarking “[p]assengers who have a known close contact exposure in the past 14 days” are to be “den[ie]d boarding if not fully vaccinated without documentation of recovery” but may “board at [the] operator’s discretion if fully vaccinated and asymptomatic.” *Id.* Nor need operators collect SARS-CoV-2 viral testing for “fully vaccinated passengers.” *Id.* at 5. And operators may “advise passengers and crew that—if they are fully vaccinated—they may gather or conduct activities outdoors, including engaging in extended meal service or beverage consumption, without wearing a mask”; they may “designate areas as only accessible to fully vaccinated passengers and crew where masks and physical distancing are not required”; and they may “advise passengers and crew that they do not have to wear a mask or maintain physical distance in any areas” for “ships with at least 95% of crew and 95% of passengers fully vaccinated.” *Id.* at 8. Numerous “requirements” for physical distancing and food services become “recommendations” for “ships with at least 95% of crew and 95% of passengers fully vaccinated.” *Id.* at 9.

To challenge the Conditional Sailing Order and its *de facto* freeze on cruise operations, Florida sued CDC on April 8, 2021 in the U.S. District Court for the Middle District of Florida. Florida complained, *e.g.*, that CDC had exceeded its statutory and regulatory authority, acted arbitrarily and capriciously, denied requisite opportunity for notice and comment absent “good cause” for deviating, and exercised an unconstitutional delegation of legislative authority. PI

Order at 1–2. After Florida sought a preliminary injunction, the court found that Florida was likely to prevail and preliminarily enjoined CDC “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).” *Id.* at 123. At the same time, the court stayed its preliminary injunction until July 18, “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,’” unless it approved a narrower proposal from CDC (which was not forthcoming). *Id.* On July 6, 2021, CDC noticed an appeal to the Eleventh Circuit and unsuccessfully moved the district court for a stay pending appeal. Order, Dkt. 98, *Florida v. Becerra*, No. 8-21-cv-8329-SDM-AAS (M.D. Fla. July 7, 2021). The next day, CDC sought a stay pending appeal from the Eleventh Circuit, Defendants’ Time-Sensitive Motion for a Stay Pending Appeal, *Florida v. Becerra*, No. 21-12243 (11th Cir. July 7, 2021) (“CDC Stay Mot.”), which ordered Florida to respond by yesterday, July 12, as Florida did last night.

Shortly before Florida filed suit, the Governor of Florida issued an Executive Order on April 2, 2021 prohibiting businesses in Florida from “requiring patrons or customers to provide any documentation certifying COVID-19 vaccination or post-transmission recovery to gain access to, entry upon, or service from the business.” Fl. Exec. Order No. 21-81 (Apr. 2, 2021). Until that order expired, businesses that failed to comply were not “eligible for grants or contracts funded through state revenue.” *Id.* Thereafter, the same prohibition took the form of permanent legislation. Specifically, Florida’s House and Senate passed a bill that the Governor signed into law on May 3, 2021, flatly prohibiting all businesses in Florida from “requir[ing] patrons or customers to provide any documentation certifying COVID-19 vaccination or post-infection recovery to gain access to, entry upon, or service from the business operations in [Florida].” Fla. Stat. § 381.00316(1) (2021) (hereinafter the “Ban”). Violations of this prohibition can trigger fines of up to “\$5,000 per violation.” *Id.*

While NCLH has an international focus, it is headquartered in Miami, and its 28-ship fleet is based there. Del Rio Decl. ¶¶ 4, 7–8. NCLH recently developed a new terminal at PortMiami, which is capable of accommodating substantial interstate and international traffic. *Id.* ¶ 4. Within some 30 minutes of departing from PortMiami, NCLH’s ships reach international waters and then sail to interstate and foreign ports, many of which require proof of vaccination before passengers can enter without onerous strings. *Id.* ¶¶ 4, 16–18.

From the onset of the COVID-19 pandemic, NCLH has done everything within its power to withstand COVID-19 and to protect its passengers and crew. *Id.* ¶ 6. To begin, NCLH voluntarily suspended operations shortly after the WHO declared a pandemic. *Id.* ¶ 7. Since then, it has navigated complex regulatory, compliance, and public-health challenges to set up its imminent return to sailing. *Id.* ¶¶ 7–13, 16–21. NCLH partnered with Royal Caribbean Group to create the Healthy Sail Panel, a panel of world-renowned public-health experts who advise the cruise industry regarding the protocols that will best reduce COVID-19-related risks. *Id.* ¶ 12.

In light of the recommendations from the Healthy Sail Panel and other leading authorities, NCLH has concluded that the right way to ensure everyone’s health and safety is by requiring full vaccination on cruises. *Id.* ¶ 13. Customer surveys indicate that the vast majority of likely passengers want to sail with others who have been completely vaccinated and can prove it. *Id.* ¶ 14; Decl. of Dr. Jukka Laitamaki (“Laitamaki Decl.”) ¶¶ 9–10. Today, it is more essential than ever for NCLH to maintain the confidence and trust of its passengers that their cruises will not only be enjoyable and carefree, but healthy and safe. Laitamaki Decl. ¶¶ 9, 12–16.

So that all concerned can set sail safely and smoothly, NCLH’s planned cruises require proof that 100% of passengers and crew have been vaccinated against COVID-19. Del Rio Decl. ¶ 13. That is how NCLH plans to comply with CDC’s Conditional Sail Order and Manual, as reflected in NCLH’s certifications and applications for a Conditional Sailing Certificate, which CDC approved on July 9, 2021. *See id.* ¶ 20; Vieira Decl. Ex. 4 at 1. Requiring vaccination documentation is all the more imperative given the vaccination protocols required by relevant foreign ports. Del Rio Decl. ¶¶ 16–18. To name just a few such foreign ports that NCLH is slated to visit on upcoming voyages, Belize, Bahamas, British Virgin Islands, and Honduras all require proof of vaccination before passengers can enter without testing. *Id.* ¶ 18.

Simply stated, NCLH cannot sail as planned unless and until Florida’s Ban gives way. If NCLH cannot require vaccine documentation, then it cannot verify whether its passengers have in fact been fully vaccinated against COVID-19. Decl. of Dr. Stephen Ostroff (“Ostroff Decl.”) ¶¶ 18–20. There is no adequate substitute for documentary proof when it comes to maximizing onboard safety. Risks of exposure to COVID-19 will invariably tick up if NCLH is denied the ability to verify that passengers have been fully vaccinated—and nothing short of documentation enables reliable verification. *See id.* ¶ 20.

Nor can NCLH complete its communications with passengers, as consensually agreed, without completing the exchange of paperwork that stands to save lives. *Id.* ¶¶ 18–20. Inability to verify vaccination status would also undercut NCLH’s ability to attract, assure, and please passengers. Demand for cruises has returned, but cruise lines still face critical challenges in rebuilding confidence, particularly among an older passenger base. A recent survey of more than 5,000 readers of Cruise Critic found that 80% of respondents preferred to sail on ships that require vaccination, just as NCLH would. Del Rio Decl. ¶ 14; Laitamaki Decl. ¶¶ 9–10, 15–16.

If Florida’s Ban stands, then the only way NCLH can require vaccine documentation and maximize safety, comfort, and confidence would be by eschewing operations in Florida. That would be a tragedy for all concerned. Florida itself has successfully argued in federal court that disruptions to the cruise industry cause far-reaching, adverse ripple effects and deprive Florida of “an essential part of [its] economy.” Fla.’s Am. Mot. for Prelim. Inj., Dkt. 25, *Florida v. Becerra*, No. 8:21-cv-839-SDM-AAS, at 2 (M.D. Fla. Apr. 8, 2021) (“Fla. Brief”). With cruises suspended, Florida has “lost tens of millions of tax dollars” and been forced “to expend around \$20 million in state unemployment benefits.” *Id.* at 22.

Florida is a major hub for cruise voyages both nationally and internationally, and it has been vital for the cruise industry, just as the cruise industry has been vital for it. *See* Del Rio Decl. ¶¶ 33, 35. About 60% of all U.S. cruise embarkations come from Florida. Fla. Brief at 2–3. In 2019 alone, around 13.6 million cruise passengers and crew came ashore in Florida. *Id.* at 3. That all came to a sudden halt when COVID-19 hit. As Florida has noted, while cruises were unable to sail, “[t]he cruise industry has been ‘ravaged,’ with ‘companies reporting billions of dollars in losses, causing some of them to downsize their fleets and sell ships for scrap.’” *Id.*

To the extent that Florida loses cruises, damages ripple still further, as “many Florida businesses” depend on cruise passengers and crew to “spend money in Florida’s local economies.” *Id.* at 3. Florida’s ports lost over \$297 million in revenue due to the cruise industry shutdown through February and project total losses of \$398 million in revenue through July. *See id.* Ex. 26 at 2–3. The cruise industry supports “nearly 159,000 total jobs paying \$8.1 billion in income” within the State. *Id.* at 2. These include jobs associated with hospitality, transportation, recreation, and amusement establishments; wholesalers of products such as fuel, soap and beverages, which outfit ships; baggage handling; manufacturers of equipment for communications, navigation, and on-board machinery like boilers and laundry machines; security providers; and

interior-design and computer consultants. *Id.* Ex. 1 at 46. In sum, large chunks of Florida’s economy hang in the balance, as Judge Merryday emphasized in finding that the cruise industry has a “ubiquitous footprint” in Florida and an “enormous financial effect, which reaches into most sectors of Florida’s economy.” PI Order at 114.

The same dynamics that hold for the cruise industry generally hold for NCLH specifically. Today, NCLH employs well over 100 people who work on a turn-around day at its PortMiami terminal. Del Rio Decl. ¶¶ 4, 35. Before Florida enacted § 381.00316, NCLH’s subsidiaries had 15 ships planning to embark from Florida this coming fall and winter seasons with appropriate safeguards. *Id.* ¶ 31. So long as Florida’s statute remains operative, however, these voyages will be placed at risk of cancellation, disruption, and possible outbreak. If Florida’s Ban forces NCLH to slash or compromise its operations in Florida, then NCLH will lose the benefit of its enormous investment, the terminal’s employees stand to lose their employment, passengers and crew will stay home, and the resulting lack of spending will cascade through sector after sector of Florida’s economy. The result would be incalculable, unrecoverable losses—of revenue, goodwill, and reputation for the business, of compensation and opportunities for employees, of the free flow of interstate and foreign commerce, and potentially even of human life and safety. *Id.* ¶¶ 25–35; *see also* Laitamaki Decl. ¶¶ 8, 12–17.

LEGAL STANDARD

“A preliminary injunction may be entered when a plaintiff establishes four elements: ‘(1) a substantial likelihood of success on the merits; (2) a substantial threat of irreparable injury; (3) that the threatened injury to the plaintiff outweighs the potential harm to the defendant; and (4) that the injunction will not disserve the public interest.’” *Friedenberg v. Sch. Bd. of Palm Beach Cnty.*, 911 F.3d 1084, 1090 (11th Cir. 2018). All four elements are amply satisfied here.

ARGUMENT

I. NCLH IS LIKELY TO PREVAIL ON THE MERITS

NCLH is likely to prevail because Florida’s Ban, e.g., (1) is preempted by federal law, (2) violates the First and Fourteenth Amendments, and (3) violates the Dormant Commerce Clause, any one of which suffices to establish NCLH’s likelihood of success.¹

¹ In addition, Florida’s Ban (4) violates the substantive due process component of the Fourteenth Amendment, as alleged in NCLH’s parallel complaint. Compl. ¶¶ 152–61. Page constraints preclude NCLH from elaborating on this count at present, and it should be unnecessary

A. Florida’s Ban Is Preempted By Federal Law.

Under the Supremacy Clause, “the laws of the United States . . . shall be the supreme law of the land; and the judges in every state shall be bound thereby, anything in the Constitution or laws of any State to the contrary notwithstanding.” U.S. Const. art. VI. Accordingly, Congress may “pre-empt, *i.e.*, invalidate, a state law through federal legislation,” *Oneok, Inc. v. Learjet, Inc.*, 575 U.S. 373, 376 (2015), and “[f]ederal regulations have no less pre-emptive effect than federal statutes.” *Fidelity Fed. Sav. & Loan Ass’n. v. de La Cuesta*, 458 U.S. 141, 151 (1982). Beyond using “express language in a statute,” federal law may “implicitly pre-empt a state law, rule, or other state action,” via “conflict pre-emption,” which occurs “where ‘compliance with both state and federal law is impossible,’ or where ‘the state law ‘stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.’” *Oneok*, 575 U.S. at 377–78 (quoting *California v. ARC Am. Corp.*, 490 U.S. 93, 100–01 (1989)); *accord, e.g., Am. Ins. Ass’n v. Garamendi*, 539 U.S. 396, 421–25 (2003). Conflict pre-emption applies “where state law limited the availability of an option that the federal agency considered essential to ensure its ultimate objectives.” *Geier v. Am. Honda Motor Co., Inc.*, 529 U.S. 861, 882 (2000).

In this case, Florida’s Ban is preempted regardless of whether that preemption is characterized as express or implied. Congress and CDC have expressed an intent to preempt state laws to the extent they conflict with regulations promulgated under 42 U.S.C. § 264, including the Conditional Sailing Order and the Technical Instructions thereunder. By eliminating NCLH’s ability to verify its passengers’ vaccination status, Florida’s Ban would eliminate NCLH’s essential option for complying with the Conditional Sailing Order. It follows that the Ban conflicts with and is preempted by federal law, at least as applied to NCLH.

Both Congress and CDC have stated their intent to preempt state laws that conflict with CDC’s authority under 42 U.S.C. § 264. Pursuant to § 264(a), the HHS Secretary (through CDC) is “authorized to make and enforce such regulations as in his judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases.” Section 264(e) then makes explicit that the statute and regulations carry preemptive effect specifically “to the extent that [any] such [state] . . . provision conflicts with an exercise of Federal authority under this section or section 266 of this title.” 42 U.S.C. § 264(e). In turn, CDC expressly invoked its preemptive

to pile it atop the points made herein in order to establish likelihood of success. Even so, NCLH stands ready to elaborate on this count through additional briefing if doing so will assist the Court.

authority under 42 U.S.C. § 264 when it issued the Conditional Sailing Order and specified how conflict preemption now operates:

In accordance with 42 U.S.C. 264(e), this Order shall supersede any provision under State law (including regulations and provisions established by political subdivisions of States), that *conflict with* an exercise of Federal authority, including instructions by U.S. Coast Guard or HHS/CDC personnel permitting ships to make port or disembark persons under stipulated conditions, under this Order.

85 Fed. Reg. at 70158 (emphasis added).

The basis for conflict preemption is straightforward. As CDC submitted to the Eleventh Circuit last week: “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.” CDC Stay Mot. at 14. In particular, Florida’s Ban forecloses the compliance options afforded by (1) the Conditional Sailing Order’s Technical Instructions, and (2) the Conditional Sailing Order’s Operating Manual. Notably, the Middle District of Florida’s preliminary injunction should not be taken as negating this preemptive effect: its *preliminary* assessment of *likelihood* of success is not precedent in any sense, and it by no means takes Congress’s statute or CDC’s regulations off the books as this Court now assesses the state of the law for itself. See *Univ. of Tex. v. Camenisch*, 451 U.S. 390, 395 (1981); *JB Weld Co. v. Gorilla Glue Co.*, 978 F.3d 778, 794 (11th Cir. 2020). Nor does Judge Merryday’s preliminary injunction take effect by its terms until July 18, before which date the Eleventh Circuit should be positioned to rule on CDC’s pending stay request.

1. Florida’s Ban Conflicts With The Conditional Sailing Order’s Technical Instructions.

CDC’s Technical Instructions pursuant to the Conditional Sailing Order provide that, “[i]n lieu of conducting a simulated voyage, cruise ship operator responsible officials, at their discretion, may,” among other things, “submit to CDC a clear and specific vaccination plan and timeline to limit cruise ship sailings to 95 percent of passengers **who have been verified by the cruise ship operator as fully vaccinated** prior to sailing.” See Vieira Decl. Ex. 2 at 9 (emphasis added). But Florida’s Ban prohibits NCLH from “requir[ing] patrons or customers to provide **any documentation certifying COVID-19 vaccination**” in order to embark on a cruise. Fla. Stat. § 381.00316(1) (emphasis added). And vaccine documentation is the only reliable way to “verify” a passenger’s vaccination status. See Ostroff Decl. ¶¶ 17–18.

Nor can this conflict be dispelled by positing in the abstract that NCLH might try to thread the needle between federal and Florida law by somehow “verif[ying]” passengers’ vaccination without requiring documentation of same. Such theorizing does not deny that Florida is imposing a practical “obstacle to the accomplishment and execution of the full purposes and objectives” of the federal scheme. *Oneok*, 575 U.S. at 377. As the Supreme Court explained in *de la Cuesta*, a State cannot restrict regulated entities from exercising the options afforded to them by federal law: “Although compliance with both § 545.8–3(f) [the federal regulation] and the *Wellenkamp* rule [handed down by California courts] may not be ‘a physical impossibility,’ *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. at 142–143, the California courts have forbidden a federal savings and loan to enforce a due-on-sale clause solely ‘at its option’ and have deprived the lender of the ‘flexibility’ given it by the Board.” 458 U.S. at 155; *see also Geier*, 529 U.S. at 881–82 (2000) (citing *de la Cuesta* and other decisions as “finding conflict and pre-emption where state law limited the availability of an option that the federal agency considered essential to ensure its ultimate objectives”); *Garamendi*, 539 U.S. at 420–25 (finding conflict preemption where state law posed “an obstacle to the success” of the federal government’s chosen approach to handling an issue with international implications). The conflict here comes to a sharp point considering that NCLH has certified—under penalty of perjury—in applying to CDC for a Conditional Sailing Certificate that the requisite percentage of passengers “will be confirmed as fully vaccinated.” Del Rio Decl. Ex. 2 at 1. And CDC issued a Conditional Sailing Certificate to NCLH in reliance on that certification. Vieira Decl. Ex. 4 at 1. Of course, **documentation** of vaccination is the most natural, appropriate **confirmation** of same. And Florida cannot lawfully get in the way of NCLH following through on its commitments to CDC in this fashion. *Cf. Nantahala Power & Light Co. v. Thornburg*, 476 U.S. 953, 973 (1986) (approval by FERC of federal rate preempts contrary determination by state agency); *Martin v. Medtronic, Inc.*, 254 F.3d 573, 583–84 (5th Cir. 2001) (FDA approval preempts contrary arguments under state law).

In sum, the basis for preemption is clear. Florida’s Ban prohibits NCLH from requiring the documentation that would fittingly “verify” and “confirm” its passengers’ vaccinations so as to ensure federal compliance. “Although compliance with both [CDC instructions] and [Florida’s law] may not be a physical impossibility,” Florida has “forbidden” the practical means to certify vaccination and “depriv[ed]” cruise lines of “flexibility” afforded by CDC, *de la Cuesta*,

458 U.S. at 155, while also “actively impeded[ing]” CDC’s core federal objective of ensuring safe cruises, CDC Stay Mot. at 14.

2. *Florida’s Ban Conflicts With The Conditional Sailing Order’s Operations Manual.*

Florida’s Ban is also preempted by CDC’s May 26 Operations Manual, which affords special dispensation to cruise operators who serve vaccinated passengers. See Vieira Decl. Ex. 3 at 5. Numerous provisions in the Manual give NCLH discretion to permit certain activities if and only if its passengers are “fully vaccinated.” Because NCLH’s discretion depends on NCLH ascertaining its passengers’ vaccination statuses, NCLH’s ability to exercise its discretion hinges on its ability to require vaccine documentation. Accordingly, Florida’s law is blocking NCLH from pursuing and obtaining certain federal benefits and it is denying NCLH flexibility afforded by federal law. Florida’s law is also preventing NCLH from reliably ascertaining whether it qualifies for the Operations Manual’s safe harbor from physical-distancing requirements and related obligations, which are likewise contingent on passengers’ vaccination status. See Vieira Decl. Ex. 3 at 9. In these respects, too, the Ban “stands as an obstacle to the accomplishment and execution of the full purposes and objectives” of federal law. *Oneok*, 575 U.S. at 377.

B. *Florida’s Ban Violates The First Amendment.*

“In the fields of medicine and public health . . . information can save lives.” *Wollschlaeger v. Governor of Fla.*, 848 F.3d 1293, 1313 (11th Cir. 2017) (en banc) (citation and internal quotation marks omitted). Remarkably, Florida’s Ban shuts off the communication of vital, potentially life-saving information between businesses and their customers. This poses a serious First Amendment problem, even as Florida lacks any serious case for withstanding First Amendment scrutiny. Especially considering the politicized nature of vaccination information, the Ban should be struck down as a content-based, speaker-based prohibition on noncommercial speech concerning a subject disfavored by the State—and one that does not come anywhere close to withstanding strict scrutiny. Alternatively, even if the Ban is treated as a restraint on commercial speech, it is incapable of satisfying the intermediate scrutiny that then applies.

1. *As Applied To NCLH, Florida’s Ban Is An Unconstitutional, Content-Based Restriction On Noncommercial Speech.*

Because Florida’s Ban prohibits speech based on its content, it is “‘presumptively invalid.’” *Otto v. City of Boca Raton*, 981 F.3d 854, 862 (11th Cir. 2020) (quoting *R.A.V. v. City of St. Paul*, 505 U.S. 377, 382 (1992)); see also *Turner Broad. Sys., Inc. v. FCC*, 512 U.S. 622,

641–62 (1994). “A content-based law is one that ‘applies to particular speech because of the topic discussed or the idea or message expressed.’” *Otto*, 981 F.3d at 862 (quoting *Reed v. Town of Gilbert*, 576 U.S. 155, 163 (2015)). Here, one and only one type of medical documentation runs afoul of Florida’s Ban: “[D]ocumentation certifying COVID-19 vaccination.” Fla. Stat. 381.00316(1). Now why would Florida specially disfavor communication **only** of vaccination information, **only** for COVID-19? Anyone paying attention to Florida politics and statements by the Governor knows the answer. Embracing COVID-19 vaccinations and other protective measures (such as masks) puts one opposite Florida’s leaders and the positions they have staked out in a raging political and culture war. Whatever else Florida can do to advance its polemic, however, it cannot go so far as preventing like-minded businesses and customers from communicating as they see fit to protect themselves. Indeed, both the Supreme Court and Eleventh Circuit have struck down such state bans on health-related communications on a particular topic as impermissibly content-based. *See, e.g., Sorrell v. IMS Health, Inc.*, 564 U.S. 552, 564 (2011) (“The statute thus disfavors marketing, that is, speech with a particular content.”); *Wollschlaeger*, 848 F.3d at 1307 (“The record-keeping and inquiry provisions expressly limit the ability of certain speakers—doctors or medical professionals—to write and speak about a certain topic—the ownership of firearms—and thereby restrict their ability to communicate and/or convey a message.”).

Moreover, the Ban is speaker-based. A law is speaker-based if it “imposes a burden based on the . . . identity of the speaker.” *Sorrell*, 564 U.S. at 567. Here, the Ban identifies one group of disfavored speakers—“business entit[ies]”—and disqualifies them from requiring certain information about a certain topic. Fla. Stat. § 381.00316(1); *see also Otto*, 981 F.3d at 863 (restrictions on speech-based therapy were “speaker-focused”); *Wollschlaeger*, 848 F.3d at 1313 (prohibition against doctors inquiring about patients’ firearm ownership was “speaker-focused”). This is another reason why strict scrutiny applies. *See Otto*, 981 F.3d at 867–68.²

² Any attempt by Florida to characterize the Ban as an economic regulation should be unavailing. *See, e.g., Sorrell*, 564 U.S. at 566–70 (strictly scrutinizing law restricting treatment of pharmacy records as content-based, notwithstanding Vermont’s attempts to couch the regulation as economic regulation of conduct, and holding that “[a]n individual’s right to speak is implicated when information he or she possesses is subjected to ‘restraints on the way in which the information might be used or disseminated’”); *see also Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 756 (1976) (recognizing First Amendment to receive

Once applied, strict scrutiny is fatal to the Ban. *See id.* “Content-based laws . . . are presumptively unconstitutional and may be justified only if the government proves that they are narrowly tailored to serve compelling state interests.” *Reed*, 576 U.S. at 163; *see United States v. Alvarez*, 567 U.S. 709, 725 (2012) (quoting *Brown v. Ent. Merchants Ass’n*, 564 U.S. 786, 792 (2011)). “Cases where this standard is met are few and far between.” *Otto*, 981 F.3d at 868 n.6; *see also Sorrell*, 564 U.S. at 571 (“In the ordinary case it is all but dispositive to conclude that a law is content based.”). Florida lacks any compelling interest in prohibiting the unvarnished exchange of public-health information between consenting parties who are trying to “save lives.” *Wollschlaeger*, 848 F.3d at 1313. Even setting that defect aside, Florida has not even tried to explore less-restrictive alternatives for advancing any putative interest, such as requiring special accommodations for passengers who may have special justifications for foregoing vaccinations or for withholding documentation. In *Wollschlaeger*, “nothing in the record suggest[ed] that patients who are bothered or offended by such questions are psychologically unable to choose another medical provider.” *Id.* at 1315. Just so here: Nothing suggests that customers who are averse to getting vaccinated or to documenting the same cannot find businesses that cater to their preferred approach. Categorically prohibiting all exchanges of a particular stripe, without first identifying any “real problem,” let alone one commensurate with the supposed solution, is antithetical to the narrow, restrained approach the Constitution demands within this sensitive realm. *See, e.g., United States v. Playboy Ent. Grp.*, 529 U.S. 803, 827 (2000).

2. Even If The Ban Were A Restriction On Commercial Speech, It Is Constitutionally Infirm As Applied To NCLH.

Even if the Court were to treat the Ban as limited to commercial speech, the Ban still cannot survive the “heightened scrutiny” applicable to content-based restrictions on commercial speech.

information from a willing speaker). Nor can Florida properly defend its Ban as mere regulation of “commercial speech,” the “core notion” of which is confined “to speech that proposes a commercial transaction.” *Tobinick v. Novella*, 848 F.3d 935, 950 (11th Cir. 2017) (quoting *Bolger v. Young Drug Prods. Corp.*, 463 U.S. 60, 66 (1983)). Even venturing well outside that core, sharing of vaccine documentation is wholly removed from any advertising or marketplace concerns: any rationale for this Ban is **not** about the fundamental business exchange but about what should be the ordained view of public health and safety assuming business terms are otherwise unobjectionable and desired. *See Tobinick*, 848 F.3d at 951–52 (doctor’s articles were not commercial speech despite referencing doctor’s services and generating revenue because “the articles themselves . . . never propose a commercial transaction”); *Otto*, 981 F. 3d at 865 (scrutinizing state prohibition as non-commercial because “what is being regulated is not, say, an advertisement for therapy, but the therapy itself”).

The Supreme Court outlined the “heightened scrutiny” standard in *Sorrell*, which requires “that the statute directly advances a substantial governmental interest and that the measure is drawn to achieve that interest,” inasmuch as there “must be a fit between the legislature’s ends and the means chosen to accomplish those ends.” 564 U.S. at 572 (citations and internal quotation marks omitted); *see also Wollschlaeger*, 848 F.3d at 1311–12 (applying heightened scrutiny to content-based restriction on commercial speech). Florida lacks any “substantial governmental interest” in restricting the free flow of basic information confirming vaccination status for an especially menacing disease. For much the same reasons that Florida does not come close to satisfying strict scrutiny, it also fails the heightened scrutiny applicable to content-based regulation of commercial speech, which is increasingly disfavored by the Supreme Court. The Ban is not “proportional to the resulting burdens placed on speech” and evinces no “fit between the legislature’s ends and the means chosen to accomplish those ends.” *Sorrell*, 564 U.S. at 572; *see also Wollschlaeger*, 848 F.3d at 1314–16 (holding that Florida’s ban on doctors’ questioning patients regarding firearm ownership did not survive heightened scrutiny because the ban was not narrowly tailored to further Florida’s asserted interests).

C. Florida’s Ban Violates The Dormant Commerce Clause.

Under the Commerce Clause, “Congress shall have Power . . . To regulate Commerce with foreign Nations, and among the several States.” U.S. Const. art. I, § 8, cl. 3. “Although the clause speaks literally only to the powers of Congress, it is well settled” that the Commerce Clause “has a ‘dormant’ aspect as well, namely, one that serves as ‘a substantive restriction on permissible state regulation of interstate commerce.’” *Bainbridge v. Turner*, 311 F.3d 1104, 1108 (11th Cir. 2002) (quoting *Dennis v. Higgins*, 498 U.S. 439, 447 (1991)). Among other things, the Dormant Commerce Clause “works to keep states from ‘ventur[ing] excessively into the regulation of . . . [interstate] commerce . . . [and] trespass[ing] upon national interests’” *Id.* (alterations in original) (quoting *Kassel v. Consol. Freightways Corp. of Del.*, 450 U.S. 662, 669 (1981)). The scope of “interstate commerce” has long been viewed broadly. *See, e.g., McCall v. California*, 136 U.S. 104, 109 (1890). And because “there is evidence that the Founders intended the scope of the foreign commerce power to be . . . greater” than the interstate commerce power, “[t]he need for federal uniformity is no less paramount in ascertaining the negative implications of Congress’ power to ‘regulate Commerce with foreign Nations’ under the Commerce Clause.” *Japan Line, Ltd. v. Los Angeles Cnty.*, 441 U.S. 434, 448–49 (1979).

“To determine whether a statutory scheme violates the dormant Commerce Clause,” courts “employ two tiers of analysis.” *Bainbridge*, 311 F.3d at 1108. “If the scheme ‘directly regulates or discriminates against interstate commerce, or . . . favor[s] in-state economic interests over out-of-state interests,’ courts ‘have generally struck down the statute without further inquiry.’” *Id.* (quoting *Brown-Forman Distillers Corp. v. N.Y. State Liquor Auth.*, 476 U.S. 573, 579 (1986)). “When, however, a statute has only indirect effects on interstate commerce and regulates evenhandedly,” courts will “examine[] whether the State’s interest is legitimate and whether the burden on interstate commerce clearly exceeds the local benefits.” *Id.* at 1109 (quoting *Brown-Forman*, 476 U.S. at 579). Excessive burdens on specific industries or industry sectors are subject to invalidation. *See, e.g., Walgreen Co. v. Rullan*, 405 F.3d 50, 52 (1st Cir. 2005) (certificate-of-need law regulating all pharmacies was unconstitutional as applied to retail pharmacies); *Trailer Marine Transp. Corp. v. Rivera Vazquez*, 977 F.2d 1, 2 (1st Cir. 1992) (motor-vehicle fee was unconstitutional as applied to trailers transporting goods).

When state statutes in practice regulate wholly out-of-state conduct, they violate the Dormant Commerce Clause. *Lebamoff Enters. Inc. v. Whitmer*, 956 F.3d 863, 872 (6th Cir. 2020) (quoting *Healy v. Beer Inst., Inc.*, 491 U.S. 324, 336 (1989)); *Legato Vapors, LLC v. Cook*, 847 F.3d 825, 827 (7th Cir. 2017); *Sam Francis Found. v. Christies, Inc.*, 784 F.3d 1320, 1324 (9th Cir. 2015); *Am. Booksellers Found. v. Dean*, 342 F.3d 96, 104 (2d Cir. 2003). Such a statute “exceeds the inherent limits of the enacting State’s authority and is invalid regardless of whether the statute’s extraterritorial reach was intended by the legislature.” *Healy*, 491 U.S. at 336.

Although Florida’s Ban does not discriminate by favoring in-state businesses over out-of-state ones, it poses a serious affront to the Dormant Commerce Clause. And that affront is specially flagrant as applied to the cruise industry. Cruise ships carry passengers from across the U.S. into ports of other nations and other States; they flow from Florida into rich and varied channels of interstate and international commerce. Del Rio Decl. ¶ 21. After disembarking from Florida, NCLH’s vessels reach international waters and sail to interstate and foreign ports, many of which require proof of vaccination to enter without testing. *Id.* ¶ 17. For instance, some NCLH vessels are scheduled to travel to U.S. territories, such as Puerto Rico and the U.S. Virgin Islands, *see* Del Rio Decl. ¶ 23, where they would be subject to the Conditional Sailing Order, *see* 85 Fed. Reg. at 70158, and beyond the scope of Judge Merryday’s injunction, *see* PI Order at 123. Yet Florida would disrupt all of that on the slender basis that a business like NCLH

operates in Florida and therefore must follow Florida's anomalous dictates. Such overreach has profound negative repercussions for cruise lines' relationships and operations across other States and other Nations. As already explained, Florida is pulling the rug out from under NCLH's existing plans and arrangements nationwide and internationally. Indeed, by "'project[ing] its legislation' into other States" and specifying what NCLH can require from passengers anywhere in the country, Florida is regulating commerce outside of its own borders and thus violating the Dormant Commerce Clause. *Am. Booksellers Found.*, 342 F.3d at 104 (quoting *Brown-Forman*, 476 U.S. at 584).

In sum, Florida's Ban has the effect of blocking or hampering the operation of cruise lines in and out of Florida, which is a major interstate and international port. That excessively burdens the free flow of commerce between States and between Nations. See *Fla. Transp. Servs., Inc. v. Miami-Dade Cnty.*, 703 F.3d 1230, 1235 (11th Cir. 2012) ("The Port of Miami is one of the busiest ports in the nation, fully engaged in interstate commerce, predominantly foreign commerce."); see also *Young v. Coloma-Agaran*, 2001 WL 1677259, at *11, *15 (D. Haw. Dec. 27, 2001).

To withstand the balancing appropriate in these circumstances, Florida must marshal strong justification commensurate with the drastic burden it is imposing beyond its borders. Here, however, Florida ostensibly is hard pressed to summon *any* creditable justification. This is a case where any putative local benefits will prove to be negligible, if they exist at all. Florida has no legitimate interest in restricting the exchange of potentially life-saving, health-related information. And Florida certainly has no justification for forcing business like NCLH either to shut down altogether or else betray all of their passengers who want simply to sail safely and smoothly. See *Fla. Transp. Servs.*, 703 F.3d at 1260–62 (rejecting a county's assertion of local benefits because "the Port Director's permitting practices do not rationally contribute to these purported local benefits"). Once this Court balances the relevant considerations based on the available evidence, NCLH is likely to prevail under the Dormant Commerce Clause.

II. ABSENT AN INJUNCTION, NCLH WILL SUFFER IRREPARABLE HARM

The irreparable harm faced by NCLH is glaring and profound. To begin, violation of NCLH's First Amendment rights constitutes irreparable harm by definition. Moreover, NCLH's economic harm is irreparable because recovery of NCLH's monetary damages may be blocked by the State's sovereign immunity. Further still, scuttling of NCLH's plans and commitments to its passengers threatens to damage its reputation and customer goodwill in ways that are classically

irreparable. Last, forcing NCLH to sail without being able to verify passengers' vaccination status poses undue risk to human health and safety, loss of which is likewise irreparable.

First Amendment. Florida's Ban poses irreparable harm by infringing upon NCLH's First Amendment rights. "The 'alleged violation of a constitutional right . . . triggers a finding of irreparable harm.'" *Gayle v. Meade*, 2020 WL 3041326, at *20 (S.D. Fla. June 6, 2020) (quoting *Jolly v. Coughlin*, 76 F.3d 468, 482 (2d Cir. 1996)). To the extent NCLH makes a substantial showing that protected communications with passengers are being chilled, "no further showing of irreparable injury is necessary." *Id.* at *20 (quoting *Mitchell v. Cuomo*, 748 F.2d 804, 806 (2d Cir. 1984)); *see also Siegel v. LePore*, 234 F.3d 1163, 1178 (11th Cir. 2000).

Sovereign Immunity. Second, NCLH's looming monetary damages are irreparable, given the State's sovereign immunity. *See Odebrecht Constr., 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." *Id.* (citing cases); *see also ABC Charters, Inc. v. Bronson*, 591 F. Supp. 2d 1272, 1310 (S.D. Fla. 2008).

Serious Harm to Business & Loss of Goodwill. Third, the damage NCLH faces defies quantification. After months of Herculean effort, planning and expense, NCLH has at last positioned itself to resume business in a way that is safe and sound—and it has staked its reputation and its relationships with customers on setting sail August 15 with everyone's vaccine documentation in hand. Del Rio Decl. ¶¶ 27–28; Laitamaki Decl. ¶¶ 11–13, 16–17. If, instead, NCLH is forced to cancel its plans or drop the protocols to which it has committed, then it will disappoint all those are now counting on it, at which point no court can restore their faith. Laitamaki Decl. ¶¶ 8, 12–13, 16–17. Such "loss of control of reputation, loss of trade, and loss of goodwill" constitutes classic irreparable harm. *Sylvan Learning Inc. v. Learning Sols., Inc.*, 795 F. Supp. 2d 1284, 1299 (S.D. Ala. 2011) (quoting *Ferrellgas Partners, L.P. v. Barrow*, 143 F. App'x 180, 190–91 (11th Cir. 2005)); *see also Tim Hortons USA, Inc. v. Tims Milner LLC*, 2019 WL 2515006, at *5–6 (S.D. Fla. June 17, 2019). Even short of "the complete and imminent destruction of the business," a "serious injury that cannot be quantified" also belongs under the heading of irreparable harm. *ABC Charters*, 591 F. Supp. 2d at 1309. "[I]rreparable harm may result from the loss of a central, key component of the business" *Id.* (citing *Galvin v. N.Y. Racing Ass'n, Inc.*, 70 F. Supp. 2d 163, 170 (E.D.N.Y. 1998), *aff'd*, 166 F.3d 1200 (2d Cir. 1998)).

Risk Of COVID-19. Although Florida may urge NCLH to sail while abandoning vaccination documentation, no one should want that; the resulting risk of outbreak would threaten irreparable harm of an invidious kind, even as an especially dangerous variant gains ground globally. Florida would prevent NCLH from minimizing COVID-19 exposure. Del Rio Decl. ¶¶ 19–35. Such exposure can result in serious illness and death that courts thereafter can never repair. See *Gayle*, 2020 WL 3041326, at *20. Moreover, any renewed outbreak may spell a return to the shutdown that, as Florida has elsewhere noted, “ravaged” the industry and inflicted “billions of dollars in losses,” never to be recouped. Fla. Brief at 3; Laitamaki Decl. at ¶¶ 9, 16.

III. THE BALANCE OF EQUITIES AND PUBLIC INTEREST WEIGH HEAVILY IN FAVOR OF ENJOINING FLORIDA’S BAN

Numerous, weighty interests uniformly align with NCLH’s as it seeks relief enabling its ships to sail safely. Assessment of the public interest and balance of equities “merge when, as here, the [g]overnment is the opposing party.” *Gonzalez v. Governor of Ga.*, 978 F.3d 1266, 1271 (11th Cir. 2020) (quoting *Swain v. Junior*, 961 F.3d 1276, 1293 (11th Cir. 2020)). These factors here favor an injunction with singular, striking force. Indeed, no one should want to see NCLH disabled from resuming operations on terms that CDC has blessed and that all stakeholders—employees, passengers, public-health authorities, foreign ports—are encouraging and embracing.

Of course, “it is always in the public interest to protect constitutional rights.” *Strawser v. Strange*, 44 F. Supp. 3d 1206, 1210 (S.D. Ala. 2015) (quoting *Phelps–Roper v. Nixon*, 545 F.3d 685, 690 (8th Cir. 2008)); see also *Charles H. Wesley Educ. Found., Inc. v. Cox*, 324 F. Supp. 2d 1358, 1369 (N.D. Ga. 2004), *aff’d*, 408 F.3d 1349 (11th Cir. 2005). For the same reasons NCLH is likely to prevail on the merits, the public interest is on its side.

Even setting aside the merits, however, the equities favoring NCLH are overwhelming and unanswerable. Florida itself has stressed how any harm to cruise lines like NCLH in turn ripples to hundreds of thousands of individuals who depend on cruise lines for income. Unless enjoined, the Ban threatens tens of thousands of cruise passengers, tens of thousands of Florida workers and businesses who depend on cruise voyages for income, local economies, Florida’s ports, and even foreign populaces. According to the State, the cruise industry supports “nearly 159,000 total jobs paying \$8.1 billion in income” within Florida. Fla. Brief at 2. Also according to the State, it is “against the public interest to force a person out of a job.” *Id.* at 25. For the same reasons that Florida was correct (and was successful) in making these points, it would be wrong to enforce its Ban at the expense of NCLH as NCLH pursues the right path forward.

Although Judge Merryday may have erred in his merits analysis, there should be no faulting his assessment of why it is beneficial for NCLH and other cruise lines to be resuming operations on terms that are safe and well considered. The cruise industry has a “ubiquitous footprint” in the State and an “enormous financial effect, which reaches into most sectors of Florida’s economy.” PI Order at 114–15. During the shutdown, Florida’s ports lost over \$297 million in revenue through February 2021 and project losses of \$398 million in revenue through July. Fla. Brief, Ex. 26 at 2–3. Without cruises, Florida has “lost tens of millions of tax dollars” and been forced “to expend around \$20 million in state unemployment benefits.” Fla. Brief at 22. To quote Florida once more, “[t]he effect on the health of the local economy is a proper consideration in the public interest analysis.” *Id.* at 24–25 (quoting *All. for the Wild Rockies v. Cottrell*, 632 F.3d 1127, 1138 (9th Cir. 2011)). We agree. If Florida is nevertheless intent on disabling or imperiling vital contributions to its economy, this Court should rescue the public interest and countless third parties by enjoining it.

It also bears noting that Florida’s Ban reduces incentives for vaccination, thereby undermining one of the best tools to combat COVID-19. See Ostroff Decl. ¶¶ 10–14. As dangerous as COVID-19 can be, widely-available COVID-19 vaccines have proven safe and effective in limiting its spread. *Id.* ¶¶ 9–15. Tellingly, Florida itself touted the availability of vaccines as its first reason for impugning CDC’s Order. Fla. Brief at 5. And when balancing Florida’s COVID regulations against the rights of rental owners, the Middle District of Florida found that “the threatened harms to the public” due to COVID “outweigh decisively the injury—if any—to the plaintiffs” who challenged the health measures. *Alsop v. DeSantis*, 2020 WL 4927592, at *4–5 (M.D. Fla. Aug. 21, 2020) (collecting cases). The same holds here. If there is any exigency, it is the exigency posed by COVID-19—not the concerted use of best practices to keep COVID-19 away from cruise ships. The public interest clearly lies in fighting the COVID-19 pandemic with maximum cooperation, attention, and resources. Granting the requested relief will powerfully serve that interest by clearing the way for NCLH to sail as NCLH should—armed with proper protections and free of intrusive impediments by Florida.

CONCLUSION

For the foregoing reasons, NCLH respectfully requests that the Court set an expedited schedule and grant a preliminary injunction by August 6, 2021 prohibiting Florida from enforcing its Ban on requests for vaccine documentation pending resolution of the merits.

REQUEST FOR HEARING

Pursuant to Local Rule 7.1(b)(2), NCLH respectfully requests that the Court schedule a hearing and permit oral argument to resolve the factual and legal issues involved in this as-applied constitutional challenge to Florida's Ban. NCLH estimates that two hours should be sufficient.

DATED: July 13, 2021

Respectfully submitted,

QUINN EMANUEL URQUHART & SULLIVAN LLP

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Attorneys for Plaintiffs Norwegian Cruise Line Holdings Ltd., NCL (Bahamas) Ltd., Seven Seas Cruises S. de R.L., and Oceania Cruises S. de R.L.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 13th day of July 2021, the foregoing document was electronically filed with the Clerk of Court using CM/ECF. I also certify that the foregoing document is being served this day on the party identified below, either via transmission of Notice of Electronic Filing generated by CM/ECF or in some other authorized manner for those counsel or parties who are not authorized to receive electronic Notices of Electronic Filing.

VIA EMAIL & U.S. MAIL

Dr. Scott Rivkees, in his official capacity as State Surgeon
General, Florida Department of Health
4052 Bald Cypress Way
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Telephone: (850) 245-4444

Defendant

By: /s/ John F. O'Sullivan
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**UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF FLORIDA**

NORWEGIAN CRUISE LINE HOLDINGS LTD., a Bermuda Company; **NCL (BAHAMAS) LTD.**, d/b/a NORWEGIAN CRUISE LINE, a Bermuda Company; **SEVEN SEAS CRUISES S. DE R.L.**, d/b/a REGENT SEVEN SEAS CRUISES, a Panama Limited Liability Company; **OCEANIA CRUISES S. DE R.L.**, d/b/a OCEANIA CRUISES, a Panama Limited Liability Company;

Plaintiffs,

v.

SCOTT A. RIVKEES, M.D., State Surgeon General and Head of the Florida Department of Health, in his official capacity;

Defendant.

Case No. 1:21-cv-22492-KMW

DECLARATION OF FRANK J. DEL RIO

I, Frank J. Del Rio, declare as follows:

1. I make this declaration on the basis of my personal and professional knowledge and experience, information available to me in my position in Norwegian Cruise Line Holdings Ltd. (“NCLH”), and publicly available information.

2. I am currently the President, Chief Executive Officer, and a Director on the Board of Directors of NCLH, which is headquartered in Miami, Florida. I assumed these roles in 2015 and am responsible for both the day-to-day operations and long-term strategic plan of NCLH.

3. Under my leadership, NCLH has delivered industry-leading financial results and an unparalleled guest experience. NCLH has also significantly strengthened its global footprint, including by adding seven new ships and a private island destination in Harvest Caye, Belize.

4. As part of NCLH’s internationally focused model, in conjunction with Miami-Dade County, NCLH developed an iconic terminal, known as the Pearl of Miami (Terminal B), for its operations at PortMiami in Miami, Florida, one of the cruise industry’s largest and most essential international ports. PortMiami accommodates substantial interstate and international traffic and,

within as little as thirty minutes of departing from PortMiami, NCLH's ships reach international waters and sail to interstate and foreign ports.

5. I have worked as an executive in the cruise industry for 28 years. Previously, I served from 2002 to 2016 as Chairman and Chief Executive Officer of Prestige Cruise Holdings, Inc., the parent company operating both Oceania Cruises and Regent Seven Seas Cruises. I founded Oceania Cruises in 2002 and oversaw its growth into a competitive cruise line in the cruise industry's premium market space. NCLH acquired Prestige in 2014 and as part of the transition I assumed my current roles at NCLH. I also worked as co-Chief Executive Officer, Executive Vice President, and Chief Financial Officer of Renaissance Cruises from 1993 to 2001.

6. Since the start of the COVID-19 pandemic, NCLH has prioritized the health and safety of its passengers and crew.

7. On March 13, 2020, two days after the World Health Organization declared COVID-19 a global pandemic, NCLH voluntarily suspended all cruise operations to help combat the spread of the virus. The next day, CDC issued its No Sail Order prohibiting further embarkations, and NCLH's fleet has remained dormant ever since.

8. This action resulted in the overnight mooring and docking of our entire 28-ship fleet, which remains inactive to date.

9. NCLH also managed the complex task of safely repatriating nearly 30,000 crew members back to their respective countries—which numbered in excess of 50 countries over six continents—while transitioning its fleet of 28 large cruise ships, which have a book value of \$17 billion, to various states of minimum manning status.

10. NCLH's halt in operations due to the pandemic has cost the company to date in excess of \$6 billion. I estimate that employees and businesses in the State of Florida have lost approximately \$2 billion in outlays from NCLH due to the halt of NCLH's operations in 2020.

11. To remain a going concern, NCLH bolstered its liquidity through multiple historic capital markets transactions, exceeding \$7.5 billion.

12. Early in the pandemic, NCLH partnered with Royal Caribbean Group to form the Healthy Sail Panel, a group of world-renowned public health experts tasked with advising and recommending protocols for safe and healthy sailing amidst continuing COVID-19-related risks.

13. In light of the recommendations from the Healthy Sail Panel and other leading industry and public health advice, NCLH has concluded that the most effective way to ensure the

health and safety of passengers and crew is to require full vaccination on cruises by everyone on board. The fact that 34 million Americans have contracted COVID-19 and six hundred thousand have died tells me that the trifecta of mask-wearing, social distancing, and washing hands were not sufficient to curb the transmission and effects of COVID-19.

14. Various third-party industry surveys indicate that a vast majority of NCLH's target cruise passengers prefer completely vaccinated voyages. For example, Cruise Critic, a leading online cruise website, shows that 80% of cruise passengers would prefer fully vaccinated voyages. (The results of this survey are attached as **Exhibit 1**.) Thankfully, demand for NCLH cruises has returned with passengers ready to cruise even as concerns with COVID-19 persist. I attribute the demand for NCLH cruises in large part to our plan for 100% vaccination. People are booking a year or more in advance in reliance upon our 100% vaccination plan. They are doing so despite uncertainty about the longevity of the virus and reports indicating that it continues to spread around the world. They are doing so, in other words, because they trust NCLH to protect them from the threat of COVID-19.

15. Maintaining our passengers' trust and rebuilding consumer confidence remains challenging, particularly among NCLH's older passenger base. The maintenance of consumer confidence and goodwill is essential for sustainable business success in the cruise industry. Cultivating passenger confidence and trust in the health and safety of cruise voyages has become more vital than ever in the midst of the COVID-19 pandemic. Unless it is able to verify vaccination status, NCLH's ability to attract and assure its passengers will be severely undercut.

16. Moreover, requiring full vaccination for 100% of passengers and crew is consistent with the vaccination protocols required by many foreign ports where NCLH ships are scheduled to visit.

17. Many foreign ports require proof of vaccination to enter, proof of vaccination to enter without a mandatory quarantine, or proof of vaccination to enter without testing.

18. Indeed, NCLH has scheduled several upcoming voyages to foreign ports that require proof of vaccination to enter without testing, including Belize, Bahamas, British Virgin Islands, and Honduras.

19. I am greatly concerned about the health and safety of the local populations at our destinations around the world if we do not sail with 100% fully vaccinated passengers and crew at this time. NCLH depends on its relationships with the local populations at its destinations, and

many of these populations lack the access to healthcare and other resources that we have in the United States. If we expose these local populations to unvaccinated passengers or crew and COVID-19 infections predictably result, these critical constituencies may be badly damaged and they may understandably blame NCLH for it. NCLH should not be running those risks. Put simply, without destinations to cruise to, we cannot effectively operate saleable cruise itineraries.

20. For multiple reasons and for everyone's sake, NCLH has planned all of its cruises throughout the world requiring proof that 100% of passengers and crew have been vaccinated against COVID-19. This will ensure that NCLH is in compliance with CDC's Conditional Sail Order and Manual and it is a key premise of submissions NCLH has made to CDC seeking approval. In fact, NCLH has attested to CDC under the potential threat of criminal penalties that at least 95% of passengers and 95% of its crew on its upcoming cruise "will be confirmed as fully vaccinated prior to sailing." See Attestation by a Cruise Ship Operator in Lieu of a Simulated Voyage (attached hereto as **Exhibit 2**). When NCLH submitted this attestation, NCLH planned—and it continues to plan—to "confirm[]" passengers' and the crew's COVID-19 vaccination status through documentation, which I understand to be the only reliable way of confirming vaccination status in this context.

21. After diligent efforts in navigating complex regulatory, compliance, and public health challenges, and at considerable expense, NCLH will soon be ready to offer safe cruises embarking from the United States. To get to this point, NCLH has had to navigate moving regulatory targets as well as satisfy its own strict standards for safe cruising.

22. Starting August 7, 2021, NCLH's cruise ship Norwegian Encore will offer passenger revenue voyages from Washington to Alaska.

23. Starting August 15, 2021, NCLH's cruise ship Norwegian Gem will offer several passenger revenue voyages from Florida to the Bahamas, Honduras, Belize, Mexico, the Dominican Republic, the U.S. Virgin Islands, and the British Virgin Islands. Other NCLH ships embarking from Florida are scheduled for voyages to Puerto Rico. Tens of thousands of passengers have already purchased tickets to participate in these and other voyages offered by NCLH departing or arriving in Florida, including over 20,000 between now and October (1,265 of those passengers specifically booked tickets for the Norwegian Gem's August 15 voyage) and many multiples of them who are scheduled to sail between now and early 2022.

24. Unfortunately, Florida Statute § 381.00316 (the “Ban”) purports to make it unlawful for any business operating in the state of Florida, including NCLH, to require customers to provide any documentation certifying vaccination against COVID-19 and authorizes fines for up to \$5,000 per violation. No other jurisdiction that NCLH operates in around the world prohibits documenting passengers’ vaccination status as Florida now does.

25. This Statute creates grave liability risks and substantial compliance obstacles for NCLH and forces NCLH into a dangerous dilemma. If subject to the Statute’s prohibition, NCLH must either drop its plans to verify vaccination status on Florida cruises or else cease its operations in Florida. Neither option is consistent with NCLH’s commitment to passengers, crew, and all those who are counting on us, such as local stevedores, local suppliers, travel agents, and the economies of the local destinations we visit. Instead, we want to resume our cruises in the way we know to be best in the current pandemic environment—safe, sound, and enjoyable for all those onboard.

26. Only by verifying the vaccination status of cruise passengers can we best guard against the introduction of COVID-19 aboard our ships and the potential spread thereof. This approach follows from NCLH’s commitment to the health and safety of passengers, crew, and the local populations at the destinations we visit. I consider it irresponsible, counterproductive, and damaging to our brand to deviate from that approach in order to make home ports in Florida viable.

27. I am especially alert to and concerned about the resilience, mutations, and resurgence of COVID-19 and the emerging variants. I am following the news of the spread of the Delta variant, which caused a severe outbreak in the United Kingdom just five weeks after it was first introduced in the country, when the county had declared victory over COVID-19. I understand that the Delta variant is grossly more contagious than prior strains. From all of the advice I have received from the Healthy Sail Panel, from experts such as Former Commissioner of the Food and Drug Administration Dr. Scott Gottlieb, Former Secretary of Health and Human Services Governor Mike Leavitt, and Former Deputy Director of the National Center for Infectious Diseases at CDC Dr. Stephen Ostroff, among others, vaccination is the most effective way to protect passengers, crews, and locals from the spread of COVID-19. The introduction and potential transmission of COVID-19 on NCLH voyages must be shut down by every means possible. I want to close every possible loophole and opportunity that would allow the virus to enter into the ship’s population and cause injury, and demanding proof of full vaccination is our

best tool to prevent this scenario from occurring. That is why NCLH is planning to require that passengers, in addition to showing proof of COVID-19 vaccination, test negative for COVID-19 before boarding NCLH cruises. This protocol is consistent with advice I have received from leading public health experts.

28. At this time, our plans to resume sailing are predicated upon 100% vaccination and proof of same. We've informed all of our passengers of this plan, and they too are counting on it as they plan their cruises. There is no other way that we can possibly provide the safest and most pleasant cruise experience that we have promised to all of them.

29. Documenting vaccinations is the only reliable way for us to verify vaccinations. No other alternative provides the same level of assurance that passengers have in fact been vaccinated. But NCLH does not stop at documenting vaccine status: It also tests passengers and crew for COVID-19 before they come aboard, because NCLH wants to take maximum precautions against COVID-19 entering any of its ships.

30. Without 100% fully vaccinated passengers, the cruising experience for those who cannot demonstrate vaccination status would not meet the NCLH's established standards. The cruising experience will be compromised because those who are not vaccinated would have limited dining options, as well as limited entertainment options, such as spa, theater, and casino: there would be no buffet, they would be restricted to visiting certain designated areas of the ship, sitting in a segregated area of the theater, and they would be limited to controlled tours when disembarking. Unvaccinated customers would also have fewer options to explore destinations and would have to buy a tour offered by the cruise. The unvaccinated passenger would also pay more, but for a diminished experience. We would have to require unvaccinated passengers to submit themselves to a series of COVID-19 tests that the customer would pay for and they would have to provide proof that they have bought COVID insurance. This would cost upwards of \$200 per passenger.

31. Under Florida's Ban, NCLH will be forced to modify or cancel the itinerary of the cruise ship Norwegian Gem because its itineraries embark from Miami, Florida, and its passengers are expecting 100% vaccination of passengers and crew on board. The cancellation could cost NCLH approximately \$4 million in lost revenues per seven-day cruise, and likely cost the broader cruise ecosystem that supports the Norwegian Gem sailing hundreds of thousands of dollars per

cruise. These losses will only become greater over time, as NCLH's subsidiaries have fifteen ships planning to embark guests in Florida this coming fall and winter seasons.

32. This change would also disrupt the tens of thousands of passengers who have booked their tickets for a voyage aboard an NCLH cruise departing or arriving in Florida between now and early 2022, including the 1,265 passengers who booked tickets specifically for the Norwegian Gem's August 15 voyage, causing NCLH to suffer a loss of goodwill that I see no prospect of repairing.

33. Florida is vital to NCLH's business. Florida has several ports (Miami, Ft. Everglades, Port Canaveral, and Tampa) large enough to accommodate cruise ships and is a major source market for our customer base and a major home port for the cruise industry. National and international passengers travel to these ports to cruise. We have invested hundreds of millions of dollars in order to operate in Florida and spend hundreds of millions of dollars there annually when operating at normal levels.

34. Florida's Ban on vaccine verification will prevent NCLH from optimizing its customers' and crew's protections against COVID-19, thereby increasing the risk of undermining our operations, our reputation, and our bottom-line. If NCLH is forced to comply with Florida's Ban, then NCLH cannot sail as planned. Moreover, I see no good option for resuming operations in Florida. If we do not abandon our Florida operations entirely, then NCLH will have to revise its operations in ways that are costlier, less safe, less appealing for our passenger base, less likely to meet our commitments to CDC, and are beneath our brand and the quality of experience passengers have come to expect from NCLH. In particular, we would have to implement stringent, onerous mitigation measures for passengers who do not or cannot verify that they are vaccinated. Such measures, without limitation, would likely include requiring passengers who do not or cannot verify COVID-19 vaccination to (1) pay a significant upcharge to cruise; (2) purchase travel insurance; (3) provide proof of a negative result from a COVID-19 PCR test within three days of departure and another negative test result immediately before boarding; (4) refrain from entering common areas where large numbers of people congregate; (5) limit their activities to restricted areas on NCLH's ships; and (6) limit their options for shore excursions. NCLH might also need to require mask-wearing and social distancing for all passengers on board, regardless of vaccination status. Not only would this inferior approach to mitigation be less safe, but it would detract from the NCLH experience, reduce passenger goodwill, detract from potential revenue by

limiting unvaccinated passengers' access to certain cruise experiences and services, and be more burdensome and costlier to implement than a 100% vaccinated cruise involving vaccine verification through documentation.

35. A significant reduction in Florida operations would be financially devastating to the company, as well as to local, state, and federal governments, most significantly Miami-Dade County. The Ban may also result in a loss or diminishment of employment for our contract workers at the PortMiami terminal (well over 100 on a turn-around day), not to mention the employees working transit and hospitality in the area. The crew on our ships, approximately 1,800 per voyage, could also be at risk of unemployment if NCLH cannot resume and maintain operations as currently planned. The loss of revenue caused by the Ban in calendar year 2021 could exceed \$100 million and could also result in a loss or diminishment of employment for NCLH employees in South Florida.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on July 12, 2021


FRANK J. DEL RIO

Exhibit 1

Cheers to 25 years: Celebrate with Us!

[Home](#) > [Cruise Health and Safety](#) > [Survey: Cruisers Overwhelmingly Approve COVID-19 Vaccine Requirements To Cruise](#)

Survey: Cruisers Overwhelmingly Approve COVID-19 Vaccine Requirements To Cruise



Chris Gray Faust
Managing Editor

In a Cruise Critic reader survey, a whopping 80 percent of respondents would prefer to sail on a cruise ship with a vaccine requirement.

The survey, which received over 5,000 responses and was sent on May 28, is the first to measure the site's readership on their actual preferences for returning

vaccine requirement, not their actual preference.

The top reason that people gave for preferring a vaccinated ship makes sense: 89 percent said they felt more safe sailing on a ship with fellow vaccinated travelers. Those preferring the vaccinated ships also want the more traditional cruise experience, without masks, social distancing and/or testing requirements, with 69 percent citing that as a reason.

Of the 4,036 people who preferred sailing on a ship with a vaccine requirement, a full 19 percent said that they received the COVID-19 vaccine specifically so they could cruise.

Slightly over 13 percent of the respondents said they would rather sail on a ship without a vaccine requirement. While most of those cruisers said that they were not planning on getting vaccinated, 21 percent said that they were traveling with others who were unable to get the shots, such as children under 12.

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Terry Sim

*Specialities : Groups and
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★★★★★ 58 reviews

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*Specialities : Adventure
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★★★★★ 39 reviews



Jeanie Leonard

*Specialities : All Inclusive
and Destination Weddings*

★★★★★ 27 reviews

Contact Agent



For those who preferred the vaccine requirements, most – 70 percent -- were comfortable not wearing a mask on a ship that had a mandate.

The CDC has said in its guidelines for cruise resumption that even ships without a vaccine requirement could set aside places, such as restaurants, bars, casinos, spas and other areas, just for vaccinated passengers.

The Cruise Critic survey found that 72 percent of all respondents said they were vaccinated and would value having those areas onboard. Only 9.7 percent said they were unvaccinated and would be upset by having areas for vaccinated passengers.

The survey also found that 67 percent of all respondents would be ready to sail from the U.S. within the next six months. The Caribbean, as well as Bermuda and The Bahamas, were the top picks for first sailings, from 71 percent.

Wondering which ships and cruise lines have a vaccine requirement? [Cruise Critic has a list](#). Also check out our breakdown of the [CDC guidance for vaccinated vs. unvaccinated ships](#).

Updated July 07, 2021

How was this article?



[Home](#) > [First Time Cruiser](#) > [Will You Have To Wear A Mask On Your Next Cruise? Probably](#)

Will You Have To Wear A Mask On Your Next Cruise? Probably

Chris Gray Faust
Managing Editor



facet of post-COVID-19 cruising is emerging: Passengers might have to wear masks when they sail, at least some of the time.

Masks, whether homemade or medical grade, have become a staple of life in communities that have been affected by COVID-19. Many states and cities require people to wear masks in enclosed public areas, such as grocery stores, to protect others. (According to the Centers for Disease Control and Prevention, face coverings can "slow the spread of the virus and help people who might have the virus and do not know it from transmitting it to others.")

While the cruise lines are examining different health protocols, there's no getting around the fact that there are times on ships when it's hard to socially distance, which is a requirement by the CDC for sailing to resume. And those are the points where passengers might have to wear masks, cruise line executives say.

Already there are signs this will happen. In April, Royal Caribbean applied for a patent for "[Seaface](#)," described as "sanitary masks for virus isolation purposes." River cruise lines in Europe and the United States that plan to return to sailing in June say masks will be part of the experience.

Related: [What Is Happening With Test Cruises in 2021?](#)

In an interview with Cruise Critic earlier this month, [Norwegian Cruise Line Holdings CEO and President Frank Del Rio](#) said that, at least when ships first start sailing again, health precautions and rules will look very similar to what's happening on land.





Clues to how masks will be used on ships can be found in the plans put together by European and American river and small ship companies, which are resuming sailing as early as June 1.

Related: [What the River Cruise Season Looks Like For 2021: And Looking Ahead To 2022](#)

Scylla, which operates German and international sailings, is slated to start June 1, with cruises on the Rhine River. The line, as well as A-ROSA, which caters to a similar German clientele, have stated that mouth and nose coverings will be required to be worn in public spaces.

On U.S. rivers, two cruise lines aim to have their boats -- all with less than 250 passengers and crew -- sailing by early this summer. American Cruise Lines [aims to return June 20](#) on the Columbia and Snake rivers in the Pacific

[Company](#) has also set a return date for the Columbia and Snake rivers, as well as the Mississippi River, in July.

While masks for guests aren't called out specifically in the lines' health plans, the leaders of both river companies say that it's likely that they will have to be used, at least in some circumstances when passengers can't socially distance.

Related: [What Will U.S. Cruise Ships Look Like When They Return? Unpacking The Latest CDC Rules](#)

"I think it's very likely that we'll have to require it worn at certain times, like boarding and unboarding the buses. Places where it will be especially difficult to mandate that people are always 6 feet apart. Or when people are right at the gangway and it's likely that there'll be in close proximity to a crew member who's assisting them with something," American Cruise Line President and CEO Charles B. Robertson said.

"But if people are just out on the sundeck for instance, in most cases, I think we would not require that they wear face masks then."

John Waggoner, CEO and President of American Queen Steamboat Company, agreed that masks might be part of the experience, at least in the beginning:

"Masks have been shown to be very, very effective. It not only protects the person that might have the masks on, but it protects other people. My guess is yes, the majority of our guests and the majority of the crew members will probably have masks on board."





But wearing masks has become a controversial point on land, and the debate over whether people will want to wear them on cruises is equally divisive.

Related: [Is the Cruise Ship Buffet About to Make a Comeback?](#)

On the Cruise Critic forums, opinions vary, with many people, including those who love cruising and sail frequently, saying that wearing a mask is a deal-breaker.

"I don't relish the idea of wearing a mask anytime I step out my room," [wintertextancruise](#) wrote on [a recent thread](#). "I wear them here for the stores, but I hate them with a passion and I don't like the idea of wearing one my whole vacation."

"I don't believe you're going to see passengers required to wear masks," [graphicguy](#) wrote. "If that is the case, no one is going to spend \$1 000-\$2 000-\$3 000+ to go on a vacation and have to wear a mask. I think

such as mask wearing in public places.

Related: [Will I Have to 'Social Distance' on My Next Cruise?](#)

"I would be hesitant to go on a cruise that didn't require masks until the time comes that most have acquired immunity, either by surviving the disease or through a vaccine. Keep your germs to yourself!" wrote **julig22**.

While others agree with executives who note that as changes occur on land -- with masks often required in public places -- people at sea will also have to adjust.

Related: [What Is Royal Caribbean Doing to Keep You Safe?](#)

"I think most of us who enjoy what cruising has to offer accept the fact that there will be significant changes. We can simply choose to go or not and that is OK," **winterbliss** wrote.

On the luxury and small ship end, travel agent Adam Martindale of Cruise Planners said he thought his clients who were already willing to travel early would comply.

"I think that wearing the mask while walking around the ship won't be an issue for most people. They can take it off when they go to the restaurant or to the bar," he said. "Especially if the cruise lines make something fun and interactive, which I'm sure they will."

Not Forever





What's important about any health or safety protocol surrounding COVID-19 is that scientists and health officials are learning more about the virus and the best efforts to contain it by the week -- and what we have to do now might change in the future.

Related: [Here's Why You Don't Know What Post-COVID-19 Cruising Looks Like Yet](#)

In an [interview with Cruise Critic](#), Carnival Corp. President and CEO Arnold Donald said that while he's not willing to commit to masks being required on board, "some guests will choose to do on their own." For the crew, it depends on timing and what the public health recommendations are.

"Obviously, wearing masks in certain places like the theater is probably not as taxing as trying to wear it during dinner when you're trying to eat," he said. "But we'll see what happens with all that. Society and people adapt. They figure things out."

How was this article?



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Exhibit 2

The President and Chief Executive Officer of the operating cruise company, the Chief Ethics and/or Compliance Officer of the operating cruise company and all parent companies, and the highest-ranking Medical Officer of the operating cruise company and all parent companies must sign the following attestation:

ATTESTATION BY A CRUISE SHIP OPERATOR
IN LIEU OF A SIMULATED VOYAGE

In accordance with 18 U.S.C. § 1001, I do hereby certify that the following conditions are true and correct to the best of my knowledge and belief for Norwegian Gem [insert name of cruise ship]:

- Restricted passenger voyages will only operate with 95%¹ of crew who are fully vaccinated.²
- A clear and specific vaccination plan and timeline to limit cruise ship sailings to 95% of passengers who will be confirmed as fully vaccinated prior to sailing has been submitted to CDC.

I understand that any false statement made in connection with the submission may subject me to criminal penalties under 18 U.S.C. § 1001. I further understand that this attestation is being submitted to the CDC in lieu of Norwegian Gem [insert name of cruise ship] conducting a simulated voyage under the CDC's Framework for Conditional Sailing Order.

DocuSigned by:

Harry Sommer

B933CB67D1074BD...

Signature Official 1

Harry Sommer - Chief Executive Officer - Norwegian Cruise Line

Name and Title

6/10/2021

Date

DocuSigned by:

Daniel S. Farkas

340FF900C6AB461...

Signature Official 2

Dan Farkas - Executive Vice President General Counsel - NCLH

Name and Title

6/10/2021

Date

DocuSigned by:

Dr. Carlos Gonzalez

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Signature Official 3

Carlos J. Gonzales - Chief Medical Officer - Norwegian Cruise Line Holdings

Name and Title

6/10/2021

Date

¹ This excludes any newly embarking crew in quarantine.

² People are considered fully vaccinated for COVID-19 ≥ 2 weeks after they have received the second dose in a 2-dose series (Pfizer-BioNTech or Moderna), or ≥ 2 weeks after they have received a single-dose vaccine (Johnson & Johnson [J&J]/Janssen). This applies to COVID-19 vaccines currently authorized for emergency use by the U.S. Food and Drug Administration: Pfizer-BioNTech, Moderna, and Johnson & Johnson (J&J)/Janssen COVID-19 vaccines. This can also be applied to COVID-19 vaccines that have been authorized for emergency use by the World Health Organization (e.g. AstraZeneca/Oxford).

Signature Official 4

Date

Name and Title

Signature Official 5

Date

Name and Title

Signature Official 6

Date

Name and Title

**UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF FLORIDA**

NORWEGIAN CRUISE LINE HOLDINGS LTD.; NCL (BAHAMAS) LTD., d/b/a NORWEGIAN CRUISE LINE; SEVEN SEAS CRUISES S. DE R.L., d/b/a REGENT SEVEN SEAS CRUISES; OCEANIA CRUISES S. DE R.L., d/b/a OCEANIA CRUISES;

Plaintiffs,

v.

SCOTT A. RIVKEES, M.D., State Surgeon General and Head of the Florida Department of Health, in his official capacity;

Defendant.

Case No. 1:21-cv-22492-KMW

DECLARATION OF OLGA VIEIRA

I, Olga Vieira, do hereby depose and state:

1. I am of legal age and I make this declaration on the basis of my personal and professional knowledge and experience as well as publicly available information.
2. I am a partner at the law firm of Quinn Emanuel Urquhart & Sullivan LLP and counsel to Plaintiffs Norwegian Cruise Line Holdings Ltd., NCL (Bahamas) Ltd., Seven Seas Cruises S. de R.L., and Oceania Cruises S. de R.L. in the above-captioned matter.
3. Attached hereto as Exhibit 1 is a true and correct PDF copy of the Letter from CDC to Cruise Industry Colleagues dated April 28, 2021.
4. Attached hereto as Exhibit 2 is a true and correct PDF copy of CDC's Technical Instructions for Simulated Voyages by Cruise Ship Operators under CDC's Framework for Conditional Sailing Order dated May 14, 2021, available at <https://www.cdc.gov/quarantine/cruise/ti-simulated-voyages-cso.html>.
5. Attached hereto as Exhibit 3 is a true and correct PDF copy of CDC's COVID-19 Operations Manual for Simulated and Restricted Voyages under the Framework for Conditional Sailing Order dated May 26, 2021, available at <https://www.cdc.gov/quarantine/cruise/covid19-operations-manual-cso.html>.

6. Attached hereto as Exhibit 4 is a true and correct PDF copy of CDC's Conditional Sailing Certificate for the Norwegian Gem dated July 9, 2021.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on July 12, 2021



OLGA VIEIRA

Exhibit 1



Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30329-4027

April 28, 2021

Dear Cruise Industry Colleagues,

Since April 12, 2021, senior leadership from the Centers for Disease Control and Prevention (CDC) and other relevant federal agencies have engaged in twice-weekly meetings with representatives from various cruise lines. The objective of these meetings has been to engage in dialogue and exchange information with individual cruise line representatives¹ regarding the impact of vaccines² and other scientific developments since the Framework for Conditional Sailing Order (CSO) was issued in October 2020. Participants had the opportunity to ask operational questions about the CSO and CDC's published technical instructions for cruise ships.

During these discussions, individual cruise line representatives were able to express their concerns as to the pace and phases of the CSO, ask questions related to the implementation of the CSO, and reiterate their desire to resume cruising as soon as possible. CDC subject matter experts discussed the public health challenges of cruising safely and responsibly during a global pandemic, particularly regarding the emergence of SARS-CoV-2 variants of concern. These challenges include ensuring cruise ship passenger operations are conducted in a way that protects crew, passengers, port personnel, and U.S. communities. CDC experts explained the rationale behind certain requirements of the CSO and similarities with other requirements and recommendations regarding maritime operations from international public health entities.

We acknowledge that cruising will never be a zero-risk activity and that the goal of the CSO's phased approach is to resume passenger operations in a way that mitigates the risk of COVID-19 transmission onboard cruise ships and across port communities. We remain committed to the resumption of passenger operations in the United States following the requirements in the CSO by mid-summer, which aligns with the goals announced by many major cruise lines. In furtherance of this mutual effort, we provide the following clarifications to its Phase 2A technical instructions issued on April 2, 2021.

We look forward to reviewing plans submitted by the cruise lines for Phase 2A and moving into the next phase of the CSO soon.

Clarifications

Timeline to resuming passenger operations under the phased approach

- The 30 calendar day timeframe for the submission to CDC of a cruise ship operator's notice for conducting a simulated voyage and the 60 calendar day timeframe for submission to CDC of the

¹ Cruise industry participants included American Queen Steamboat Company, Bahamas Paradise Cruise Line, Carnival Corporation, Cruise Line International Association, Disney Cruise Line, Norwegian Cruise Line Holdings, Royal Caribbean Group, and Viking Cruises.

² As part of these discussions, CDC reviewed CLIA's vaccine position statement which CDC understands to be that trade group's current position regarding the role of vaccines in restarting cruising.

cruise ship operator's COVID-19 Conditional Sailing Certificate application as set forth in the CSO are suggested as guidelines. CDC Maritime Unit will respond to submissions within 5 business days. CDC expects to quickly approve applications that are both complete and accurate.

- CDC encourages the finalization of the Phase 2A port agreements to allow cruise ships to embark non-essential crew for simulated and restricted voyages. Prior to finalization of the Phase 2A agreements with port and local health authorities, CDC will allow cruise ships to embark 50 percent of the non-essential crew expected to sail on the first restricted voyage. CDC expects that a full complement of crew will not be needed for a cruise ship operator to conduct a simulated voyage because such simulations may be conducted with a small percentage of passengers.

Phase 2A: Port agreements – General Components

- In documenting 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, the cruise ship operator may enter into a multi-port agreement (as opposed to a single port agreement) provided that all relevant port and local health authorities (including the state health authorities) are signatories to the agreement. Such multi-port agreements may be particularly suitable if one port has limited medical or housing capacity and a nearby port is able to supplement these capacities.

Phase 2A: Port agreements – Vaccination Components

- In completing the vaccination component of a Phase 2A agreement, including a plan and timeline for vaccination of cruise ship crew prior to resuming passenger operations, cruise ship operators must disclose and document their current plans to vaccinate crew. This includes if a cruise ship operator only plans to encourage crew to be vaccinated on a voluntary basis once vaccines become more widely available.
- In completing the vaccination component of a Phase 2A agreement, including presentation of proposals regarding how the cruise ship operator intends to incorporate vaccination strategies to protect passengers, cruise ship operators must disclose and document their current strategy. This includes if a cruise ship operator only plans to encourage passengers to be vaccinated on a voluntary basis once vaccines become more widely available.

Phase 2A: Port agreements – Medical and Housing Components

- In determining the sufficiency of shoreside medical and housing facilities, port authorities and local health departments should consider the cruise ship operator's plan and timeline for vaccination of crew and presentation of proposals incorporating vaccination strategies to maximally protect passengers. Those cruise ship operators with a clear and specific vaccination plan and timeline may have only a limited need for shoreside medical and housing facilities compared to operators who only plan or propose to encourage vaccinations.

Phase 2A: Port agreements – Medical Components

- CDC acknowledges that shoreside medical facilities and healthcare systems cannot guarantee bed capacity. In documenting a cruise ship operator's contractual arrangement with such

facilities or systems, redundant contracts, or contracts allowing for preferential acceptance of patients on a space-available basis, will be considered acceptable.

Phase 2A: Port agreements – Housing Components

- In determining whether a cruise ship operator has contractual arrangements for shoreside housing facilities in sufficient quantities to meet the needs of travelers for isolation or quarantine, the parties to a Phase 2A agreement may consider the ability of travelers to use their own personal vehicles to return safely to their residences. The parties should consider the time needed for travelers to drive to their final destinations to avoid the need for overnight stays en route. At a minimum, the health department at the final destination must be notified and travelers must be advised to complete their isolation or quarantine at home. For more information, please visit CDC's [Interim Guidance for Transporting or Arranging Transportation by Air into, from, or within the United States of People with COVID-19 or COVID-19 Exposure](#) webpage.
- CDC routinely works with state and local health departments and the U.S. Department of Homeland Security to prevent travelers from boarding commercial airplanes if they:
 - o are known or suspected to have a contagious disease, or
 - o were exposed to a contagious disease that poses a threat to the public's health.
 - For more information see [Travel Restrictions to Prevent the Spread of Disease](#).

Accordingly, the parties to a Phase 2A agreement should consider the housing needs of travelers who are unable to return to their residences by private vehicle as they will not be permitted to board commercial flights.

- In documenting that the parties to a Phase 2A agreement have deliberated and jointly considered the needs of travelers under quarantine or isolation, including needs relating to security and legal considerations to prevent travelers from violating any mandatory isolation or quarantine, it is assumed that a government entity may issue an order for mandatory isolation or quarantine, and that the cruise ship operator would cooperate with the government entity in addressing security needs.
- Referencing the requirement that shoreside housing provide separate ventilation systems for all travelers who are not part of the household, CDC notes that a standard hotel room with a thermostat on the wall or individual air handling unit is an example of housing that would meet this requirement.

We remain committed to providing any requested technical assistance with Phase 2A agreements and looks forward to receiving these port agreements from the industry. Any technical questions from the cruise ship operators or other relevant stakeholders regarding the Phase 2A port agreements should be addressed to eocevent349@cdc.gov.

We would like to take this opportunity to provide you with our current thinking regarding the following possible updates.

Upcoming Updates***Color-coding update***

- Cruise ship operators may be allowed to use commercial travel to disembark crew regardless of the cruise ship's color status. Cruise ship operators will be restricted from using commercial travel for crew who have tested positive for SARS-COV-2, the virus that causes COVID-19 (unless they have documentation of recovery from a COVID-19 infection in the previous 90 days) and are within their isolation period and their close contacts (unless fully vaccinated) who are within their quarantine period.

Testing and quarantine updates during restricted voyages based on vaccination status

- CDC will update testing and quarantine requirements for passengers and crew to closely align with CDC's guidance for fully vaccinated and not fully vaccinated persons.

	Not Fully Vaccinated Crew	Fully Vaccinated Crew
Embarkation Day Testing	- NAAT	- Viral (NAAT or antigen)
Quarantine Testing [& Duration]	- NAAT [end quarantine after day 10 if negative]	- Viral (NAAT or antigen) [end quarantine after day 7 if negative]
End of Quarantine Testing	- NAAT	- Viral (NAAT or antigen)
Routine Screening Testing	- Viral (NAAT or antigen)	- Viral (NAAT or antigen)
Disembarkation Day Testing	- Viral (NAAT or antigen)	- Not applicable

Updates for fully vaccinated passengers and crew

In lieu of conducting a simulated voyage, cruise ship operator responsible officials, at their discretion, may sign and submit to CDC an attestation under 18 U.S.C. § 1001 that 98 percent of crew are fully vaccinated and submit to CDC a clear and specific vaccination plan and timeline to limit cruise ship sailings to 95 percent of passengers who have been verified by the cruise ship operator as fully vaccinated prior to sailing.

We appreciate your support, and that of our partners, as we work together to fight COVID-19.

Sincerely,



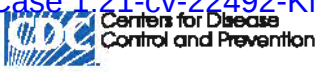
CAPT Aimee Treffiletti, USPHS
Maritime Unit
Global Migration Task Force

CC:

Gary Rasicot
Department of Homeland Security

Joel Szabat
Department of Transportation

Exhibit 2



Technical Instructions for Simulated Voyages by Cruise Ship Operators under CDC's Framework for Conditional Sailing Order

Summary of Recent Changes

May 14, 2021

Clarified screening and laboratory testing requirements for passengers.

Audience

This document is intended to assist cruise ship operators in preparing to conduct simulated ("trial") voyages in advance of restricted passenger voyages under a COVID-19 Conditional Sailing Certificate. This includes conducting simulated voyages insofar as practicable to test the efficacy of the cruise ship operator's ability to mitigate the risks of COVID-19 onboard its cruise ship as per the terms of CDC's [Framework for Conditional Sailing Order](#) (CSO), developing an after-action report, and addressing any identified deficiencies.

Purpose

This document provides technical instructions for Phase 2B of CDC's CSO for cruise ship operations in U.S. waters to ensure health and safety protections for travelers (crew and future passengers) and port personnel prior to resuming passenger operations in a way that mitigates the risk of spreading COVID-19.

These instructions are not intended as, and do not constitute, a comprehensive statement regarding a cruise ship operator's duties and obligations under CDC's CSO. These instructions reflect CDC's reasoned judgement based on the best available current science regarding the subject areas covered in the document. Cruise ship operators should carefully consider and incorporate these instructions in developing their own health and safety protocols.

Notifying and Requesting CDC Approval to Conduct a Simulated Voyage

A cruise ship operator should notify CDC and request CDC's approval to conduct a simulated voyage at least 30 calendar days^[1] prior to the date on which the cruise ship operator proposes to conduct the simulation. Submit notifications and requests to CDC electronically through eocevent349@cdc.gov. Additionally, this notice and request for approval must:

- Specify the dates and location of the proposed simulation.
- Verify that the cruise ship operator is eligible to conduct a simulated voyage as per the terms of the CSO and these technical instructions.
- Submit documentation that the cruise ship operator has a written agreement (or a multi-port agreement) with all U.S. port and local health authorities where the cruise ship intends to dock or make port during a simulated voyage. The written agreement must specifically include the name of the cruise ship that will be conducting the simulation and meet the standards of the CSO and CDC's technical instructions for [Phase 2A](#) of CDC's CSO.
- Provide a copy of the cruise ship operator's proposed written notification to volunteer passengers. This written notification must advise volunteer passengers that they are participating in health and safety protocols that are unproven and untested in the United States for purposes of simulating a cruise ship voyage and that sailing during a pandemic is an inherently risky activity. At the cruise ship operators' discretion, this written notification can occur through website posting, email, or written letter to the volunteer passengers.

- Provide a copy of the cruise ship operator's proposed informed consent form to be signed by all persons who will be participating as volunteer passengers in the simulated voyage. This proposed informed consent must advise all such persons that the simulated voyage will be conducted on a consensual basis and not as a condition of employment or in exchange for consideration or future reward. For the purpose of these technical instructions, passage on board the ship, accommodations, provision of food and beverages, participation in shore excursions and private island visits, and attendance at entertainment events while participating as part of a simulated voyage will not be deemed a form of consideration. At the cruise ship operator's discretion, this written informed consent can be obtained either on paper or electronically using a digital signature.
- Identify and provide one or more points of contact for persons who will be overseeing and implementing the proposed simulation for each cruise ship. This must include points of contact who will be physically present on the ship during the simulated voyage.
- Include the protocols or practices to be simulated, which must, at a minimum, incorporate the requirements for conducting simulated voyages under these technical instructions.
- Be signed by the cruise ship operator's responsible officials, meaning the Chief Executive Officer (or equivalent) of the operating cruise company and all parent companies, the Chief Compliance Officer (or equivalent) of the operating cruise company and all parent companies, and the highest-ranking Medical Officer of the operating cruise company and all parent companies.
- Certify under 18 U.S.C. § 1001 that all of CDC's requirements relating to the protection of crew onboard cruise ships in U.S. waters (i.e., Phase 1 of the CSO) have been satisfied and continue to be met.

CDC will respond to these requests in a timely manner. CDC may deny the request to conduct a simulated voyage if the cruise ship operator is not in compliance with any of CDC's requirements for the mitigation of COVID-19 onboard cruise ships, technical instructions, or orders, or if in CDC's determination the simulated voyage does not provide adequate safeguards to minimize the risk of COVID-19 for all participants. CDC may also oversee and inspect any aspect of the simulated voyage, including through in-person or remote means allowing for visual observation.

[1] The 30-calendar day timeframe is suggested as a guideline. CDC will respond to submissions within 5 business days. CDC expects to quickly approve applications that are both complete and accurate.

Eligibility for Conducting a Simulated Voyage

As part of the cruise ship operator's notification and request to conduct a simulated voyage, a cruise ship operator must verify that it meets the following eligibility criteria:

- The cruise ship operator has received a determination by CDC that a plan submitted in response to the No Sail Order and Suspension of Further Embarkation; Notice of Modification and Extension and Other Measures Related to Operations published at 85 FR 21004 (April 15, 2020) (i.e., "No Sail Order response plan"), as modified and extended July 16, 2020 (published at 85 FR 44085 (July 21, 2020)), and September 30, 2020 (published at 85 FR 62732 (October 5, 2020)) is complete and accurate, including having submitted to CDC a signed Acknowledgment of No Sail Order Response Plan Completeness and Accuracy.
- The cruise ship operator has continued to submit the Enhanced Data Collection (EDC) form as specified in CDC technical instructions or orders. If the cruise ship has been operating outside of U.S. waters, the cruise ship operator has submitted the EDC form during (at a minimum) the 28 days preceding the ship's expected arrival in U.S. waters and will continue to submit the EDC form after the ship enters U.S. waters.
- The cruise ship operator has observed and continues to observe all elements of its No Sail Order response plan including by following the most current CDC recommendations and guidance for any public health actions related to COVID-19, or if any deviations from the plan have occurred such deviations have been reported and corrective actions taken to the satisfaction of CDC.
- The cruise ship operator has arranged for and submitted and continues to arrange for and submit laboratory test results as required by CDC for every crew member on board ships operating in U.S. waters. If the cruise ship operator has ships operating outside of U.S. waters and intends for these ships to return to operating in U.S. waters while the CSO remains in effect, then the operator has arranged for and submitted laboratory test results as required by CDC for every crew member on board these ships.
- If the cruise ship received any ship-to-ship transfers in the last 14 days, crew must have come from a ship that was not Red.

- If the cruise ship operator has any land-based embarkation crew, such crew were laboratory tested for SARS-CoV-2 upon embarkation and quarantined per CDC technical instructions or orders immediately upon embarking the ship.
- The cruise ship operator has a written agreement (or a multi-port agreement) with all U.S. port and local health authorities where the cruise ship intends to dock or make port during a simulated voyage. The written agreement must specifically include the name of the cruise ship that will be conducting the simulation and meet the standards of the CSO and CDC's technical instructions for [Phase 2A](#) of CDC's CSO. The written agreement must include a:
 - port component (including a vaccination component) between the cruise ship operator and port authority to determine the number of cruise ships operating out of any single port in order to not overburden the public health response resources of any single jurisdiction in the event of a COVID-19 outbreak;
 - medical care component between the cruise ship operator and health care entities, addressing evacuation and medical transport to onshore hospitals for passengers and crew in need of medical care, in accordance with CDC technical instructions and orders; and
 - housing component between the cruise ship operator and one or more shoreside facilities for isolation and quarantine of passengers or crew members with COVID-19 and close contacts, identified from the day of embarkation through disembarkation for each voyage.

Requirements Relating to Volunteer Passengers

A simulated voyage must be designed and conducted insofar as practicable to test the efficacy of the cruise ship operator's ability to mitigate the risk of COVID-19 onboard a cruise ship. This includes using volunteers simulating the role of passengers. A cruise ship operator must observe the following requirements relating to volunteer passengers:

- The minimum number of required volunteer passengers for each simulated voyage must be at least 10% of the maximum number of passengers permitted onboard for the first two restricted voyages as per the terms of the cruise ship operator's Phase 2A agreement with U.S. port and local health authorities.
- The cruise ship operator must advise volunteer passengers of CDC's [Travel Health Notice for COVID-19 and Cruise Ship Travel for Travelers Who Are Not Fully Vaccinated](#) prior to the simulated voyage. At the cruise ship operators' discretion, this information can be provided via linking to CDC's [webpage](#), through email, or written letter to the volunteer passengers.
- All volunteer passengers must be informed in writing that they are participating in a simulation of health and safety protocols that are unproven and untested in the United States for purposes of simulating a cruise ship voyage and that sailing during a pandemic is an inherently risky activity. At the cruise ship operators' discretion, this written notification can occur through website posting, email, or written letter to the volunteer passengers. A copy of this written notification must also be provided to CDC as part of the cruise ship operator's notification and request to conduct a simulated voyage.
- All volunteer passengers must be at least eighteen years old or older on the day of the simulation and at the time that their consent to participate is obtained.
- The cruise ship operator must ensure **all** volunteer passengers have either:
 - Proof of being [fully vaccinated](#) against COVID-19 using an U.S. Food and Drug Administration (FDA)-authorized vaccine or a vaccine product that has received emergency use listing from the World Health Organization (WHO); or
 - If not fully vaccinated, written documentation from a healthcare provider or self-certified statement that the volunteer passenger has no medical conditions that would place the volunteer at [high risk for severe COVID-19](#) as determined through CDC guidance.
- The simulation must be conducted with the signed informed consent of all participants and not as a condition of employment or in exchange for consideration or future reward. For the purpose of these technical instructions, passage on board the ship, accommodations, provision of food and beverages, participation in shore excursions and private island visits, and attendance at entertainment events while participating as part of a simulated voyage will not be deemed a form of consideration. The cruise ship operator must document this signed informed consent for each participant in writing, either on paper or electronically. The cruise ship operator must also preserve the paper or electronic consent forms and make them available to CDC upon request at any time while the CSO remains in effect.
- All volunteer passengers must be evaluated for [signs and symptoms](#) of COVID-19 prior to embarkation and disembarkation. Cruise ship operators must educate all volunteer passengers about the [signs and symptoms](#) of COVID-19 and the need to notify cruise ship medical staff immediately if symptoms develop.

- All volunteer passengers must agree in writing to post-disembarkation specimen collection for COVID-19 testing at 3 to 5 days after completion of the simulated voyage, unless they are fully vaccinated or have documentation of recovery from COVID-19 in the past 90 days. Cruise ship operators are advised that as a condition of receiving a COVID-19 Conditional Sailing Certificate, at least 75% of all volunteer passengers who are not fully vaccinated and do not have documentation of recovery from COVID-19 must provide their post-disembarkation specimen to the selected laboratory (see options for post-disembarkation testing below) for COVID-19 testing within the specified time frame. CDC may lower the 75% post-disembarkation testing requirement for future simulated voyages based on lessons learned from previous simulated voyages and other factors.
- To facilitate contact tracing, the cruise ship operator must advise all volunteer passengers to notify the cruise ship operator if they develop symptoms of COVID-19 or are diagnosed with COVID-19 with any SARS-CoV-2 [viral test](#) within 14 days after the voyage. Passengers who develop symptoms within 14 days should be advised to be tested. The cruise ship operator must in turn report aggregate results to CDC in the after-action report or through an amended after-action report.

Requirements Relating to the General Components of a Simulation and Simulated Activities

A simulated voyage must be designed and conducted insofar as practicable to test the efficacy of the cruise ship operator's ability to mitigate the risk of COVID-19 on board a cruise ship. This includes observing the general components of a simulation and simulating the following shipboard activities:

- At least one simulation must be conducted for each ship for which the cruise ship operator intends to commence restricted passenger voyages. The simulation(s) must occur prior to the cruise ship operator's application for a COVID-19 Conditional Sailing Certificate under the CSO.
- The cruise ship's color-coding status must be Green or Orange at the time of the simulated voyage. If the cruise ship's color-coding status is Yellow or Red, then the simulation must be postponed until such time as the ship's status changes to Green or Orange. Cruise ship operators will not be required to submit a new request to conduct a simulated voyage in the event of postponement, but operators must notify CDC of the revised dates of the simulation.
- If the cruise ship operator has entered into a Phase 2A agreement with the port or local health authority of more than one port and the cruise ship operator intends for the ship to dock at more than one U.S. port during restricted passenger voyages, then the simulated voyage(s) must include each U.S. port.
- The cruise ship operator must maintain a list of all passengers, crew, port personnel, and other persons who participated in the simulated voyage. This list must be preserved and made available to CDC upon request at any time while the CSO remains in effect.
- Simulated voyages must be between 2-7 days in length with a least one overnight stay^[2] to test the efficacy of the cruise ship operator's ability to mitigate the risk of COVID-19 onboard the cruise ship, including through embarkation, disembarkation, and post-disembarkation testing.
- Activities conducted on voyages that occurred outside of U.S. waters during the period of the No Sail Order (NSO) and the CSO that were not conducted as part of a CDC-approved simulated voyage, do not count towards the activities that must be simulated on a simulated voyage. However, cruise ship operators may incorporate best practices and lessons learned from these voyages as part of the simulation and in the after-action report submitted to CDC.
- The cruise ship operator must meet standards during the simulated voyage for hand hygiene, use of face masks, and social distancing for passengers and crew, as well as ship sanitation, as required by CDC technical instructions or orders.
- The cruise ship operator must modify meal service and entertainment venues to facilitate social distancing during the simulated voyage.
- The following activities must be simulated onboard each ship for which the cruise ship operator intends to commence restricted passenger voyages before applying for a COVID-19 Conditional Sailing Certificate. However, at the cruise ship operator's discretion, these activities may be conducted as part of the same simulated voyage or as part of separate simulated voyages:
 - Embarkation and disembarkation procedures, as approved by U.S. port and local health authorities as part the cruise ship operator's Phase 2A agreements, including procedures for terminal check-in.
 - Onboard activities, including seating and meal service at dining and entertainment venues.

- Transfer of symptomatic passengers or crew, or those who test positive for SARS-CoV-2, from cabins to isolation rooms.
- Onboard and shoreside isolation and quarantine, as per the terms of the cruise ship operator's Phase 2A agreements, of at least 5% of all passengers and non-essential crew.
- Recreational activities that the cruise ship operator intends to offer as part of any restricted passenger voyages, e.g., casinos, spa services, fitness classes, gymnasiums.
- Private-island shore excursions if any are planned during restricted passenger voyages. The following measures must be observed on the private island:
 - Only one ship can port at the island at any one time.
 - A routine screening testing protocol must be implemented for island staff who are expected to interact with volunteer passengers or crew, unless they are fully vaccinated or have documentation of recovery from COVID-19 in the past 90 days.
 - Mask use and social distancing must be observed in indoor areas while on the island.
- Port of call shore excursions if any are planned during restricted passenger voyages. The following measures must be observed on port of call shore excursions:
 - Shore excursions must only include passengers and crew from the same ship.
 - Cruise ship operator must ensure all shore excursion tour companies facilitate social distancing, mask wearing, and other COVID-19 public health measures throughout the tour while in any indoor areas.
 - Cruise ship operators must have a protocol for managing persons with COVID-19 and close contacts at all foreign ports of call. At a minimum, the protocol must include the following:
 - Disembarkation and housing of persons with suspected or confirmed COVID-19 needing shore-based hospital care and their travel companion(s) for the duration of their isolation or quarantine period.
 - Commercial repatriation of U.S.-based persons with COVID-19 and close contacts only after meeting criteria to end isolation and quarantine per CDC guidance. For commercial repatriation of foreign-based persons with COVID-19 and close contacts, cruise ship operators must consult with all relevant public health authorities.

[2] To fully test all procedures during a simulated voyage, CDC recommends a minimum voyage length of 3 days with 2 overnight stays.

Requirements Relating to Screening and Laboratory Testing

Cruise ship operators must screen passengers for signs or symptoms of COVID-19 and screen for a known close contact exposure to a person with COVID-19 within the past 14 days.

- Passengers with signs or symptoms of COVID-19
 - Deny boarding if not fully vaccinated and without documentation of recovery^[1].
 - May board at operator's discretion if fully vaccinated or with documentation of recovery and embarkation day test is negative by viral test (antigen-negative must be confirmed with NAAT. If an alternate infectious etiology (e.g., influenza, respiratory syncytial virus (RSV), Legionella, Streptococcal pharyngitis) is identified through laboratory testing, routine infection control precautions recommended for the diagnosis should be followed.
- Passengers who have a known close contact exposure in the past 14 days
 - Deny boarding if not fully vaccinated and without documentation of recovery ^[1]
 - May board at operator's discretion if:
 - fully vaccinated and asymptomatic
 - with documentation of recovery from COVID-19 and asymptomatic

A cruise ship operator must observe the following requirements relating to laboratory testing of passengers and crew who are not fully vaccinated or do not have documentation of recovery from COVID-19 ^[1] as part of a simulated voyage:

- Day of Embarkation Testing: testing must be performed by NAAT using one of the following testing instruments and processes with same day results:

- Previously approved Phase 1 onboard point-of-care equipment, or
 - Other testing instruments and processes approved by CDC
 - Prior to collecting specimens and conducting testing: Cruise ship operators must contact CDC at eocevent349@cdc.gov at least 7 calendar days prior to collecting specimens for approval. Include “Additional Laboratory Screening Testing for Passenger Voyages on [SHIP NAME]” in the subject line as part of your request for CDC approval.
 - CDC’s response to the cruise ship operator’s email may include additional information regarding best practices that may assist cruise ship clinicians or public health staff in collecting and transporting specimens.
- Results must be available prior to boarding the cruise ship. Volunteer passengers who test positive for SARS-CoV-2 should be denied boarding, unless determined to be a persistent positive by cruise ship medical personnel.
- Day of Disembarkation Testing: testing must be performed by NAAT using one of the following testing instruments and process with same day results:
 - Previously approved Phase 1 shoreside laboratory, or
 - Previously approved Phase 1 onboard point-of-care equipment, or
 - Other testing instruments and processes approved by CDC
 - Prior to collecting specimens and conducting testing: Cruise ship operators must contact CDC at eocevent349@cdc.gov at least 7 calendar days prior to collecting specimens for approval. Include “Additional Laboratory Screening Testing for Passenger Voyages on [SHIP NAME]” in the subject line as part of your request for CDC approval.
 - CDC’s response to the cruise ship operator’s email may include additional information regarding best practices that may assist cruise ship clinicians or public health staff in collecting and transporting specimens.
 - Results must be available before the passenger leaves the cruise ship, seaport, or offsite testing location, but specimen collection and testing can occur onboard or shoreside.
- Post Disembarkation Testing Options: To validate the efficacy of the cruise ship operator’s ability to mitigate the risk of COVID-19 onboard the cruise ship, post disembarkation testing for volunteer passengers is required for simulated voyages.
 - As a condition of receiving a COVID-19 Conditional Sailing Certificate, cruise ship operators must have at least 75% of all passengers who are not fully vaccinated and do not have documentation of recovery from COVID-19 provide their post disembarkation specimen to the selected laboratory for COVID-19 testing 3 to 5 days after completion of the simulated voyage. Passengers who are fully vaccinated or who have documentation of recovery from COVID-19 ^[1] are exempt from post disembarkation testing. CDC may lower the 75% post-disembarkation testing requirement for future simulated voyages based on lessons learned from previous simulated voyages and other factors.
 - The cruise ship operator must in turn report aggregate results to CDC in the after-action report.
 - Cruise ship operators have the option of supplying all volunteer passengers with a self-collected nasal mid-turbinate [nucleic acid amplification test](#) (NAAT) specimen collection kit to be shipped directly to a laboratory.
 - All volunteer passengers must:
 - Receive education on self-collection technique.
 - Be instructed to collect the specimen 3 to 5 days after completion of the simulated voyage for testing.
 - Be instructed to store and ship the specimen directly to the laboratory within the specifications of the manufacturer.
 - The shoreside laboratory must use a NAAT that has been authorized for emergency use by FDA and that has been evaluated on the [FDA reference panel](#) [\[2\]](#) for SARS-CoV-2 with a limit of detection (LOD) value $\leq 18,000$ NDU/ml. CDC must approve the cruise ship operator’s selection of a CLIA-certified laboratory. All additional requirements as listed for Shoreside COVID-19 Laboratory Screening Testing of All Crew, above, must also be followed.
 - Cruise ship operators can alternatively direct volunteer passengers to obtain a nasopharyngeal (NP) specimen at a shoreside laboratory for SARS-COV-2 testing 3 to 5 days after completion of the simulated voyage for testing.
 - The shoreside laboratory must use a NAAT that has been authorized for emergency use by FDA and that has been evaluated on the FDA reference panel for SARS-CoV-2 with a limit of detection (LOD) value

12-000-00000. CDC must approve the cruise ship operator's selection of a CLIA/Certified Laboratory. All additional requirements as listed for Shoreside COVID-19 Laboratory Screening Testing of All Crew, above, must also be followed.

- Cruise ship operators must conduct laboratory testing of any passengers or crew who report illness consistent with COVID-19 during the simulated voyage (as well as any identified close contacts) using point-of-care equipment and parameters approved by CDC as part of Phase 1 of the CSO. Refer to the [Technical Instructions for Mitigation of COVID-19 Among Cruise Ship Crew](#) for requirements of onboard COVID-19 testing for symptomatic travelers and close contacts.
- Cruise ship operators must continue to conduct routine screening testing of crew according to the corresponding color-coding interval. Cruise ship operators at their discretion may stagger whole ship crew testing during the corresponding color-coding interval (e.g., weekly, every two weeks, every 28 days). For example, the cruise ship operator may choose to test the same percentage of crew on each day of the week if required to test weekly. To ensure consistency, screening testing must be completed within 4 consecutive days of each color-coding interval and the testing schedule for each crew member should remain the same across all color-coding intervals.

[1]Documentation of recovery from COVID-19 includes the following:

- Paper or electronic copies of their previous positive viral test result (dated no more than 90 days ago), and
- A signed letter, on official letterhead that contains the name, address, and phone number of a licensed healthcare provider or public health official, stating that the traveler has been cleared to end isolation and therefore can travel. A letter that states that they have been cleared to end isolation to return to work or school is also acceptable. The letter does not have to specifically mention travel.

Considerations Genetic Sequencing

If positive specimens are identified within 14 days after the voyage, it may be difficult to differentiate between exposures that occurred on board the ship and after disembarkation. In such situations the cruise ship operator may wish to request that a laboratory conduct genetic sequencing of SARS-CoV-2-positive specimens to determine the likelihood that the exposures occurred on board. If sequencing is being considered, please consult with CDC for additional information and instructions through eoevent349@cdc.gov. Results should also be made available to CDC as part of the after-action report. CDC will be available to assist cruise operators in interpreting results of any genetic sequencing.

- If sequencing will be performed: specimens can be stored at 2–8°C for no more than 72 hours from the time of collection. The 72-hour timeframe is a strict requirement for specimen quality. Specimens that require storage longer than 72 hours must be frozen at $\leq -70^{\circ}\text{C}$.
- If specimens are shipped: prior to shipping, specimens should be frozen at $\leq -70^{\circ}\text{C}$ and shipped on dry ice. The quality of the specimen directly affects sequencing and virus culture success. Ideally, specimens should have a reverse transcription polymerase chain reaction (RT-PCR) cycle threshold (Ct) value of ≤ 28 . If Ct values are not available, specimens that are positive/strong positive for SARS-CoV-2 may be sent (avoid weakly positive samples).

Advisory Related to Terminating a Simulated Voyage to Protect Health and Safety

CDC advises cruise ship operators that it may require them to immediately end a simulated voyage and take other actions to protect the health and safety of volunteer passengers and crew if a threshold of COVID-19 cases is met or exceeded during the simulation. During simulated voyages, this threshold is met when 1.5% of COVID-19 cases is detected in passengers or 1.0% of COVID-19 cases is detected in crew. This threshold may be modified for future simulated voyages or restricted passenger voyages based on lessons learned from simulated voyages or restricted passenger voyages, the evolution of the pandemic, or other factors. In the event that a simulated voyage is ended early to protect health and safety, CDC will consult with the cruise ship operator regarding any deficiencies to be noted in the operator's action-action report and how such deficiencies are to be corrected prior to approving any additional simulated voyages.

In addition, if a simulated voyage is ended early due to the above threshold being met or exceeded during the simulation, the cruise ship operator will have to repeat the simulated voyage at a later date. If the threshold for the voyage is met or exceeded during the simulation, the cruise ship operator will also have to advise all travelers to avoid commercial air travel or ground transportation for 14-days post voyage, unless they have one of the following:

- Proof of being **fully vaccinated** against COVID-19 using an U.S. Food and Drug Administration (FDA)-authorized vaccine or a vaccine product that has received emergency use listing from the World Health Organization (WHO), or
- Documentation of recovery from COVID-19 in the past 90 days, which includes the following:
 - Paper or electronic copies of their previous positive viral test result (dated no more than 90 days ago), and
 - A signed letter, on official letterhead that contains the name, address, and phone number of a licensed healthcare provider or public health official, stating that the traveler has been cleared to end isolation and therefore can travel. A letter that states that they have been cleared to end isolation to return to work or school is also acceptable. The letter does not have to specifically mention travel.

Requirements Related to the Simulated Voyage After-Action Report (AAR)

A cruise ship operator must observe the following requirements relating to the post-simulation after-action report:

- The cruise ship operator must document in writing any deficiencies observed in its health and safety protocols and describe how the cruise ship operator intends to address those deficiencies prior to applying for a COVID-19 Conditional Sailing Certificate. A deficiency is any significant departure from the cruise ship operator's health and safety protocols or, if such health and safety protocols are followed, any documented transmission of COVID-19 that requires a change, modification, or adjustment of the operator's protocols to ensure safer and healthier sailing.
- The cruise ship operator must report all post-disembarkation test results in aggregate to CDC in the after-action report. To obtain a COVID-19 Conditional Sailing Certificate, cruise ship operators must have at least 75% of all passengers who are not fully vaccinated and do not have documentation of recovery from COVID-19 provide their post disembarkation specimen to the selected laboratory for COVID-19 testing. CDC may lower the 75% post-disembarkation testing requirement for future simulated voyages based on lessons learned from previous simulated voyages and other factors.
- The after-action report must include the cruise ship operator's assessments and conclusions regarding the efficacy of its health and safety protocols at mitigating the risk of COVID-19 onboard a cruise ship and whether any changes, modifications, or adjustments to these protocols will occur based on "lessons learned" from the simulated voyage.
- Where appropriate, the cruise ship operator may incorporate into the after-action report discussion of best practices and lessons learned from voyages that occurred outside of U.S. waters during the period of the NSO or CSO and were not a part of the simulation.
- Where appropriate, the cruise ship operator may incorporate into the after-action report photographic, video, testimonial, or other evidence documenting that the simulated voyage was conducted in accordance with the cruise ship operator's health and safety protocols and these technical instructions.
- The after-action report must be submitted to the CDC as soon as practicable at the end of the simulation and as part of the cruise ship operator's application for a COVID-19 Conditional Sailing Certificate.
- CDC may conduct such oversight and inspection of simulated voyages as it deems necessary in its discretion, including through in-person or remote means allowing for visual observation. The findings and/or observations of these inspections will be shared with the cruise ship operator and must be incorporated into the operator's after-action report.

CDC will provide the cruise ship operator with a template for completing the after-action report after approving the operator's request to conduct a simulated voyage.

Role of Vaccinations During Simulated Voyages

- For purposes of CDC vaccination guidance, cruise ships are considered residential, non-healthcare, congregate settings representing a global population.

Option in Lieu of a Simulated Voyage

In lieu of conducting a simulated voyage, cruise ship operator responsible officials, at their discretion, may sign and submit to CDC an attestation under 18 U.S.C. § 1001 that 95 percent of crew (excluding any newly embarking crew in quarantine) are fully vaccinated and submit to CDC a clear and specific vaccination plan and timeline to limit cruise ship sailings to 95 percent of passengers who have been verified by the cruise ship operator as fully vaccinated prior to sailing.

Simulated Voyages and the Passenger Vessel Safety Act

Cruise ship operators are advised that CDC has no responsibility for enforcing requirements relating to the Passenger Vessel Safety Act and no authority to waive these statutory requirements.

CDC's Mask Order

All persons, including port personnel, crew, and passengers (including those that are fully vaccinated) are advised that CDC's [Order](#) requires wearing of masks on conveyances entering, traveling within or leaving the United States, and in U.S. transportation hubs (see [maritime-specific Frequently Asked Questions](#)) remains in effect.

Reporting to Federal Agencies During Simulated Voyages

CDC requires daily submission of the "Enhanced Data Collection (EDC) During COVID-19 Pandemic Form" for passengers and crew. This EDC Form will be used to conduct surveillance for COVID-19 on board cruise ships using cumulative reports of COVID-19-like illness, which includes acute respiratory illness (ARI), influenza-like illness (ILI), pneumonia, and additional COVID-19-like illness (aCLI) clinical criteria.

Access to the online EDC form has been provided to cruise lines by the Cruise Lines International Association (CLIA) or CDC. Cruise lines that do not have access should contact CLIA or CDC (email eocevent349@cdc.gov).

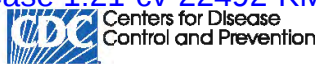
In addition to this daily surveillance via the online EDC form, cruise ship operators must continue to report to USCG via Advance Notice of Vessel Arrival (ANOA) as required by regulation. Cruise ship operators are reminded that USCG considers COVID-19 illness on board a cruise ship a hazardous condition and must be immediately reported to the local Captain of the Port when the cruise ship is within waters subject to the jurisdiction of the United States.

Acute Gastroenteritis (AGE) cases must be reported to CDC's Vessel Sanitation Program (VSP) in accordance with VSP's 2018 [Operations Manual](#).

Illnesses of public health concern that are neither COVID-19 nor AGE, and all deaths must be reported to the [CDC Quarantine Station](#) with jurisdiction for the port.

Page last reviewed: June 4, 2021

Exhibit 3



COVID-19 Operations Manual for Simulated and Restricted Voyages under the Framework for Conditional Sailing Order

Summary of Recent Changes

May 26, 2021

Provided cruise ship operators with more discretion regarding fully vaccinated travelers. Provided additional discretionary considerations for ships with at least 95% of crew and 95% of passengers fully vaccinated.

May 18, 2021

Clarified disembarkation testing is only for cruises more than 4 nights.

May 14, 2021

Added sections for Screening of Embarking Passengers for Restricted Voyages, Testing of Embarking and Disembarking Passengers for Restricted Voyages, Test Selection and Specifications for Passenger Screening Testing on Restricted Voyages, and Onboard COVID-19 Testing for Symptomatic Passengers and their Close Contacts.

Audience

This document is intended to assist cruise ship operators in ensuring health and safety protections during simulated and restricted passenger operations in a way that mitigates the risk of spreading COVID-19. This document is issued under CDC's [Framework for Conditional Sailing Order](#) (CSO) and its requirements must be observed in the same manner as other technical instructions issued under the CSO. This document also contains recommendations to further reduce the spread of SARS-CoV-2, the virus that causes COVID-19, that cruise ship operators should consider for incorporation into their health and safety protocols as best practices.

In addition, cruise ship operators must continue to adhere to requirements in CDC's [Technical Instructions for Mitigation of COVID-19 Among Cruise Ship Crew](#) during passenger voyages.

CDC will update this information as needed and notify cruise ship operators of such updates.

Purpose

CDC's oversight and inspection of cruise ships during simulated and restricted passenger voyages will be based on this Operations Manual. The findings and/or observations of these inspections will be shared with the cruise ship operator. Cruise ship operators are expected to align their health and safety protocols with any CDC findings and observations. Such findings and observations must also be incorporated into the cruise ship operator's simulated voyage after-action report or as a condition of applying for and retaining permission to conduct restricted passenger voyages. Based on these inspections, CDC may also issue additional recommendations to the cruise ship operator that the operator should consider for adoption into their health and safety protocols as best practices.

As per the terms of the CSO, cruise ship operators, upon request, must make their properties and records available for inspection to allow CDC to ascertain compliance. Such properties and records include but are not limited to vessels, facilities, vehicles, equipment, communications, manifests, list of passengers, and employee and passenger health

Inspections of cruise ships during simulated and restricted passenger voyages:

- May be conducted by CDC with or without prior notification to the cruise ship operator;
- May be conducted by CDC through in-person or remote means;
- Will be conducted by CDC during a portion of the simulated voyage or restricted passenger voyage;
- May include CDC inspectors sailing on the simulated or restricted passenger voyage with prior notification to the cruise ship operator; and
- Will not have an associated fee^[1] or inspection score.

Persons are prohibited from interfering with the ability of CDC inspectors to inspect and conduct oversight, including but not limited to interfering with CDC's ability to interview cruise ship crew and personnel or visually inspect and oversee collection of laboratory specimens and laboratory testing.

This manual is not intended as, and does not constitute, a comprehensive statement regarding a cruise ship operator's duties and obligations under CDC's CSO. These instructions reflect CDC's reasoned judgement based on the best available current science regarding the subject areas covered in the document. Cruise ship operators should carefully consider and incorporate these instructions in developing their own health and safety protocols.

[1] When not under the Conditional Sailing Order, cruise ship operators pay a fee based on the ship's size for operational inspections or reinspections conducted by [CDC's Vessel Sanitation Program](#).

Applicability of the VSP 2018 Operations Manual

Cruise ship operators must continue to follow the Vessel Sanitation Program (VSP) [2018 Operations Manual](#)  [\[PDF – 291 pages\]](#). In addition to ascertaining compliance in implementing and maintaining public health standards in accordance with the CSO's [Technical Instructions](#), CDC inspectors will further evaluate adherence to environmental health and sanitation standards outlined in the current VSP 2018 [Operations Manual](#).

All variances involving passenger interactive experiences previously approved by [VSP](#) are suspended until further notice.

CDC will recommend or direct the master of a vessel not to sail when an imminent health hazard is identified and cannot be immediately corrected, in accordance with VSP's 2018 [Operations Manual](#).

Preventive Measures

Cruise ships involve the movement of large numbers of people in settings where they are likely to have close contact with one another. Close-contact environments facilitate transmission of SARS-CoV-2 and other respiratory viruses from person to person through exposure to respiratory droplets, aerosols, or contact with contaminated surfaces. Cruise ships may also be a means by which infected persons travel between geographic locations.

Requirements

To further reduce the spread of SARS-CoV-2, cruise ship operators must:

- Inform passengers of any mandatory public health measures prior to boarding
- Place posters in high-traffic areas that encourage [hand hygiene](#) to [help stop the spread](#)
- Ensure handwashing facilities are well-stocked with soap and a method to dry hands, such as paper towels or air dryers, in accordance with the 2018 VSP Operations Manual

Cruise ship operators must continue to follow the preventative measures for crew outlined in CDC's [Technical Instructions for Mitigation of COVID-19 Among Cruise Ship Crew](#).

Recommendations

- Incorporate COVID-19 vaccination strategies to maximally protect passengers and crew in the maritime environment, seaports, and in land-based communities.
- Encourage passengers to avoid touching eyes, nose, and mouth with unwashed hands.
- Reduce face-to-face interactions between crew and passengers to the extent practicable.
- Discourage handshaking and encourage the use of non-contact methods of greeting.
- Promote respiratory and [hand hygiene](#) and cough etiquette.
- Inform passengers that use of cigarettes, e-cigarettes, pipes, or smokeless tobacco can lead to increased contact between potentially contaminated hands and their mouths.
- Place [hand sanitizer](#) (containing at least 60% alcohol) in multiple locations and in sufficient quantities to encourage hand hygiene

Surveillance for COVID-19

Because of the close-contact environment on cruise ships and the potential for asymptomatic and pre-symptomatic transmission, it is important that [close contacts](#) of individuals with SARS-CoV-2 infection be quickly identified and tested.

Requirements

To reduce the spread of SARS-CoV-2, cruise ship operators must:

- Implement procedures for maintaining records associated with active COVID-19 surveillance and make these records available to CDC upon request for review. These records include:
 - Surveillance log for acute respiratory illness (ARI), influenza-like illness (ILI), pneumonia, and additional COVID-19-like illness (aCLI) symptoms, positive [antigen](#) results, and positive [nucleic acid amplification test](#) (NAAT) results.
 - Medical documentation of prior positive SARS-CoV-2 viral test results for crew.
 - Because retesting for SARS-CoV-2 is [not recommended](#) during the 90 days post lab-confirmed diagnosis (unless symptomatic), records must be available to review the ship's tracking of the 90-day timeframe for crew who have tested positive prior to these crew resuming routine laboratory testing.
 - Records relating to the isolation of persons positive for SARS-CoV-2 and the quarantine of close contacts. These include dates of isolation and quarantine, originally assigned cabin numbers, cabin numbers for isolation and quarantine, medical records, and sign and symptom logs.
 - Records relating to the [contact tracing](#) of any identified [close contacts](#).
 - All medical records must be maintained for at least 90-days and must be made available to CDC upon request for review.

Recommendations

To further reduce the spread of SARS-CoV-2, cruise ship operators as a best practice should:

- Consider the use of wearable recording technology, e.g. proximity bands, to rapidly identify close contacts if contact tracing is necessary.

Medical Centers

Medical centers on cruise ships can vary widely depending on ship size, itinerary, length of cruise, and passenger demographics.

Requirements

To reduce the spread of SARS-CoV-2, cruise ship operators must:

- Carry a sufficient quantity of personal protective equipment (PPE) needed and laboratory supplies listed on CDC's Interim Guidance for Ships on Managing Suspected or Confirmed Cases of Coronavirus Disease 2019.
- Healthcare personnel must adhere to Standard and Transmission-based Precautions when caring for patients with suspected or confirmed SARS-CoV-2 infection. Recommended PPE is described in the [Infection Control Guidance](#).
- Maintain adequate supplies of antipyretics (e.g., acetaminophen and ibuprofen), [antivirals and other therapeutics for COVID-19](#) [\[PDF - 227 pages\]](#) [\[PDF - 227 pages\]](#) [\[PDF - 227 pages\]](#), if commercially available, other antimicrobial medications, oral and intravenous steroids, and supplemental oxygen. Information to estimate needed medical staffing and equipment can be found in the [Federal Healthcare Resilience Task Force Alternate Care Site Toolkit](#) [\[PDF - 227 pages\]](#) [\[PDF - 227 pages\]](#), Supplement 2.
- As [treatment](#) and testing become more available in the United States, cruise ships must align with the latest CDC recommendations.
- Healthcare personnel must stay up to date on [COVID-19 training](#) and [Interim Clinical Guidance for Management of Patients with Confirmed Coronavirus Disease \(COVID-19\)](#).

Laboratory

Requirements

To reduce the spread of SARS-CoV-2, cruise ship operators must:

- Ensure that a CDC-approved onboard testing instrument is properly installed, and the CDC-approved assay is being used.
- Designate a laboratory point of contact (POC) responsible for managing quality assurance and quality control and decision-making.
- Ensure test results are traceable from specimen collection through reporting to the individual, including all supporting materials, records, and equipment.
- Follow assay storage and handling guidance found in the assay's FDA EUA [Instructions for Use](#) [\[PDF - 2 pages\]](#) (IFU) document.
- Develop and maintain a **testing manual** to be followed on each applicable ship for the testing instrument and assay. The testing manual must be made available to CDC inspectors upon request for review.
 - The testing manual must include the following content:
 - [CDC's Nasopharyngeal Specimen Collection Infographic](#) [\[PDF - 2 pages\]](#)
 - Specimen collection, storage, and handling procedures, including documentation and labeling of specimens
 - Instructions for Use (IFU) for the CDC-approved onboard testing instrument
 - Reporting procedures for results, including how results are reported and who receives test results
 - Equipment manual provided by the manufacturer
 - Procedure for daily documentation of testing location & reagent storage area temperatures
- Maintain the following records as part of the **testing manual** or in a separate document accessible to CDC inspectors:
 - Personnel training records for specimen collection, labeling, storage, testing, and reporting
 - Documentation that all onboard medical personnel involved with specimen collection and laboratory testing have completed "[Ready? Set? Test! Checklist](#) [\[PDF - 4 pages\]](#)" (regulatory sections do not apply)
 - Documentation that all onboard medical personnel involved with specimen collection and laboratory testing have completed [competency testing](#) [\[PDF - 11 pages\]](#) [\[PDF - 11 pages\]](#) [\[PDF - 11 pages\]](#).
 - Documentation that all onboard medical personnel have read and reviewed:
 - [Good Laboratory Practices for Waived Testing Sites: Survey Findings from Testing Sites Holding a Certificate of Waiver Under the Clinical Laboratory Improvement Amendments of 1988 and Recommendations for Promoting Quality Testing](#)
 - "[To Test or Not to Test? Considerations for Waived Testing](#)" [\[PDF - 60 pages\]](#)
 - "[Ready? Set? Test! Patient Testing Is Important. Get the right results.](#)" [\[PDF - 56 pages\]](#)
 - Preventative equipment maintenance records as specified by the manufacturer and quality assurance as described in the "[Ready? Set? Test! Checklist](#) [\[PDF - 4 pages\]](#)"
 - Daily documentation of the testing & reagent storage area temperatures

- Supply/lot information into records (list of kits, reagents, supplies with lot numbers, expiration dates, storage conditions and other relevant information found in the IFU).
- Documentation of corrective action if any quality assurance failures occur
- Documentation of testing, including equipment logs, maintenance records, quality control documents, and test results
- Display instructions, infographics, and similar material in close vicinity to where the CDC-approved onboard testing instrument is used and in clear view of the medical personnel using the instrument. The following posters must be displayed near the onboard testing instrument:
 - [Specimen collection instructions](#)  [PDF – 2 pages]
 - [“Ready Set? Test!” Poster](#)  [PDF – 1 page]

Screening of Embarking Passengers for Restricted Voyages

- Cruise ship operators must screen passengers for [signs or symptoms](#) of COVID-19 and screen for a known [close contact](#) exposure to a person with COVID-19 within the past 14 days.
 - Passengers with signs or symptoms of COVID-19
 - Deny boarding if not [fully vaccinated](#) and without documentation of recovery².
 - May board at operator’s discretion if fully vaccinated or with documentation of recovery and embarkation day test is negative by viral test (antigen-negative must be confirmed with NAAT). If an alternate infectious etiology (e.g., influenza, respiratory syncytial virus (RSV), Legionella, Streptococcal pharyngitis) is identified through laboratory testing, routine infection control precautions recommended for the diagnosis should be followed.
 - Passengers who have a known close contact exposure in the past 14 days
 - Deny boarding if not [fully vaccinated](#) and without documentation of recovery²
 - May board at operator’s discretion if:
 - fully vaccinated and asymptomatic
 - with documentation of recovery from COVID-19 and asymptomatic

[2] Documentation of recovery from COVID-19 includes the following:

- Paper or electronic copies of their previous positive viral test result (dated no more than 90 days ago), and
- A signed letter, on official letterhead that contains the name, address, and phone number of a licensed healthcare provider or public health official, stating that the traveler has been cleared to end isolation and therefore can travel. A letter that states that they have been cleared to end isolation to return to work or school is also acceptable. The letter does not have to specifically mention travel.

Testing of Embarking and Disembarking Passengers for Restricted Voyages

Screening Testing of All Embarking and Disembarking Passengers for Restricted Voyages

	Not Fully Vaccinated Passengers	Fully Vaccinated Passengers
Embarkation Day Testing	Viral (NAAT or antigen)	Not Applicable*
Disembarkation Testing [^]	Viral (NAAT or antigen)	Not Applicable
Back-to-Back Sailing ^v Testing	Viral (NAAT or antigen)	Not Applicable

^ Disembarkation testing is only required for voyages of more than 4 nights.

✧ Back-to-back sailing refers to passengers who stay on board for two or more voyages.

- Cruise ship operators must [collect specimens for SARS-CoV-2 viral testing](#)³ as follows, unless passengers are fully vaccinated or have documentation of recovery in the past 90 days:
 - All⁴ newly embarking passengers on the day of embarkation.
 - All⁴ disembarking passengers if the voyage is more than 4 nights. Specimens may be collected up to 24-hours prior to disembarkation but results must be available prior to disembarking.
 - All⁴ passengers on back-to-back sailings prior to the ship sailing on the next voyage.
- CDC may oversee the collection of passenger specimens through remote means allowing for visual observation.
- Cruise ship operators must immediately transport the specimens to the testing equipment location. Locations may include a Clinical Laboratory Improvement Amendments (CLIA)-certified laboratory, onboard laboratory, pier-side equipment, or an offsite area.
- Passengers who receive a positive viral test result for SARS-CoV-2 prior to embarkation, and any of their close contacts who are not fully vaccinated, must be denied boarding. Cruise ship operators may use confirmatory NAAT testing for a positive antigen screening test following CDC's [Interim Guidance for Antigen Testing for SARS-CoV-2](#).
- Cruise ship operators must follow their [Phase 2A port agreements](#) to ensure all travelers identified through embarkation and disembarkation day testing as positive for SARS-CoV-2 are appropriately managed.
- Cruise ship operators must report all laboratory results in aggregate to CDC through the Enhanced Data Collection (EDC) form.
 - To ensure the integrity of testing, persons with positive NAAT results must not be retested, and the original positive results must be reported. Subsequent negative results do not negate an initial positive result.
 - Confirmatory testing for a positive antigen screening test should take place as soon as possible after the antigen test, and not longer than 48 hours after the initial antigen testing. If more than 48 hours separate the two specimen collections, or if there have been opportunities for new exposures, a NAAT should be considered a separate test – not a confirmation of the earlier test.

[3] Viral tests for SARS-CoV-2 include nucleic acid amplification tests (NAAT) and antigen tests. Examples of NAAT include but are not restricted to reverse transcription polymerase chain reaction (RT-PCR), reverse transcription loop-mediated isothermal amplification (RT-LAMP), transcription-mediated amplification (TMA), nicking enzyme amplification reaction (NEAR), helicase-dependent amplification (HDA). Tests used must be cleared or authorized for emergency use by the U.S. Food and Drug Administration (FDA).

[4] CDC considers all positive viral test results as new cases, unless laboratory documentation of a previous SARS-CoV-2 by viral test result within the previous 90-days is provided, and the individual is asymptomatic. Cruise ship operators may use confirmatory NAAT testing for a positive antigen screening test following [Interim Guidance for Antigen Testing for SARS-CoV-2](#). Cruise ship operators must have a protocol for evaluating documentation of recovery, including reviewing previous laboratory results.

- Medical personnel should document all positive SARS-COV-2 test results (pre-embarkation, throughout the passenger's voyage, and post-disembarkation) in the ships' medical records. These medical records must be made available for CDC inspection upon request.
- Passengers who test positive for SARS-COV-2 should not be re-tested (e.g., as part of a contact investigation) until 90-days post lab-confirmed diagnosis, unless they are symptomatic. Symptomatic passengers must be isolated and re-evaluated, including retesting for SARS-CoV-2. If an alternate infectious etiology (e.g., influenza, respiratory syncytial virus (RSV), Legionella, Streptococcal pharyngitis) is identified through laboratory testing, routine infection control precautions recommended for the diagnosis should be followed.

Test Selection and Specifications for Passenger Screening

Testing on Restricted Voyages

- When choosing a testing method, cruise ship operators should consider the differences in sensitivity between NAAT and antigen tests. At this time, CDC prefers NAAT for use on cruise ships because it is less likely to miss cases of SARS-CoV-2 infection (i.e., higher sensitivity) when compared to antigen testing.
- Cruise ship operators, at their discretion, may contact CDC at eoevent349@cdc.gov prior to procuring antigen test systems to ensure the selected test meets the specifications listed below. Include "Screening Testing for Passengers – [SHIP NAME]" in the subject line.
- Tests must be performed as authorized under their Emergency Use Authorization (EUA) and described in the manufacturer's instructions for use (IFU). Any specimen type and source specified in the IFU may be used and must be collected by, or under the supervision of, a health care professional.
 - Refer to the U.S. Food and Drug Administration (FDA) website for a list of the SARS-CoV-2 point-of-care and rapid tests that have received [Emergency Use Authorization \(EUA\)](#) [↗](#).
 - Tests that have been authorized for use in a point-of-care setting will have a W, for Waived, in the Authorized Settings column of the FDA table.
 - The laboratory or testing site must use a test authorized for point-of-care use by the FDA and must follow the manufacturer's instructions for each test.
- Viral test (including NAAT and antigen tests) systems must be:
 - CLIA-waived by FDA;
 - Allow for specimen-to-test system transfer in a way that minimizes the risk of contamination.
- For antigen testing, cruise ship operators should follow CDC's [Interim Guidance for Antigen Testing for SARS-CoV-2](#).
- Shoreside testing must be conducted by a CLIA-certified laboratory using a viral test (i.e., NAAT or antigen).
- For NAAT, the test must have been cleared or authorized for emergency use by FDA and evaluated on the [FDA reference panel](#) [↗](#) for SARS-CoV-2 with a limit of detection (LOD) value $\leq 18,000$ NDU/ml.⁵
- Self-tests are not accepted at this time.
- Screening testing staff must be trained and competent in specimen collection, be able to properly use testing equipment, follow all manufacturer's instructions, and have access to and use recommended [personal protective equipment \(PPE\)](#) for specimen collection, handling, and testing.
 - CDC may ensure competency by conducting oversight of these practices through remote, visual observation.
 - Cruise ship operators must maintain onboard SARS-CoV-2 testing equipment to manufacturer's specifications.
- The SARS-CoV-2 virus has developed [mutations](#) with the potential to negatively impact the performance of tests for its detection.
 - The FDA webpage on [Molecular Tests Impacted by SARS-CoV-2 Mutations](#) [↗](#) provides information regarding the potential impact of viral mutations on COVID-19 tests.
 - CDC will continue to assess the information provided by the FDA, public health authorities, and the test manufacturer to determine which tests should remain in use or be approved for future use.

[5] NDU=RNA NAAT detectable unit; CDC's laboratory 2019-nCoV RT-PCR diagnostic panel was used to define the LOD cut-off value. A high LOD indicates that the assay has a lower sensitivity which may result in more false negative results, especially in asymptomatic infected people. A lower LOD represents an assay's ability to detect a smaller amount of viral material in a given sample, signaling a more sensitive test.

Onboard COVID-19 Testing for Symptomatic Passengers and their Close Contacts

Cruise ship operators must follow requirements as outlined in CDC's

<https://www.cdc.gov/quarantine/cruise/management/technical-instructions-for-cruise-ships.html> for onboard COVID-19 testing for symptomatic travelers (crew and passengers) and close contacts.

Infection Prevention and Control Plan

Infection prevention and control (IPC) is key to reducing the spread of SARS-CoV-2. Procedures and records associated with IPC implementation will be evaluated during inspections. Each cruise ship must maintain a written **Infection Prevention and Control Plan (IPCP)** that details standard procedures and policies to specifically address infection control and cleaning/disinfection procedures to reduce the spread of COVID-19.

Requirements

To reduce the spread of SARS-CoV-2, cruise ship operators must include the following as part of a written IPCP:

- Duties and responsibilities of each department and their staff for all passenger and crew public areas.
- Steps in IPC management and control and the triggers required for action at each step. At a minimum, triggers must address a graduated approach to IPC management in response to increasing case counts.
- Disinfectant products or systems used, including the surfaces or items the disinfectants will be applied to, concentrations, and required contact times. Use disinfectant products or systems that are listed on the Environmental Protection Agency (EPA) [List N: Disinfectants for Coronavirus \(COVID-19\)](#) [\[E\]](#) .
- Procedures for informing passengers and crew members that a threshold of COVID-19 has been met or exceeded. This section must address the procedures for notification of passengers and crew currently onboard the ship and those embarking the vessel on the subsequent voyage.
- Graduated procedures for returning the vessel to normal operating conditions after a threshold of COVID-19 has been met or exceeded, including de-escalation of cleaning and disinfection protocols.
- Procedures to protect passengers and crew from exposure to disinfectants, if not already included in the ship's safety management system. At a minimum, this must include the following:
 - Safety data sheets (SDSs)
 - PPE per [CDC guidance](#) for crew
 - Health and safety procedures to minimize respiratory and dermal exposures to both passengers and crew
- Procedures to align with the preventive measures based on the color-coding status outlined in CSO [Technical Instructions](#).

Mask Use

At this time, all persons, including port personnel, crew, and passengers are advised that CDC's Mask [Order](#) remains in effect and requires the wearing of masks on conveyances entering, traveling within, or leaving the United States, and in U.S. transportation hubs. (see [Maritime-specific Frequently Asked Questions](#)).

- While the Order permits temporarily removing a mask for brief periods of time while eating or drinking, removal of the mask for extended meal service or beverage consumption would constitute a violation of this Order.
- Cruise ship operators, at their discretion, may advise all passengers and crew that they do not have to wear a mask if outdoors. CDC still recommends that people wear a mask if they are not fully vaccinated and in a crowded area.
- Masks do not have to be worn while inside one's own cabin.
- Travelers should not wear a mask when doing activities that may get the mask wet, like swimming at the beach or in recreational water facilities. A wet mask can make it difficult to breathe and may not work as well when wet. This means it is particularly important for bathers to maintain physical distancing of at least 6 feet (2 meters) when in the water with others who are not traveling companions or part of the same family.

Fully Vaccinated Travelers

- Cruise ship operators, at their discretion, may advise passengers and crew that—if they are fully vaccinated—they may gather or conduct activities outdoors, including engaging in extended meal service or beverage consumption, without wearing a mask.
- Cruise ship operators, at their discretion, may advise crew who are fully vaccinated that they do not have to wear a mask or maintain physical distance in areas of the ship that are inaccessible to passengers.

- Cruise ship operators, at their discretion, may designate areas as only accessible to fully vaccinated passengers and crew where masks and physical distancing are not required (e.g., casinos; bars; spas; entertainment venues; and dining areas, including self-serve buffets).
- For ships with at least 95% of crew and 95% of passengers fully vaccinated, cruise ship operators, at their discretion, may advise passengers and crew that they do not have to wear a mask or maintain physical distance in any areas.

Requirements

To reduce the spread of SARS-CoV-2, cruise ship operators must:

- Provide passengers and crew with information on how to [properly wear, take off, and clean \(if reusable\) masks](#).
- Remind passengers and crew not to touch their masks when wearing them.
- Position posters educating passengers on how to [properly wear masks](#) in high traffic areas throughout the ship.

Physical Distancing

Strict adherence to passenger and [crew testing](#) protocols will aid in identifying potential cases of COVID-19 on board a cruise ship, however, continued prevention efforts are necessary to reduce the possibility of transmission to others if a case occurs on board the ship.

Cruise ship operators, at their discretion, may designate areas only accessible to fully vaccinated passengers and crew where masks and physical distancing are not required (e.g., casinos; bars; spas; entertainment venues; and dining areas, including self-serve buffets).

For ships with at least 95% of crew and 95% of passengers fully vaccinated, the following requirements are recommendations only.

Requirements

To reduce the spread of SARS-CoV-2, cruise ship operators must:

- Implement physical distancing protocols to provide at least 6 feet (2 meters) between individuals who are not traveling companions or part of the same family, and crowd reduction measures in all congregate and high traffic areas of the vessel.
 - [Dining](#) (also see Food Services section below)
 - Change restaurant and bar layouts to ensure that all parties remain at least 6 feet (2 meters) apart (e.g., removing tables/stools/chairs, marking tables/stools/chairs that are not for use)
 - [Elevators and Stairwells](#)
 - Limit capacity, provide floor markings, and provide marked queuing areas to eliminate congregation
 - Use floor markings in elevator lobbies and near the entrance to escalators to reinforce physical distancing of at least 6 feet (2 meters). Place decals inside the elevator to identify where passengers should stand, if needed.
 - Post signs reminding occupants to minimize surface touching. They should use an object (such as a pen cap) or their knuckle to push elevator buttons.
 - [Entertainment Venues and Activities](#)
 - Limit capacity in areas with performances, dancing, acting, and singing, and similar activities.
 - Provide physical distancing between seating areas, such as by blocking out seats to allow individuals to remain at least 6 feet (2 meters) apart.
 - Limit capacity in areas with activities such as rock-climbing walls, zip-lines, mini golf, sports courts, jogging, skating, arcade rooms, and similar activities.
 - [Casinos](#)
 - Block out seats and gaming equipment to allow individuals to remain at least 6 feet (2 meters) apart
 - Limit customers' sharing of objects (e.g., items used in table games, dice) when possible, and [clean and disinfect](#) these objects between uses as much as possible
 - Set up physical barriers where it is difficult for individuals to remain at least 6 feet (2 meters) apart

- Provide physical distancing of at least 6 feet (2 meters) between equipment, such as by blocking out or removing equipment
- **Public Toilet Rooms**
 - Ensure handwashing facilities are well-stocked with soap and a method to dry hands, such as paper towels or air dryers, in accordance with the 2018 VSP Operations Manual.
 - Add physical barriers, such as plastic flexible screens, between toilet room sinks, stalls, and urinals, especially when they cannot be at least 6 feet (2 meters) apart.
 - Ensure that people standing in line can maintain a 6-foot (2-meter) distance from one another. Post signs or markers to help attendees maintain the appropriate physical distance of at least 6 feet (2 meters).
 - Clean public toilet rooms regularly using products from the [EPA List N: Disinfectants for Coronavirus \(COVID-19\)](#) , at least twice per day (e.g., in the morning and evening or after times of heavy use).
 - Provide information on how to wash hands properly. Hang [signs](#)  [\[PDF – 1 page\]](#) in toilet rooms.
- **Gangways**
 - Provide physical guides, such as floor markings and signage, to instruct passengers to maintain a 6-foot (2-meter) distance from one another
- **Recreational Water Facilities (RWFs)**
 - Reduce the bather load for each facility to meet [physical distancing](#). When physical distancing of at least 6 feet (2 meters) between bathers is not possible, such as in small whirlpool spas, RWFs should be used by the same family or traveling companions only. This can be accomplished by close monitoring. Exceptions to physical distancing are permitted when necessary to:
 - Rescue a distressed swimmer, perform cardiopulmonary resuscitation (CPR), or provide first aid; or
 - Evacuate the water or pool deck due to an emergency.
 - Place seating area items located in or around RWFs, such as tables, chairs, loungers, sun beds, and poufs, 6 feet (2 meters) apart from each other to adhere to [physical distancing](#). These items can be grouped together for families and traveling companions.
 - Follow the [physical distancing](#) protocols of 6 feet (2 meters) for lines to use slides and other interactive RWF areas.
- **Access Points (such as dining room entrances, guest services, disembarkation points)**
 - Ensure that crew and passengers maintain 6 feet (2 meters) of physical distance while waiting for access.
- **Signs and Messages**
 - Post [signs](#), in highly visible locations (such as at entrances and in toilet rooms), to promote steps that [prevent the spread](#) of the virus (such as practicing physical distancing of at least 6 feet (2 meters)), and properly wearing a cloth mask).

Recommendations

To further reduce the spread of SARS-CoV-2, cruise ship operators as best practices should:

- Consider the use of wearable proximity alerting technology, e.g. proximity bands, to alert the wearer of physical distancing infractions to assist with maintaining physical distancing protocols.
- Implement additional physical distancing protocols to provide at least 6 feet (2 meters) between individuals who are not traveling companions or part of the same family, and crowd reduction measures.
 - **Elevators and Stairwells**
 - Encourage occupants to take stairs when possible, especially when elevator lobbies are crowded or when only going a few flights.
 - Where feasible, designate certain stairwells or sides of stairwells as “up” and “down” to better promote physical distancing of at least 6 feet (2 meters).
 - Use stanchions (for lobbies only; not inside elevators) or other ways to mark pathways to help people travel in one direction and stay 6 feet (2 meters)
 - Consider limiting the number of people in an elevator.
 - Encourage escalator and elevator passengers to wash their hands and avoid touching their face after holding on to handrails or touching buttons.
 - Consider adding supplemental air ventilation or local air treatment devices in frequently used elevator cars.

- Limit to reservation only time slots or **limit capacity**.

HVAC Systems

When indoors, ventilation mitigation strategies can help reduce viral particle concentration. The lower the concentration, the less likely viral particles can be inhaled into the lungs (potentially lowering the inhaled dose); contact eyes, nose, and mouth; or fall out of the air to accumulate on surfaces. Protective ventilation practices and interventions can reduce the airborne concentrations and reduce the overall viral dose to occupants.

Heating, Ventilation, and Air Conditioning (HVAC) preventive measures should be implemented to minimize the possibility of dispersing the COVID-19 virus through the air. A layered approach should be applied using more than one preventive measure.

Requirements

To reduce the spread of SARS-CoV-2, cruise ship operators must:

- Ensure ventilation systems operate properly for the occupancy level for each space.
 - Make sure air filters are properly sized and within their recommended service life.
 - Inspect filter housing and racks to ensure appropriate filter fit and minimize air that flows around, instead of through, the filter.
- Ensure toilet room exhaust fans are functional and operating at full capacity.
- Ensure sufficient negative air pressure in medical centers, and predetermined isolation and quarantine cabins.

Recommendations

To further reduce the spread of SARS-CoV-2, cruise ship operators as best practices should:

- Consider closing exclusively indoor RWFs, due to ventilation concerns.
- Increase the introduction of outdoor air:
 - Open outdoor air dampers beyond minimum settings to reduce or eliminate HVAC air recirculation.
 - Open windows and doors, when weather conditions allow, to increase outdoor air flow. Do not open windows and doors if doing so poses a safety or health risk.
- Use fans to increase the effectiveness of open windows:
 - Avoid placing fans in a way that could potentially cause contaminated air to flow directly from one person to another.
- Rebalance or adjust HVAC systems to increase total airflow to occupied spaces when possible.
- Turn off any demand-controlled ventilation (DCV) controls that reduce air supply based on occupancy or temperature during occupied hours.
- Improve central air filtration:
 - **Increase air filtration**  to as high as possible without significantly reducing design airflow. Increased filtration efficiency is especially helpful when enhanced outdoor air delivery options are limited.
 - Filters with a higher number of Minimum Efficiency Reporting Value (MERV) have higher efficiency and ability to capture particles from the air. High-Efficiency Particulate Air (HEPA) filters can achieve at least 99.97% removal of viral particles in the air.

- Consider portable high-efficiency particulate air (HEPA) fan/filtration systems to enhance air cleaning, especially in higher risk areas such as the medical center or areas frequently inhabited by people with a higher likelihood of having COVID-19 and/or an increased risk of getting COVID-19).
- Consider using ultraviolet germicidal irradiation (UVGI) as a supplemental treatment to inactivate SARS-CoV-2, especially if options for increasing room ventilation and filtration are limited. [Upper-room UVGI systems](#)  [\[PDF – 87 pages\]](#) can be used to provide air cleaning within occupied spaces, and in-duct UVGI systems can help enhance air cleaning of recirculated air inside central ventilation systems.

Food Services

Passenger interactive experiences include, but are not limited, to interactive cooking, culinary workshops and demonstrations, mixology/blending classes, and galley and other “behind the scene” tours.

Cruise ship operators, at their discretion, may designate areas as only accessible to fully vaccinated passengers and crew where masks and physical distancing are not required (e.g., casinos; bars; spas; entertainment venues; and dining areas, including self-serve buffets).

For ships with at least 95% of crew and 95% of passengers fully vaccinated, the following requirements are recommendations only.

Requirements

To reduce the spread of SARS-CoV-2, cruise ship operators must:

- Change restaurant and bar layouts to ensure that all customer parties remain at least 6 feet (2 meters) apart (such as removing tables, stools, and chairs or marking any that are not for use).
- Limit seating capacity to allow for [physical distancing](#) of at least 6 feet (2 meters).
- Discourage crowded waiting areas by using phone app, text technology, or signs to alert patrons when their table is ready. Avoid using “buzzers” or other shared objects.
- Eliminate self-service food and drink options, such as self-service buffets, salad bars, and beverage stations.
- Provide eating utensils in a way that prevents handling by more than one person.
- Install physical barriers, such as sneeze guards and partitions in areas where it is difficult for individuals to maintain proper physical distance of at least 6 feet (2 meters), such as serving stations and food pick up areas.
- Provide physical guides, such as tape on decks and signage, to remind individuals to maintain physical distance of at least 6 feet (2 meters) where food and beverages are served.
- Provide and encourage outdoor dining and bar/beverage service options.
- Provide and encourage in-room passenger dining service.
- Limit any sharing of food, tools, equipment, or supplies by food workers, to the extent practicable.
- Ensure adequate supplies to minimize sharing of high-touch materials (e.g., serving spoons) to the extent practicable; otherwise, limit use of supplies and equipment by one group of food workers at a time and clean and disinfect between use.
- Avoid using or sharing of items that are reusable, such as menus, condiments, and any other food containers. Instead, use disposable menus, digital menus that can be disinfected between each use, online menus that can be retrieved on diners’ personal cell phones, single serving condiments, and no-touch trash cans and doors.

Recommendations

To further reduce the spread of SARS-CoV-2, cruise ship operators as best practices should:

- Consider options for consumers to order ahead of time to limit the amount of time spent in the restaurant.
- Provide alternative meal services options, such as prepackaged grab-and-go meals, for consumption on open decks or in individual cabins to minimize risks associated with congregate indoor dining.
- Use touchless payment options as much as possible, if available. If pens are needed for some purposes, disinfect between uses and/or encourage customers to use their own pens.

Cleaning and Disinfection

Numerous researchers have studied how long SARS-CoV-2 can survive on a variety of porous and non-porous surfaces. On porous surfaces, [studies report](#) inability to detect viable virus within minutes to hours; on non-porous surfaces, viable virus can be detected for days to weeks.

Cleaning of visibly dirty surfaces followed by disinfection helps prevent COVID-19 transmission. Cleaning with products containing soap or detergent reduces germs on surfaces by removing contaminants and may also weaken or damage some of the virus particles, which decreases risk of infection from surfaces. Disinfecting (using [EPA's List N](#) [☐](#)) kills any remaining germs on surfaces, which further reduces any risk of spreading infection.

Additional information on cleaning and disinfecting on cruise ships can be found on CDC's [Interim Guidance for Ships on Managing Suspected Coronavirus Disease 2019](#) and [Technical Instructions for Mitigation of COVID-19 Among Cruise Ship Crew](#).

Requirements

To reduce the spread of SARS-CoV-2, cruise ship operators must:

- Prioritize cleaning and disinfecting high-touch surfaces. Examples of high-touch surfaces include, but are not limited to: pens, counters, shopping carts, tables, doorknobs, light switches, handles, stair rails, elevator buttons, desks, keyboards, phones, toilets, faucets, and sinks.
- Use disinfectant products from the [EPA List N](#) [☐](#) that are effective against COVID-19. Check that the [EPA Registration number](#) [☐](#) on the product matches the registration number in the List N search tool. See [Tips on using the List N Tool](#) [☐](#) .
 - If products on [EPA List N](#) [☐](#) : Disinfectants for Coronavirus (COVID-19) are not available, [bleach solutions](#) can be used if appropriate for the surface.
- For RWFs: [Clean and disinfect](#) frequently touched surfaces multiple times a day, and shared objects before and after each time they are used. For example: handrails, slides, and structures for climbing or playing; lounge chairs, tabletops, pool noodles, and kickboards; and door handles and surfaces of toilet rooms, handwashing stations, diaper-changing stations, and showers. ([Considerations for Public Pools, Hot Tubs, and Water Playgrounds During COVID-19](#))

Shore Excursions & Transportation Services

Participating in shore excursions and group transportation increases a person's risk of getting and spreading COVID-19 by bringing people in close contact with others, often for prolonged periods. Additionally, participating in these activities in other communities and countries with [high prevalence of COVID-19](#) further increases the risk of introduction of COVID-19 onto cruise ships.

Fully Vaccinated Travelers

- Cruise ship operators, at their discretion, may advise passengers and crew that—if they are fully vaccinated—they may engage in self-guided or independent exploration during port stops. The cruise ship operator is additionally advised that foreign jurisdictions may have their own requirements.

Requirements

To reduce the spread of SARS-CoV-2, cruise ship operators must:

- For travelers who are not fully vaccinated, ensure all shore excursion tour companies facilitate physical distancing to allow for at least 6 feet (2 meters) between individuals who are not traveling companions or part of the same family; and adhere to mask wearing, cleaning and disinfection, and other COVID-19 public health measures throughout the tour.
- For travelers who are not fully vaccinated, restrict passenger and crew attendance so that proper [physical distancing](#) of at least 6 feet (2 meters) between individuals who are not traveling companions or part of the same family.

To further reduce the spread of SARS-CoV-2, cruise ship operators as a best practice should:

- Consider prohibiting self-guided or independent exploration during port stops by passengers and crew who are not fully vaccinated.
- Consider offering supervised shore excursions during port stops for passengers and crew who are not fully vaccinated where all participants wear a mask and maintain [physical distance](#). The cruise ship operator is additionally advised that foreign jurisdictions may have their own requirements.
- Limit shore excursions in foreign ports of call to countries listed as Level 1: COVID-19 Low in [CDC's COVID-19 Travel Recommendations by Destination](#).

Embarkation/Disembarkation Procedures

Embarkation and disembarkation places large numbers of people in close proximity—including passengers, crew, and port personnel—in indoor and sometimes small, enclosed spaces (e.g., gangways, corridors, waiting areas). This close proximity can increase the risk of introduction and transmission of COVID-19 onto cruise ships and into communities.

Requirements

To reduce the spread of SARS-CoV-2, cruise ship operators must:

- Ensure embarkation and disembarkation procedures follow the processes outlined in their Phase 2A port agreements.
- Ensure there is a private screening area for people identified as needing additional medical screening during the embarkation and check-in process.

Recommendations

To further reduce the spread of SARS-CoV-2, cruise ship operators as best practices should:

- Stagger or schedule embarkation/disembarkation times.
- Provide touchless check-in/check-out processes.
- Install signage and floor marking reminders and predetermined and spatially identified queue areas inside port terminals and onboard ships for passengers who are embarking and disembarking.
- Ensure written notifications about COVID-19 prevention and control are presented before passengers reach the check-in point to give them enough time to review prior to check-in.
- Use touchless garbage cans or pails and cashless payment options when possible. Otherwise, exchange cash or card by placing payment in a receipt tray, if available, or on the counter.
- Make alcohol-based hand sanitizer available to passengers, crew, and port personnel in these areas.

Exhibit 4



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention

July 9, 2021

Frank Del Rio
Chief Executive Officer
Norwegian Cruise Line Holdings

**RE: ACCEPTANCE OF PORT AGREEMENTS & APPROVAL OF COVID-19 CONDITIONAL
SAILING CERTIFICATE**

Dear Mr. Del Rio,

Congratulations! This letter constitutes CDC's approval of your application for a COVID-19 Conditional Sailing Certificate for the *Norwegian Gem* pursuant to the Framework for Conditional Sailing Order (CSO). This letter also constitutes CDC's acceptance of your Phase 2A Port Agreements for the *Norwegian Gem*.

You are reminded to follow CDC's requirements related to testing and quarantine of crew and passengers.

Please notify CDC by email at eocevent349@cdc.gov if the date of initial restricted voyage or itinerary should change.

We commend your company's efforts to provide a safer and healthier sailing environment for your passengers and crew and look forward to our continued partnership.

Sincerely,

A handwritten signature in black ink, reading "Aimee T. Treffiletti", is positioned below the word "Sincerely,".

CAPT Aimee Treffiletti, USPHS
Maritime Unit
Global Migration Task Force

**UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF FLORIDA**

NORWEGIAN CRUISE LINE HOLDINGS LTD., a Bermuda Company; **NCL (BAHAMAS) LTD.**, d/b/a NORWEGIAN CRUISE LINE, a Bermuda Company; **SEVEN SEAS CRUISES S. DE R.L.**, d/b/a REGENT SEVEN SEAS CRUISES, a Panama Limited Liability Company; **OCEANIA CRUISES S. DE R.L.**, d/b/a OCEANIA CRUISES, a Panama Limited Liability Company;

Plaintiffs,

v.

SCOTT A. RIVKEES, M.D., State Surgeon General and Head of the Florida Department of Health, in his official capacity;

Defendant.

Case No. 1:21-cv-22492-KMW

DECLARATION OF DR. JUKKA LAITAMAKI

I, Jukka Laitamaki, declare as follows:

1. I make this declaration on the basis of my personal and professional knowledge and experience and publicly available information. Various materials that I have relied upon in formulating my opinions set forth in this declaration are listed in **Exhibit 1** hereto.

2. I hold a Ph.D. and M.Sc. from the Cornell University School of Hotel Administration, as well as an M.Sc. from the Turku School of Economics and Business Administration. I am currently a clinical professor in the School of Professional Studies and Jonathan M. Tisch Center of Hospitality at New York University ("NYU").

3. At NYU, I teach courses on Leadership, Strategy Formulation, Business Development, and Strategic Brand Management. I have more than 30 years of higher education and consulting experience in over 20 countries on six continents and the United Nations. My areas of expertise include business strategy, branding, sustainability, and entrepreneurship with a special focus on the international hospitality, tourism, and service industries. I also lecture and

conduct research in the areas of leadership, global and competitive strategy, Blue Ocean and brand strategy, customer and brand experience management, and sustainability.

4. My research in these areas has been published in several international conferences and journals, including the European Management Journal, California Management Review, and Journal of Transnational Management.

5. Previously, I worked as a professor at the University of California Berkeley and Fordham University. At Fordham, I built the Global Professional MBA Program with 140 students from 40 countries. Newsweek recognized the program as one of the top seven international MBA programs in the United States. I also was a management consultant with the Service Management Group at McKinsey & Company.

6. Norwegian Cruise Line Holdings Ltd. ("NCLH") has agreed to compensate me at a rate of \$500 per hour for this engagement, and that rate is my standard one for providing consulting services.

7. In the course of my professional life, I have extensively analyzed and studied the cruise industry with a focus on Carnival Corporation & PLC, Royal Caribbean Cruises Ltd., NCLH, and their core strategies, innovations, and main brands of Carnival Cruise Line, Royal Caribbean, and Norwegian Cruise Line. Jukka Matti Laitamaki, *The Next Generation Cruise Ships Searching for the Blue Ocean*, The Case Centre (2020).

8. "A brand is an organization's promise to a customer to deliver what the brand stands for not only in terms of functional benefits but also emotional, self-expressive, and social benefits." David A. Aaker, *Aaker on Branding* (2014). When a brand delivers on the promise, it will earn the consumer's trust. Failing to deliver on the promise has the potential to destroy that trust and the brand itself. Brand trust has been defined as "the extent to which consumers believe that a company can deliver products and services that satisfy consumer needs and wants," Kevin Lane Keller & David A. Aaker, *The Effects of Sequential Introduction of Brand Extension*, Vol. XXIX J. of Marketing Research 35 (1992), as well as "the brand will deliver what is desired versus that which is feared." Susan Fournier, *Consumers and Their Brands: Developing Relationship Theory in Consumer Research*, 24 J. of Consumer Research 343 (1998). Earning and maintaining the trust of customers is essential to strategic success in the cruise industry, and that trust can be quickly and irrevocably lost if customers have a poor experience with a particular brand or otherwise perceive that a brand has failed to deliver on its promises.

9. The U.S. cruise industry is struggling due to the early COVID-19 crises on Diamond Princess and Grand Princess, which resulted in the loss of life and CDC's No Sail Order. Americans are still hesitant to take a cruise: according to a May 2021 poll of 1,999 U.S. adults by Harris Poll, only 50% of respondents are confident that the cruise industry can reopen safely coming out of the pandemic. These results meant that the cruise industry ranked at the bottom in terms of consumer trust in safe opening, behind retail stores (82%), restaurants (80%), hotels (79%), airlines (69%), amusement parks (63%), movie theaters (63%), and sports and concert venues (59%). According to the same survey, 59% of respondents said that if they were going to take a cruise, they would specifically look for a cruise line that mandated all crew and passengers to be vaccinated against COVID-19. Just 26% preferred that there was no mandate, and 18% said it would not matter either way.

10. A separate May 2021 survey of over 5,000 readers of Cruisecritic.com recently found that 80% of likely cruisers prefer to resume sailing on ships that require vaccinations. Of the 80% who favor vaccinated ships, 89% said they would feel more safe sailing on a ship with fellow vaccinated travelers, and 69% said they want a more traditional cruise experience, without masks, social distancing, or testing requirements. Just 14% of the respondents said they would prefer to sail on a ship without a vaccine requirement, and 7% said they had no preference.

11. NCLH's three brands (Norwegian Cruise Line, Oceania Cruises, and Regent Seven Seas) have a brand promise of safety and hygiene. The most recent data from CDC's Vessel Sanitation Program indicated that all of NCLH's ships passed the sanitation inspection (86 or higher score) with Norwegian Sky and Norwegian Spirit receiving the maximum score of 100 (<https://wwwn.cdc.gov/InspectionQueryTool/InspectionResults.aspx>). NCLH has been an innovator in the cruise industry, introducing several industry firsts including Freestyle Cruising and Value-Add Bundling of customer services and experiences. NCLH has differentiated its brands based on the flexibility that customers have for enjoying various restaurants, bars, activities, and amenities onboard. These innovations combined with the youngest fleet relative to key competitors (9.8 years weighted average at the end of 2017) have resulted in excellent customer loyalty, which stood at 62% for Regent Seven Seas, 50% for Oceania Cruises, and 40% for Norwegian Cruise Line at the end of 2017. Jukka Matti Laitamaki, *The Next Generation Cruise Ships Searching for the Blue Ocean*, The Case Centre (2020).

12. Strong brand trust and customer loyalty have produced best-in-class net yield performance for NCLH, which was 29% higher than Royal Caribbean Cruises Ltd. and 38% higher than Carnival Corporation & PLC. NCLH's brand trust would be severely harmed and could be destroyed if there were an outbreak of COVID-19 on any of its cruise ships. Beyond the extreme costs involved in sailing to a safe harbor in the wake of an outbreak, as current industry protocol requires, NCLH's brand promise for safe and hygienic cruises would be irreversibly injured.

13. It is my understanding that NCLH promised its passengers 100% vaccinated cruises before Fla. Stat. § 381.00316 was enacted on May 3, 2021, and before it took effect on July 1, 2021. A failure to keep that promise would threaten NCLH's brand trust, especially given that many of its passengers likely bought tickets, made plans, and incurred costs based on this promise.

14. "The cruise experience benefits from being impromptu. It is cruise lines' worst nightmare to have separate areas for the vaccinated and unvaccinated." *See* Fran Golden, *On Cruises That Allow Them, the Unvaccinated Are Second-Class Citizens*, Bloomberg News, <https://www.bloomberg.com/news/articles/2021-07-07/on-cruises-that-allow-them-the-unvaccinated-are-second-class-citizens> (2021). A 2019 survey found that cruise passengers find the following amenities appealing: restaurants (73%), movie theaters/stage shows (56%), spa amenities (45%), and bars (38%) (Mintel, September 2019). A 2017 study indicated that cruises were found to be "good for relaxing" (57%), "a safe way to visit unfamiliar places" (42%), "good for experiencing new cultures" (41%), and "fun for everyone" (40%) (Mintel, September 2017). Although many passengers consider cruises to be the best way to visit unfamiliar destinations, large cruise ships such as Norwegian Epic have themselves become the preferred destinations for many passengers, and their experience onboard is paramount (<https://www.cruise-international.com/the-ship-is-the-destination/>).

15. The utility that cruise passengers derive from on-board activities and amenities depends on their feeling that these activities are safe and comfortable to participate in. Thus, widespread fears of contracting COVID-19 onboard a cruise ship would significantly detract from the cruise experience, as passengers would not feel free and welcome to use many amenities or participate in many onboard activities without fear, stress, or constraint. The fear of COVID-19 has resulted in research regarding the nature and dimensions of this fear. Daniel

Kwasi Ahorsu et al., *The Fear of COVID-19 Scale: Development and Initial Validation*, Int'l J. of Mental Health and Addiction, 27 March (2020). Other research has found that during COVID-19, crises communication that focused on shared emotions between tourists and hospitality employees positively influenced “brand humanization” and “emotional attachment” that led to stronger intent to visit. Haiming Hang et al., *Building Emotional Attachment During COVID-19*, Annals of Tourism Research 83 (2020).

16. My understanding of NCLH’s policy of requiring that 100% of its crew and passengers be fully vaccinated—and of requiring documentation of crew and passenger vaccination statutes—is that this policy is a powerful tool for NCLH to build its brand trust and customer goodwill by focusing on shared emotions and countering the fear of COVID-19. Both crew and customers share the fear of COVID-19, and requiring 100% vaccinations—and documentation proving vaccination status—effectively counters that fear. Correspondingly, a ban on vaccination documentation would increase the fear of COVID-19, render NCLH’s policy less effective, and thus harm NCLH’s brand trust and goodwill and result in lower customer intent to take NCLH cruises in the future. Moreover, abandoning its documentation policy would likely be taken by customers as NCLH breaking its promise to them, thereby damaging NCLH’s brand, reputation, and standing with customers in the ways I have already noted. Last, to the extent that abandoning the policy increases the risk of an actual COVID-19 outbreak, it would entail corresponding risks of the disastrous consequences for NCLH that I have noted.

17. If NCLH were required to board passengers who do not or cannot show documentation certifying COVID-19 vaccination, NCLH would likely be forced to significantly limit the cruise experience for these passengers. Enforcing these limits would almost certainly harm NCLH’s goodwill and brand promise for providing flexibility as NCLH would need to enforce on-board barriers against passengers who did not certify vaccination against COVID-19. The resulting constraints, friction, and discomfort would undermine the cruise experience of everyone on board. Passengers who want to enjoy themselves on board do not want to have their activities strictly policed, nor do they want to worry about whether they are mixing with the wrong fellow passengers, at the wrong places as they move about a ship.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on July 12, 2021

A handwritten signature in black ink, appearing to be 'J. Laitamaki', written above a horizontal line.

DR. JUKKA LAITAMAKI

Exhibit 1

Materials Relied Upon

Sources:

Aaker (2014)

https://www.google.com/books/edition/Aaker_on_Branding/DKDKAgAAQBAJ?hl=en

Ahorsu et al. (2020) <file:///C:/Users/jl142/Desktop/The%20Fear%20of%20COVID-19%20Scale%20-%20Development%20and%20Initial%20Validation%20by%20Ahorsu%20et%20al.pdf>

CDC Vessel Sanitation Program (2021)

<https://wwwn.cdc.gov/InspectionQueryTool/InspectionSearch.aspx>

Cruisecritic.com (2021) <https://www.cruisecritic.com/ab/agents/variation-a/articles.cfm?ID=6159>

Hang et al. (2020) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7373071/pdf/main.pdf>

Harris Poll COVID Tracker (2021) <https://theharrispoll.com/the-harris-poll-covid19-tracker/>

Fournier (1998)

<file:///C:/Users/jl142/Desktop/Consumers%20and%20Their%20Brands%20by%20Fournier%20p.%20365.pdf>

Keller and Aaker (1992) <https://journals.sagepub.com/doi/pdf/10.1177/002224379202900104>

Mintel (December 2019) Cruises U.S. December 2019

Mintel (September 2017) Cruises U.S. September 2017

Laitamaki (2020)

[file:///C:/Users/jl142/Downloads/Master%20Copy%20The%20Next%20Generation%20Cruise%20Ships%20Searching%20for%20the%20Blue%20Ocean%20Case%20320-0206-1%20\(2\)%20\(1\).pdf](file:///C:/Users/jl142/Downloads/Master%20Copy%20The%20Next%20Generation%20Cruise%20Ships%20Searching%20for%20the%20Blue%20Ocean%20Case%20320-0206-1%20(2)%20(1).pdf)

Laitamaki (2021) <https://www.bloomberg.com/news/articles/2021-07-07/on-cruises-that-allow-them-the-unvaccinated-are-second-class-citizens>

Exhibit 2

JUKKA M. LAITAMAKI, Ph.D.

New York University
School of Professional Studies
Jonathan M. Tisch Center of Hospitality

7 East 12th Street Suite 721H
New York, New York 10003
Tel: 908-2940902 E-mail: JL142@nyu.edu

Ph.D., Cornell University School of Hotel Administration, USA

M.Sc., Cornell University School of Hotel Administration, USA

M.Sc., Turku School of Economics and Business Administration, Finland

Dr. Laitamaki has explored 63 countries and he is a global academic and an expert in strategy, marketing, branding, sustainability, and entrepreneurship with a special focus on international hospitality, tourism and service industries. He has over 30 years of higher education and consulting experience in over 20 countries on six continents and at the United Nations.

Dr. Laitamaki has worked as a management consultant with Service Management Group and McKinsey & Company, and as a professor at U.C. Berkeley, Fordham University, and New York University. At Fordham, he was part of the opening team of the Beijing International MBA Program which was inaugurated when President Clinton visited the University of Beijing in 1998. He built Fordham's Global Professional MBA (GPMBA) Program with 140 students from 40 countries. Newsweek recognized GPMBA as one of the top seven international MBA Programs in the U.S.

At New York University Dr. Laitamaki teaches Strategy Formulation, Business Development, and Strategic Brand Management. He lectures and conducts research in global and competitive strategy, Blue Ocean and brand strategy, customer and brand experience management, entrepreneurship, and sustainability. Dr. Laitamaki's research has been published in several international conferences and journals including the European Management Journal, California Management Review, and Journal of Transnational Management. He is a contributor on tourism policy for the textbook Travel and Tourism: An Industry Primer by Prentice Hall. Dr. Laitamaki's research on the sustainability of the Cuban tourism industry was published in the Managing Global Transitions International Research Journal, and his research on Cuban UNESCO sites was published at the THoR 2017 Sustainable Tourism Conference in Singapore. He has published a business case study regarding the global cruise line industry in the European Case Centre titled "The Next Generation Cruise Ships Searching for the Blue Ocean." Most recently he presented his work titled "The Impact of U.S. Cuba Policies on Cuban Tourism Industry: Focus on the Obama and Trump Administration at the Global Conference on Services and Retail Management, May 10-13, 2021

EDUCATION

CORNELL UNIVERSITY SCHOOL OF HOTEL ADMINISTRATION	Ithaca, NY
Ph.D., August 1990 and M.Sc., January 1989	
Major: Marketing Minor: Managerial Economics	
TURKU SCHOOL OF ECONOMICS AND BUSINESS ADMINISTRATION	Finland
Master of Economics and Business Administration 1982	
Majors: Business Law, Accounting Minor: Managerial Economics	

EXPERIENCE

2003- NEW YORK UNIVERSITY	New York, NY
Clinical Professor	
School of Professional Studies Jonathan M. Tisch Center for Hospitality and Tourism	
1990- FORDHAM UNIVERSITY GRADUATE SCHOOL OF BUSINESS	New York, NY
2003 Director, Global Professional MBA Program and Clinical Associate Professor	
1996- HELSINKI SCHOOL OF ECONOMICS AND BUSINESS ADMINISTRATION	Finland
2006 Visiting Professor, International Marketing, Global E-business and Global Branding	
2003- ADELAIDE GRADUATE SCHOOL OF BUSINESS	
2005 Visiting Professor, Global Branding	
1997- KOREA EXECUTIVE MBA PROGRAM	Seoul, Korea
1998 Visiting Professor, International Marketing	
1996 FINNISH MINISTRY OF TRADE AND INDUSTRY	Finland
Advisor, Industrial Policies for International Services	
1994- TURKU SCHOOL OF ECONOMICS AND BUSINESS ADMINISTRATION	Finland
1995 Visiting professor, Total Quality Management	
1991 IRISH MANAGEMENT INSTITUTE	Dublin, Ireland
Visiting Professor, International Marketing	
1989- UNIVERSITY OF CALIFORNIA HAAS SCHOOL OF BUSINESS	Berkeley, CA 1990
Visiting Professor, Services Marketing and Management	
1989- THE FINNISH INSTITUTE OF MANAGEMENT (LIFIM)	Finland
1991 Visiting Professor, Services Management and Marketing	
1988 McKinsey & COMPANY, Inc.	Sweden
Associate, Global Competitive Strategy Development	
1986- HAAGA INSTITUTE OF HOSPITALITY MANAGEMENT Finland	
1988 Instructor, International Hospitality Industry Management	
1984- UNIVERSITY OF LAPLAND AND OULU	Finland
1985 Instructor, Services Marketing and Management	
1981- SERVICE MANAGEMENT GROUP	Finland and USA
1985 Senior Consultant, International Service Industry Practice	

RESEARCH

Refereed Journal Articles

- "Sustainable Tourism Development Frameworks and Best Practices: Implications for the Cuban Tourism Industry." (with Lisandra Torres Hechavarría, Mariko Tada, Siying Liu, Natania Setyady, Nuntawan Vatcharasontorn, and Feizhou Zheng) Managing Global Transitions: International Research Journal Vol. 14, No.1, 2016: 7-29.
- "The Impact of the 2008 Financial Crises on Finnish and American Households." (with Raija Jarvinen) The Finnish Journal of Business Economics, 1, 2013: 41-65.
- "Global Strategies for Destination Management Organizations: Focus on Country Brand Experience Management." (with T. Hamalainen) Finnish Journal of Tourism Research, Vol 2, No 4, 2008: 5-24
- "The I² DE² A-Framework of Strategic HR Value Added Management: Best Practices in International Hospitality, Travel and Transportation Industries." (with Sinikka Laitamaki and Tarja Ruuska) Estonian Business School Review 2, 23, 2007: 7-18.
- "Building and Deploying Profitable Growth Strategies based on the Waterfall of Customer Value Added." (with Ray Kordupleski) European Management Journal 15, 2, 1997: 158-166.
- "Borderless Service Designs: Implications for Multinational Enterprise Strategies." Journal of Transnational Management 2, 2, 1996: 5-29.
- "Total Quality Research: Integrating Markets and the Organization." (with Robert Hurley), California Management Review 38, 1, 1995: 59-78.
- "Enhancing Socio-Cultural Interaction through Development of Travel Packages." (with Mary Tabacchi and Heather Searle) Visions: An International Journal of Leisure Industry 1990.

Double-Blind Refereed Articles in Conference Proceedings

- "Sustainable Tourism in Cuban UNESCO World Heritage Sites: Focus on Historic City Centers." International Conference on Tourism and Hospitality Research (THoR 2017) Singapore, December 11-12, 2017.
- "Senior Citizen Wellbeing: Differences between American and Finnish Societies." (with Raija Jarvinen) Management International Conference MIC 2015, Portoroz Slovenia, May 28-30, 2015.
- "Competitive Benchmarking of International Jazz Festival Destinations: The Six Alpha Competitiveness Criteria™" EURO CHRIE Annual Conference, Dubai UAE, October 6-9, 2014.
- "Finnish and American Household Financial Behavior During the 2008 Financial Crises." (with Raija Jarvinen) Behavioral Finance Working Group (BFWG) Conference, London UK, December 16-17, 2013.
- "Perceived Authenticity of Tour Product Experiences in Tourism Industry: A Work in Progress Framework for Finnish Arctic Tours." (with Diana Ditto) Academy of World Business Marketing and Management Development Conference, Oulu Finland July 12-15, 2010. The Best Paper Award and Keynote Speech.
- "Willingness of Guests to Participate in Hotel Sustainability Programs"(with John Paulsen) International Conference on Global Sustainable Tourism, Mbombela-Nelspruit South Africa, November 15-19, 2010.
- "Brand Experience Management (BEM): Implications for Hospitality and Financial Services." (with Raija Jarvinen and Anna-Riitta Lehtinen) Academy of World Business Marketing and Management Development Conference, Oulu Finland July 12-15, 2010.
- "International Tourists and Destination Management Framework for Benchmarking Destinations Against Competitors." Academy of World Business Marketing and Management Development Conference, Oulu Finland July 12-15, 2010.
- "A Comparative Study of the U.S. and Finnish Service Encounters: A Case of Customization or Standardization of Investment Offers." (with Raija Jarvinen and Anna-Riitta Lehtinen) Academy of World Business Marketing and Management Development Conference, Oulu Finland July 12-15, 2010.
- "Luxury Brand Experience Management: Can Hotels Learn from Luxury Retailers?" (with Carlo Fei and Diana Ditto) EURO CHRIE Annual Conference, Helsinki Finland October, 2009.
- "Measuring Perceived Quality of Higher Education with a HEDQUAL Multiple-Item Scale: Implications for Teacher Quality and Teacher Responsiveness." (with Sinikka Laitamaki) International Study Association on Teachers and Teaching Conference, Rovaniemi Finland July 2009.

- “Irrational Consumer Behavior in Financial Services: Implications for the Finnish Business and Society.” (with Raija Jarvinen and Uolevi Lehtinen) International Association of Business and Society (IABS) Conference, Tampere Finland June 27-29, 2008.
- “Drivers of Globalization in the Tourism Industry: Global Strategies for Country Destination Brands.” (with Timo Hamalainen) Travel and Tourism Research Association (TTRA) Europe Conference, Helsinki, April 2008.
- “Best Practices of Strategic HR Value Added Management in International Hospitality, Travel and Tourism Industries.” (with Sinikka Laitamaki and Tarja Ruuska) International Human Resource Management Conference, Tallinn Estonia, June 12-15, 2007
- “A Crisis Management Framework: Thai Government Responses to SARS, Southern Thailand Unrest, Tsunami and Bird Flu.” Academy of World Business, Marketing and Management Conference, Paris, July 10-13, 2006.
- “An Inclusive Multicultural Organization: The Case of New York City Hotels.” International Human Resource Management Conference, Cairns Australia, June 14-17, 2005
- “Globalization – A Historical Perspective.” 6th Workshop in International Business at the University of Vaasa Conference, August, 2001.
- “Creative Marketing-Mix Management of Frequent User Programs.” (with S. Nowlis and R. Bellingham), American Marketing Association Services Marketing Congress, 1990.
- “Value Based Pricing Strategies for Services: An Empirical Study of the Hotel Industry.” (with L.M. Renaghan), American Marketing Association Services Marketing Congress, 1987.
- “Applications of Service Quality and Services Marketing in Health Care Organizations.” (with J.R. Lehtinen), American Marketing Association 5th Annual Symposium on Health Services Marketing, 1985.

Refereed Academic Conference Presentations

- “The Impact of U.S. Cuba Policies on Cuban Tourism Industry: Focus on the Obama and Trump Administration (with Antonio Diaz Medina and Lisandra Torres Hechavarria). Global Conference on Services and Retail Management, May 10-13, 2021 Virtually hosted by University of Naples Federico II, Italy & University of South Florida, USA
- “Modelos, Medidas y Mejoras Practicas de Deserrollo Turistica Sostenible: Implicaciones Para el Sector Turistico Cubano.” (with Lisandra Torres Hechavarria University of Havana who did the presentation in Havana). Forum Provincial de Economia ANEC La Habana. 7 de Octubre del 2015 “Año 57 de la Revolucion”
- “Sustainable Tourism Development Frameworks, Measures and Best Implementation Practices: Implications for the Cuban Tourism Industry.” (with Lisandra Torres Hechavarria University of Havana, Siying Liu, Natania Setyady, Mariko Tada, Nuntawan Vatcharasoontor and Feizhou Zheng. New York University, School of Professional Studies) Management International Conference 2015 (MIC15), Portoroz, Slovenia, May 28-30, 2015.
- “Senior Citizen Wellbeing: Differences Between Nordic, American and Cuban Societies.” (with Raija Jarvinen, University of Helsinki) Management Internati. Global Service pn Services and Retail;onal Conference 2015 (MIC15), Portoroz, Slovenia, May, 2015.
- “Benchmarking Value Creation of Classical Music Holiday Destinations: is There Customer Co-creation in Bayeruth, Buxton, D’Orange, Salzburg, Savonlinna, St. Petersburg and Verona?” (with D. Quadri-Felitti) Pori Jazz for Professionals Researcher Seminar, Pori Finland, July 16, 2013.
- “Designing Luxury Hotel Experiences as Memorable Events.” (with B. O’Mahony and J. Buhring) Pori Jazz for Professionals Researcher Seminar, Pori Finland, July 12, 2012.
- “Creative Leadership and Innovation in the Boutique Hotel industry.” (with B. O’Mahony, D. Quadri-Felitti and J. Buhring) Pori Jazz for Professionals Researcher Seminar, Pori Finland, July 11, 2011.

Policy and Competitiveness Studies

- “U.S. Market Opportunities for Finnish Travel Experiences: Focus on Arctic-, Christmas-, Music-, Wellbeing-, Wildlife-, and Countryside Holidays.” Finnish Tourist Board, April 2009.
- “Towards an Efficient Service Society: Industrial Policy Report Regarding Improvement of Competitiveness and Employment in the Service Industries.” (with T. Hamalainen, M. Lehti and A. Paasio), Finnish Ministry of Trade and Industry Publication, 4, 1996.

Editor Reviewed Journal Articles

- "Emotions Play a Role in Investing (Sijoituksissa Ovat Tunteet Pelissa)." (with Raija Jarvinen) (Talouselama) Business World Journal, November 2007.
- "Training is a Strategic Choice" (Koulutus on Strateginen Valinta) Osaamisen Jalki, Fall 2005
- "Shaping the Globalization Phenomena: The Global Professional MBA Approach," Fordham Business Review, Volume 1 Number 1, 1999.
- "Northern Voice: Sustainable Development and Finnish Industries," Finland Folio, Fall 1997
- "Competitive Industry Analysis of U.S. Hotel Industry," Vitriini Hospitality Industry Journal, 1/1987.

Editor Reviewed Business Case Studies

- "The Next Generation Cruise Ships Searching for the Blue Ocean" The Case Centre, 2020.

Editor Reviewed Book Chapters

- "The Six Alpha Competitiveness Criteria for Evaluating Tourism Destinations: The Case of Arctic Destinations." A Glance of Hospitality Management, Haaga-Helia University of Applied Sciences Publication, 2010.
- "Preventing Terrorism in U.S. Shopping Malls." Security and Competitiveness of Shopping Centers, Aalto University Publication, 2010.
- "Government, Politics, and Tourism" Travel and Tourism: An Industry Primer (with P.S. Biderman, J. Lai, H.R. Messerli, P.D. Nyheim and S. C. Plog), Pearson Prentice Hall, 2008.
- "Tourism Crisis Management Framework: The Thai Experience." Disasters and Law (with Pongsak Hoontrakul), ICAFI Books, 2008.
- "Strategic Dimensions of Culture: Linkages Between Business Culture, Changing Environment and Branding Perspectives." (with V. Gupta and P. Sharma), Consumer Behavior and Brands, eds. R. Kumar, Pearson Publishing, 2003.

Peer-Reviewed Working Papers

- "Brand Experience Management (BEM): The Flight Plan to a Competitive Brand Positioning in the Blue Sky." Estonian Business School Executive Education Website, January 2008.
- "Strategies and Organizational Characteristics of Global Service Companies: An Integrative Contingency Approach." (with S. A. Parton), Fordham University Graduate School of Business Administration, Working Paper 90-7-2, September 1990.

Refereed Conference Papers: International Hospitality and Service Industries

- "Cross-Cultural Management: The Case of Tokyo Disneyland's Organizational Culture and Japanese Work Values," Academy of International Business, U.S. Northeast Region Annual Conference, June 1-3, 1995.
- "Cross-Cultural Business Education: The Role of International Study Tour Courses," Academy of International Business, U.S. Northeast Region Annual Conference, June 1-3, 1995.
- "Cross-Cultural Management: The Case of Euro Disney's Work Values and Policies," (with S. Ciosek), European Academy of International Business, Lisbon, Portugal, December 12-15, 1993.
- "International Service Designs: Implications for Strategy and Structure," Strategic Management Society, Chicago, September 12-15, 1993.
- "International Service Designs: The Eclectic Paradigm Approach," Frontiers in Services Conference, American Marketing Association and Center for Services Marketing, Nashville, September 24-26, 1992.
- "Transnational Production and Consumption of Services: Implications for Strategies and Organizational Design." (with E. Belding), Academy of International Business, Miami, October 17-20, 1991.
- "Strategies and Organizational Characteristics of Global Service Companies: An Integrative Contingency Approach," (with S. Parton) 10th Annual Strategic Management Society Conference, Stockholm, 1990.
- "Enhancing Socio-Cultural Interaction through Development of Travel Packages," Tourism -A Vital Force for Peace First Global Congress, Vancouver, British Colombia, Canada, October 23-27. 1988.

**UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF FLORIDA**

NORWEGIAN CRUISE LINE HOLDINGS LTD., a Bermuda Company; **NCL (BAHAMAS) LTD.**, d/b/a NORWEGIAN CRUISE LINE, a Bermuda Company; **SEVEN SEAS CRUISES S. DE R.L.**, d/b/a REGENT SEVEN SEAS CRUISES, a Panama Limited Liability Company; **OCEANIA CRUISES S. DE R.L.**, d/b/a OCEANIA CRUISES, a Panama Limited Liability Company;

Plaintiffs,

v.

SCOTT A. RIVKEES, M.D., State Surgeon General and Head of the Florida Department of Health, in his official capacity;

Defendant.

Case No. 1:21-cv-22492-KMW

DECLARATION OF DR. STEPHEN OSTROFF

I, Dr. Stephen Ostroff, declare as follows:

1. I am over the age of eighteen (18) years and am competent to make the statements contained herein.
2. I graduated from the University of Pennsylvania School of Medicine in 1981 and completed residencies in internal medicine at the University of Colorado Health Services Center and preventive medicine at the Centers for Disease Control and Prevention ("CDC"). I am board certified by the American Board of Internal Medicine.
3. I previously served as Deputy Director of the National Center for Infectious Diseases at the CDC. While in that role, I focused on emerging infectious diseases, food safety, and coordinating complex outbreak response. I worked at the CDC in various positions for 21 years. These positions included Associate Director for Epidemiologic Science at the National Center for Infectious Diseases, CDC Acting Deputy Director for Science and Public Health, Medical Epidemiologist for the Respiratory Diseases Branch of the Division of Bacterial and Mycotic Diseases within the National Center for Infectious Diseases, among others. I also previously held the positions of Director of the Bureau of Epidemiology and Acting Physician

General for the Commonwealth of Pennsylvania.

4. I have worked in many other government and consulting roles, including as Chief Scientist of the Food and Drug Administration (“FDA”), Deputy Commissioner for Foods and Veterinary Medicine, Acting Commissioner of the FDA, Senior Public Health Advisor and Chief Medical Officer of the Center for Food Safety and Applied Nutrition, Representative to the Pacific Islands for the U.S. Department of Health and Human Services, consultant to the World Bank, and others. In 2019, I received the FDA Distinguished Career Service Award.

5. Since 2019, I have consulted with many large companies and other institutions on strategies and protocols to keep their workforces safe, especially during the COVID-19 pandemic. I have spent a total of 41 years working in the fields of medicine and public health and have published more than 90 peer-reviewed journal articles on public health and related topics. A copy of my CV is attached as **Exhibit 1**.

6. During my time at the CDC, I coordinated investigations of complex outbreaks, including the Ebola virus, the West Nile Virus, SARS, the 2001 Anthrax Attacks, and the Bird Flu. These investigations involved, among other goals and depending on the circumstances, determining the source of the outbreaks, implementing measures to prevent further spread of disease, and coordinating response strategies across many jurisdictions and agencies.

7. While at the CDC, I served as Deputy Director of the Center that includes the Division of Global Migration and Quarantine (“DGMQ”). In that position, I was involved in decisions related to quarantine and other border control measures in response to public health issues or crises. Although CDC exercised that power rarely, I was involved in assessing whether and to what extent such measures were appropriate and to make recommendations based on all relevant considerations.

8. I have worked primarily as a consultant since 2019. I have advised pharmaceutical companies, large law firms, investment firms, professional sports teams, and others on policies and protocols to maintain workplace safety throughout the COVID-19 pandemic.

9. I have also been advising the cruise industry. I sat on the Healthy Sail Panel, a group of advisers convened by Royal Caribbean Group (“RCG”) and Norwegian Cruise Line Holdings (“NCLH”) to develop recommendations that enable the cruise industry to operate safely throughout the COVID-19 pandemic. Those recommendations are attached as **Exhibit 2**.

10. The COVID-19 pandemic is not over, and it continues to pose a threat to the cruise

industry. Absent proper precautionary measures, new variants of COVID-19 present an increased risk of transmission in areas where large numbers of people gather in close quarters, such as cruise ships. This risk is heightened if individuals who have not been fully vaccinated against COVID-19 are present in such areas.

11. Various strategies exist to reduce COVID-19-related risks. These strategies include wearing masks, widespread and regular COVID-19 testing, and most importantly vaccination. These strategies in combination are likely most efficacious at preventing the transmission and severe effects of COVID-19. But, of these strategies, vaccination against COVID-19 is easily the single most important preventive modality.

12. COVID-19 vaccines (1) protect recipients from being infected with the virus; (2) reduce the severity of illness in those who contract COVID-19; and (3) reduce the risk of transmission of COVID-19 to others. All of these benefits are critical in a cruise ship setting.

13. Mask wearing has been shown to reduce the potential for transmission of the virus and to a lesser degree protect the wearer. But wearing masks does not reduce risks the same degree that vaccination with any of the currently available vaccines does. Testing will reduce the likelihood that an infected person boards the ship, but it will not affect disease severity or subsequent transmission.

14. The mRNA vaccines developed by Pfizer and Moderna have an overall protective efficacy of about 95 percent against the original version of the COVID-19 virus and up to 90 percent against the more transmissible Delta variant, providing between 95 to 98 percent reduction in the likelihood of severe infection if one does contract the disease. Data also show that Pfizer and Moderna vaccines can result in an 80 to 90 percent reduction in transmission of COVID-19 from a fully vaccinated individual. The Johnson & Johnson vaccine is less efficacious than Moderna and Pfizer vaccines, but still provides strong protection against all known variants and is highly protective against severe disease.

15. Testing is an important adjunct measure but cannot serve as a substitute for vaccination. COVID-19 tests are susceptible to false positive and false negative results, even when repeated testing is done. False negative results occur for many reasons, including test design, low viral burden, and improper specimen collection and handling. The level of protection of masks is highly dependent on the type of mask used and how well they fit each individual. Most of the masks in common use have relatively low levels of protection against transmitting the

virus. The level of protection offered by masks is also highly dependent on how properly and consistently an individual wears it. Because studies indicate the level of virus present can be higher with some of the recent variants, the level of protection offered by masking may correspondingly be less.

16. Requiring that all passengers and crew be fully vaccinated is the single best way to guard against COVID-19 transmission on cruise ships. Preventing unvaccinated individuals from coming aboard cruise ships minimizes the risk that passengers and crew members will develop COVID-19, and reduces the possibility of severe illness if they do become infected.

17. New variants of the COVID-19 virus, such as the Delta variant, spread more easily than previous versions of the virus, and may be up to four times more transmissible. Ensuring that 100% of passengers and crew are fully vaccinated is by far the best way to mitigate COVID-19-related risks.

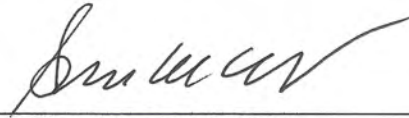
18. For cruise lines to effectively implement passenger and crew vaccination requirements, there must be an adequate way to verify vaccination status.

19. In my experience, it is not uncommon for individuals to attempt to evade public health screening protocols designed to prevent or slow the spread of disease. For example, individuals being screened for tuberculosis would take doses of TB medications in order to have a negative sputum test. Similarly, some individuals were found to skirt temperature screening protocols by taking fever reducing medications such as aspirin before having their temperatures checked.

20. A verification system based on official documentation is substantially more effective at confirming compliance with a vaccination requirement, will minimize attempts to avoid compliance, and gives an added level of assurance of the safety of the ship. No other approach to verifying vaccinations is as effective or reliable. Currently available antibody tests, which require blood collection, are not a reliable or reasonable alternative as proof of vaccination. Only documentation can supply appropriate proof.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on July 12, 2021

A handwritten signature in black ink, appearing to read "Dr. Stephen Ostroff", written above a horizontal line.

DR. STEPHEN OSTROFF

Exhibit 1

CURRICULUM VITAE

Stephen M. Ostroff, MD
310 Autumn Chase
Harrisburg PA 17110

Education:

College: University of Pennsylvania, Philadelphia, PA 1973-1977
Bachelor of Arts, Biology, Magna Cum Laude

Medical School: University of Pennsylvania, Philadelphia, PA 1977-1981
Doctor of Medicine

Post Graduate Training:

Residency: University of Colorado Health Sciences Center, Denver, CO 1981-1984
Program: Internal Medicine

Residency: Centers for Disease Control and Prevention, Atlanta, GA 1987-1989
Program: Preventive Medicine

Medical Licensure: Pennsylvania MD433885 (active)

Board Certification: American Board of Internal Medicine - 1984

Employment:

2019-present S Ostroff Consulting, LLC, Harrisburg PA

2013-2019 U.S. Food and Drug Administration, Silver Spring MD

2015-2016 (1) Commissioner (Acting) of Food and Drugs
2017 (2)

Responsibility for overall management of the FDA, which regulates food products, drugs, cosmetics, and certain tobacco products marketed in the United States.

2016- 2019 Deputy Commissioner for Foods and Veterinary Medicine
Office of Foods and Veterinary Medicine

Responsibility for coordination, management and leadership of the FDA's food program and veterinary medicine program. Includes supervision of the Office of Foods and Veterinary Medicine.

2014-2015 Chief Scientist
Office of the Commissioner

The Chief Scientist is responsible for leading and coordinating FDA's cross-cutting scientific and public health efforts. The Office of the Chief Scientist works closely with FDA's product centers, providing strategic leadership and support for FDA's regulatory

science and innovation initiatives. These initiatives include the Advancing Regulatory Science Initiative, the Critical Path Initiative, scientific professional development, scientific integrity, and the Medical Countermeasure initiative.

2013-2014 Senior Public Health Advisor & Chief Medical Officer
Center for Food Safety and Applied Nutrition
Office of Foods and Veterinary Medicine

Serves as a senior medical and public advisor on the public health implications of issues involving foods, animal feeds, nutrition, and dietary supplements, and serves as FDA spokesperson for human health issues associated with these programs.

2007-2013 Director, Bureau of Epidemiology
Physician General (Acting) (2009-2013)
Pennsylvania Department of Health
Harrisburg PA

Supervise approximately 70-person bureau responsible for disease surveillance and investigations in the Commonwealth of Pennsylvania. Areas of responsibility: infectious disease epidemiology, environmental health, and chronic disease. Physical General acts as chief advisor to the Secretary of Health and the Commonwealth on medical issues affecting public health.

2006-2007 World Bank
Human Health Consultant – South Asia Region
Honolulu HI

Served as consultant to World Bank on project development and implementation related to avian influenza and disease surveillance in south Asia region (Afghanistan, Pakistan, India, Sri Lanka, Bangladesh, Nepal, and Bhutan).

2005-2006 U.S. Department of Health and Human Services (HHS)
Office of Global Health Affairs
HHS Representative to the Pacific Islands
Honolulu HI

Coordinated HHS activities in the US affiliated Pacific Islands, including those of the Centers for Disease Control and Prevention and Health Resources and Services Administration (HRSA). Developed activities for US-affiliated Pacific in preparedness for avian influenza. Coordinated health-related activities with US Department of Interior, Department of Defense, and Department of State.

1988-2005 Centers for Disease Control and Prevention, Atlanta, GA

2002-2005 Deputy Director, National Center for Infectious Disease
Assistant Surgeon General

Coordinated complex investigations such as monkeypox, severe acute respiratory

infection (SARS), avian influenza in 2004, and tsunami response in 2004. Executive secretary of NCID Board of Scientific Counselors. President of Department of Defense Armed Forces Epidemiology Board, and engaged in NCID bioterrorism and emerging infectious disease activities. Served as member of US delegation to International Health Regulations Intergovernmental Working Group, including technical advisor to WHO on decision instrument for reporting.

1993-2002 Associate Director for Epidemiologic Science
National Center for Infectious Diseases

Responsible for conduct of epidemiologic investigations in the National Center for Infectious Diseases, including outbreak investigations and research activities. Major outbreaks included hantavirus pulmonary syndrome in 1993, Ebola hemorrhagic fever in 1995, avian influenza in 1997, West Nile virus in 1999, and anthrax in 2001. Responsible for approximately 40 Epidemic Intelligence Officers per year in NCID, submission and tracking of approximately 500 active research protocols. Chaired surveillance subcommittee on emerging diseases for Office of Science and Technology Policy's CISET committee. Coordinated CDC activities related to 1997 Food Safety Initiative with USDA and FDA. Consulted with World Bank on projects to improve surveillance capacity in Brazil and Argentina. Consultant to European Union on assessment of the European Epidemiology Training Program (EPIET). Appointed HHS coordinator for West Nile virus, and coordinated cross-departmental US Government activities related to West Nile virus. Appointed acting director of CDC's Select Agent Program; oversaw rewriting of select agent regulations in 2002.

1999 CDC Deputy Director for Science and Public Health (Acting)

1990-1993 Medical Epidemiologist, Respiratory Diseases Branch
Division of Bacterial and Mycotic Diseases, National Center for Infectious Diseases

Responsible for surveillance and investigation of non-tuberculous mycobacteria (NTM). Oversaw investigations of nosocomial and community clusters due to NTM, including Buruli ulcer in west Africa, *M. xenopi* in Indiana, and *M. haemophilum* in New York. Participated in investigations of NTM in persons with cystic fibrosis, and authored guidelines on prevention of *M. avium* complex in persons with HIV. Conducted studies in Egypt assessing World Health Organization guidelines for monitoring patterns of antimicrobial resistance among children with pneumonia. Coordinated development of National Action Plan for Multidrug Resistant Tuberculosis in response to rising incidence of MDRTB in the United States.

1989-1990 Medical Epidemiologist, Epidemiology Office
Division of Viral and Rickettsial Diseases, National Center for Infectious Diseases

Conducted surveillance for influenza, updated guidelines for control and prevention of influenza, investigated cluster of infections due to lymphocytic choriomeningitis virus, investigated outbreak of Ebola infections among non-human primates and workers in Reston VA, Indonesia, and the Philippines.

1988-1989 Preventive Medicine Residency, Enteric Diseases Branch

Division of Bacterial Diseases, National Center for Infectious Diseases

Conducted investigations of shigellosis, performed studies of sporadic yersiniosis in Norway, and evaluated patterns of *Campylobacter* strains submitted to the Centers for Disease Control

1986-1988 US Public Health Service - Centers for Disease Control
Epidemic Intelligence Service, Washington State Department of Social & Health Services, Communicable Disease Epidemiology Section, Seattle WA

Conducted outbreak investigations, including early community outbreaks of *E.coli* O157:H7; evaluated statewide reporting systems, facilitated addition of *E. coli* O157:H7 to the list of reportable diseases.

1984-1986 US Public Health Service - National Health Service Corps
Internal Medicine, Pohnpei State Hospital, Kolonia, Pohnpei, Federated States of Micronesia

Served as internist for approximately 35,000 persons in Micronesia. Responsible for 35 bed medical ward, out-patient clinic, and mentored medical students from the University of Hawaii School of Medicine.

Faculty Appointments:

1985-1986 University of Hawaii John A. Burns School of Medicine - Assistant Clinical Professor of Medicine
2009-present Penn State University College of Medicine – Adjunct Professor of Public Health Sciences
2019-present University of Pittsburgh Graduate School of Public Health – Adjunct Professor of Epidemiology

Honor Society: Phi Beta Kappa - University of Pennsylvania

Public Health Service Awards:

PHS Citation, Foreign Service Award; Isolated Hardship Award; Outstanding Unit Citation (multiple); Unit Commendation (multiple); Secretary's Recognition, Meritorious Service Medal, Secretary's Award for Distinguished Service

Selected Other Awards:

Defense Intelligence Agency Director's Award
Secretary of Defense Medal for Outstanding Public Service
U.S. Environmental Protection Agency Bronze Medal for Commendable Service
Pennsauken (NJ) High School Wall of Fame (2002)
FDA Commissioner's Special Citation (SARS Workshop and Review Team)
Council of State and Territorial Epidemiologists Pump Handle Award (2013)
FDA Distinguished Career Service Award (2019)

Appointments:

Foundations of Microbiology Lecturer - American Society for Microbiology 1995-1997
 Co-chair - Scientific Committee for the International Society for Travel Medicine Biannual Meeting, 5th meeting (1997) Geneva, Switzerland, 6th meeting (1999) Montreal Canada
 Scientific Review Committee - Robert Koch Institute, German Ministry of Health 1995
 Member, Scientific Advisory Board, Armed Forces Institute of Pathology 1996-1999
 Liaison, National Environmental Health Association, 1998
 Dispatch Editor, *Emerging Infectious Diseases*, 1995-2002 Editorial Board 2002-present
 Co-chair, Surveillance and Response Subcommittee, Emerging Infectious Diseases Working Group, Committee on Science, Engineering, and Technology of the National Science and Technology Council 1996-2000
 Member, Emerging Infectious Diseases Committee, Infectious Disease Society of America 1998-2001
 Fellow, Infectious Disease Society of America 1998-present
 Member, American Epidemiological Society, 1999-present
 Member, Department of Defense Armed Forces Epidemiology Board; Chair, Disease Control Subcommittee, 1999-2000, President 2001-2005
 Special Advisor to the President, International Society for Travel Medicine, 2001-2005
 Advisory Board, U. of Southern California Annenberg School of Communications Norman Lear Center "Hollywood, Health, and Society" 2001-2013.
 Technical Advisor- World Health Organization – Decision Instrument for revised International Health Regulations – February 2005
 Member, US Delegation to the World Health Organization Intergovernmental Work Group for the International Health Regulations – 2004-2005
 Member, Scientific Advisory Committee – Pacific Marine Biomedical Research Center – University of Hawaii 2005-2007
 Member, American Society for Microbiology Public and Scientific Affairs Board Committee on Public Health 2007-2015, Chair 2008-2015
 Chair, Pennsylvania Department of Health Institutional Review Board, 2008-2012
 Member, Pennsylvania State Board of Medicine, 2008-2012
 Member, Committee on Assessment of Future Scientific Needs for Live Variola Virus, Institute of Medicine, National Academies of Science 2008-2009
 Secretary-Treasurer (2008-2009) President Elect (2009-2010), President (2010-2011), Vice-President (2011-2012), Council of State and Territorial Epidemiologists (CSTE)
 Member, Society for Healthcare Epidemiology of America Public Policy and Government Affairs Committee, 2009-2010
 Member, National Healthcare Safety Network Working Group, Centers for Disease Control and Prevention, 2009-2013
 Member, Healthcare Infection Control Practices Advisory Committee (HICPAC), Centers for Disease Control and Prevention, 2010-2013
 HICPAC Liaison Member, Office of Infectious Diseases Board of Scientific Counselors, Centers for Disease Control and Prevention, 2010-2013
 Member, Committee on Lyme Disease and Other Tick-Borne Diseases: The State of the Science, Institute of Medicine, National Academies of Science, 2010-2011
 Member, Global and Regional Biosurveillance Collaboration Task Force, National Biosurveillance Advisory Subcommittee, Advisory Committee to the CDC Director, 2010-2012
 Fellow, American College of Physicians, 2010-present.
 Member, Commission on Public Health, Pennsylvania Medical Society, 2010-2013
 Commissioned Officer, Food and Drug Administration, 2011-2013
 Member, Committee on the Evaluation of an Updated Site-Specific Risk Assessment for the National Bio- and Agro-Defense Facility in Manhattan Kansas, National Research Council, National Academies of

Science, 2011- 2012

Member, Academy of Medicine of Washington DC, 2014-present

Member, Planning Committee for Workshop on Advancing the Discipline of Regulatory Science for Medical Product Development: An Update on Progress and a Forward-Looking Agenda, National Academy of Medicine, 2015.

Member, Board of Trustees, U.S. Pharmacopeia, Rockville MD, 2020-2025

Peer Reviewed Publications:

1. Brown MJ, Iwamori M, Kishimoto Y, et.al. Endoneurial lipid composition of normal human sural nerve. *Ann Neurol* 1979;5:239-44.
2. Griffin PG, Ostroff SM, Tauxe RV, et.al. Illnesses associated with *Escherichia coli* O157:H7 infections. *Ann Intern Med* 1988;109:705-12.
3. Goldbaum GM, Ostroff SM, Novotny TE. The costs of smoking for Washington state. *Washington Public Health* 1988;7:37-8.
4. Ostroff SM, Tarr PI, Neill MA, Lewis JH, Kobayashi JM. Toxin genotypes and plasmid profiles as determinants of systemic sequelae in *Escherichia coli* O157:H7 infections. *J Infect Dis* 1989;160:994-8.
5. Ostroff SM, Kobayashi JM, Lewis JH. Infections with *Escherichia coli* O157:H7 in Washington state: the first year of statewide disease surveillance. *JAMA* 1989;262:355-9.
6. Ostroff SM, Kobayashi JM, Lewis JH. Epidemiology and complications of *Escherichia coli* O157:H7 infections (letter). *JAMA* 1989;262:3408.
7. Ostroff SM, Griffin PM, Tauxe RV, et al. A statewide outbreak of *Escherichia coli* O157:H7 infections in Washington state. *Am J Epidemiol* 1990;132:239-47.
8. Wells JG, Shipman LD, Greene KD, et.al. Isolation of *Escherichia coli* O157:H7 and other shiga-like toxin-producing *E. coli* from dairy cattle. *J Clin Microbiol* 1991;29:985-9.
9. Lee LA, Ostroff SM, McGee HB, et.al. An outbreak of shigellosis at an outdoor music festival. *Am J Epidemiol* 1991;133:608-15.
10. Tauxe RV, Griffin PG, Ostroff SM, Wachsmuth IK. The public health importance of *Escherichia coli* O157:H7 (letter). *Laboratory Med* 1991;22:55-6.
11. Barrett TJ, Green JH, Griffin PM, et.al. Enzyme-linked immunosorbent assays for detecting antibodies to Shiga-like toxin I, Shiga-like toxin II, and *Escherichia coli* O157:H7 lipopolysaccharide in human serum. *Current Microbiol* 1991;23:189-95.
12. Mahy BWJ, Dykewicz CA, Fisher-Hoch S, Ostroff S, Tipple M, Sanchez A. Virus zoonoses and their potential for contamination of cell cultures. *Develop Biol Standard* 1991;75:183-9.
13. Ostroff SM, Hopkins DP, Sowers EG, Strockbine NK, Tauxe RV. Surveillance of *Escherichia coli* O157 isolation and confirmation, United States, 1988. *Morb Mort Week Rpt Surveillance Summary*, 1991;40-SS1:1-6.
14. Andrus JK, Ostroff SM, Kobayashi JM, Horan JM, Fleming DW. Patient care directives and infection control: the potential conflict of interest during epidemics in long-term care facilities. *Am J Prev Med* 1992;8:203-6.
15. Dykewicz CA, Dato GA, Fisher-Hoch SA, et al. Lymphocytic choriomeningitis outbreak associated with nude mice. *JAMA* 1992;267:1349-53.
16. Kapperud G, Lassen J, Ostroff SM, Aasen S. Clinical features of sporadic *Campylobacter* infections in Norway. *Scand J Infect Dis* 1992;24:741-9.
17. Ostroff SM, Kapperud G, Lassen J, Aasen S, Tauxe RV. Clinical features of sporadic *Yersinia enterocolitica* infections in Norway. *J Infect Dis* 1992;166:812-7.
18. Kapperud G, Skjerve E, Hargrett-Bean N, Ostroff SM, Lassen J. Risk factors for sporadic *Campylobacter*

- infections: results of a case-control study in southeastern Norway. *J Clin Microbiol* 1992;30:3117-21.
19. Patton CM, Nicholson MA, Ostroff SM, Ries AA, Wachsmuth IK, Blake PA. Common somatic O and heat-labile serotypes among *Campylobacter* strains from sporadic cases in the United States. *J Clin Microbiol* 1993;31:1521-30.
 20. Sniadack DH, Ostroff SM, Karlix MA, et al. A nosocomial pseudo-outbreak of *Mycobacterium xenopi* due to a contaminated potable water supply: lessons in prevention. *Hosp Epidemiol Infect Control* 1993;14:636-41.
 21. Kapperud G, Skjerve E, Vik L, et.al. Epidemiologic investigation of risk factors for *Campylobacter* colonization in Norwegian broiler flocks. *Epidemiol Infect* 1993;111:245-5.
 22. Mandel AS, Sprauer MA, Ostroff SM, Sniadack DH. State regulation of hospital water temperature. *Hosp Epidemiol Infect Control* 1993;14:642-5.
 23. Yajko DM, Chin DP, Gonzalez PC, et al. *Mycobacterium avium* complex in water, food and soil samples collected from the environment of HIV-infected individuals. *J AIDS and Human Retrovirology* 1995;9:176-82.
 24. Straus WL, Ostroff SM, Jernigan DJ, et al. Clinical and epidemiologic characteristics of *Mycobacterium haemophilum*, an emerging pathogen in immunocompromised patients. *Ann Intern Med* 1994;120:118-25.
 25. Ostroff SM, Kapperud G, Hutwagner L, et al. Sources of sporadic *Yersinia enterocolitica* infections in Norway: A prospective case-control study. *Epidemiol Infect* 1994;112:133-41.
 26. Marston BJ, Horsburgh CR, Diallo M, et al. Emergence of Buruli ulcer disease in the Daloa region of Cote D'Ivoire. *Am J Trop Med Hyg* 1995;52:219-24.
 27. Horsburgh CR, Chin DP, Yajko DM, et al. Environmental risk factors for acquisition of *Mycobacterium avium* complex in persons with human immunodeficiency virus infection. *J Infect Dis* 1994;170:362-7.
 28. Chin DP, Hopewell PC, Yajko DM, et al. *Mycobacterium avium* in the respiratory or gastrointestinal tract and the risk of *M avium* complex bacteremia in patients with human immunodeficiency virus infection. *J Infect Dis* 1994;169:289-95.
 29. Chin DP, Reingold AL, Horsburgh CR, et al. Predicting *Mycobacterium avium* complex bacteremia in patients with the human immunodeficiency virus: prospectively validated models. *Clin Infect Dis* 1994;169:668-74.
 30. Chin DP, Reingold AL, Stone EN, et al. The impact of *Mycobacterium avium* complex bacteremia and its treatment on survival of AIDS patients--a prospective study. *J Infect Dis* 1994;170:578-84.
 31. Ussery XT, Bierman JA, Valway SE, Seitz TA, DiFerdinando GT, Ostroff SM. Transmission of multidrug-resistant *Mycobacterium tuberculosis* among persons exposed in a medical examiner's office, New York. *Hosp Epidemiol Infect Control* 1995;16:160-5.
 32. Kapperud G, Ostroff SM. Control and prevention of *Campylobacter* infections. Suggestions for the design, conduct, and analysis of an epidemiologic study aimed at identification of risk factors for *Campylobacter* infections in humans. World Health Organization WHO/EMC/ZOO/98.3, 1998.
 33. Ostroff SM, Spiegel RA, Feinberg J, Benson CA, Horsburgh CR Jr. Preventing disseminated *Mycobacterium avium* complex in the HIV-infected patient. *Clin Infect Dis* 1995;21:S72-6.
 34. Ostroff SM. *Yersinia* as an emerging infection: epidemiologic aspects of yersiniosis. *Contrib Immunol Microbiol* 1995;13:5-10.
 35. Kapperud G, Ostroff SM, Nesbakken T, et al. Risk factors for sporadic *Yersinia enterocolitica* infections in Norway: a case control study. *Contrib Microbiol Immunol* 1995;13:25-28.
 36. Harrison LH, Steinhoff MC, Sridharen G, et al. Evaluation of monovalent latex agglutination reagents for diagnosis of pneumococcal infection. *Diagn Microbiol Infect Dis* 1996;24:1-6.

37. Ostroff SM, Harrison LH, Khallaf N, et al. Resistance patterns of *Streptococcus pneumoniae* and *Haemophilus influenzae* isolates recovered in Egypt from children with pneumonia. Clin Infect Dis 1996;23:1069-74.
38. Butler JC, Kilmarx PH, Jernigan DB, Ostroff SM. Perspectives in fatal epidemics. Infect Dis Clin N Amer 1996;10:917-37.
39. Ostroff SM. Emerging infectious diseases in the institutional setting: another hot zone. Infect Control and Hosp Epidemiol 1996;17:484-9.
40. Noah DL, Sobel AL, Ostroff SM, Kildew JA. Biological warfare training; infectious disease outbreak differentiation criteria. Military Med 1998;163:198-201.
41. Ostroff SM, Kozarsky P. Emerging infections and travel medicine. Infect Dis Clin N Amer 1998;12:231-41.
42. Ostroff SM. Emerging infectious diseases and the Pacific: at the crossroads. Pacific Health Dialog 1998;5:167-70.
43. Fidler DP, Heymann DL, Ostroff SM, O'Brien TP. Emerging and reemerging infectious diseases: challenges for international, national, and state law. The International Lawyer 1997;31:773-99.
44. Bloch KC, Zwerling L, Pletcher M, et al. Incidence and clinical implications of isolation of *M. kansasii*: results of a 5-year, population based study. Ann Intern Med 1998;129:698-704.
45. Ostroff SM. Emerging infectious diseases 1997-1998: the role of molecular epidemiology. Mem Inst Oswaldo Cruz 1999;94:1-3.
46. Ostroff SM. Continuing challenge of pneumococcal disease (commentary). Lancet 1999;343:1201-2.
47. Petersen LR, Ammon A, Hamouda O, et al. Development of national epidemiologic capacity to meet the challenge of emerging infections in Germany. Emerg Infect Dis 2000;6:576-84.
48. Oliver JF, Ostroff SM. Preventing *Vibrio parahaemolyticus* infection (letter). JAMA 2000;285:42-3.
49. Rotz, LD, Khan AS, Lillibridge SR, Ostroff SM, Hughes JM. Public health assessment of potential biological terrorism agents. Emerg Infect Dis 2002;8:225-9.
50. Jernigan DB, Raghunathan PL, Bell BP, Brechner R, et al. Investigation of bioterrorism-related anthrax, United States, 2001: epidemiologic findings. Emerg Infect Dis 2002;8:1019-28.
51. Noah DL, Ostroff SM, Cropper L, Thacker SB. US military officer participation in the Centers for Disease Control and Prevention's Epidemic Intelligence Service, 1951-2001. Military Med 2003;168:368-72.
52. Halsell JS, Riddle JR, Atwood JE, et al. Myopericarditis following smallpox vaccination among vaccinia-naïve US military personnel. JAMA 2003;289:3283-9.
53. Talan DA, Abrahamian FM, Moran GJ, et al. Tetanus immunity and physician compliance with tetanus prophylaxis practices among emergency department patients presenting with wounds. Ann Emerg Med 2004;43:305-14.
54. M'ikanatha NM, Churchill RE, Lautenbach E, et al. Training programs to strengthen Pennsylvania's public health response. Biosecur Bioterror 2009;7:178-86.
55. Novel Swine-Origin Influenza A (H1N1) Virus Investigation Team, Dawood FS, Jain S, et al. Emergence of a novel swine-origin influenza A (H1N1) virus in humans. NEJM 2009;360:2605-15.
56. Chen TH, Kutty P, Lowe LE, et al. Measles outbreak associated with an international youth sporting event in the United States, 2007. Pediatr Infect Dis J 2010;29:794-800.
57. Armstrong KE, McNabb SJ, Ferland LE, et al. Capacity of public health surveillance to comply with the revised International Health Regulations, USA. Emerg Infect Dis 2010;16:804-8.
58. Behraves CB, Ferraro A, Deasy M, et al. Human Salmonella infections linked to contaminated dry dog and cat food, 2006-2008. Pediatrics 2010;126:477-83.
59. Seaman V, Dearwent SM, Gable D, et al. A multidisciplinary investigation of a polycythemia vera cancer

- cluster of unknown origin. *Int J Environ Res Public Health* 2010;7:1139-52
60. Ross T, Zimmer S, Burke D, et al. Seroprevalence following the second wave of pandemic 2009 H1N1 influenza. *PLoS One*, 2010 July 14;5(7):e11601.
 61. Marchbanks TL, Bhattarai A, Fagan RP, et al. An outbreak of 2009 pandemic influenza A (H1N1) in an elementary school, Pennsylvania 2009. *Clin Infect Dis* 2011;52:S154-60.
 62. Bhattarai A, Villanueva J, Palekar RS, et al. Viral shedding duration of pandemic A H1N1 virus during an elementary school outbreak, Pennsylvania May-June 2009. *Clin Infect Dis* 2011;52:S102-8.
 63. Donnelly CA, Finelli L, Cauchemez S, et al. Serial intervals and the temporal distribution of secondary infections within households of 2009 pandemic influenza A(H1N1): implications for influenza control recommendations. *Clin Infect Dis* 2011;52:S123-30.
 64. Cauchemez S, Bhattarai A, Marchbanks TM, et al. Role of social networks in shaping disease transmission during a community outbreak of 2009 H1N1 pandemic influenza. *Proc Natl Acad Sci USA* 2011;108:2825-30.
 65. Gift RL, Palekar RS, Sodha SV, et al. Household effects of school closure during pandemic (H1N1) 2009, Pennsylvania, USA. *Emerg Infect Dis* 2010;16:1315-7.
 66. Campagnolo ER, Rankin JT, Daverio SA, et al. Fatal pandemic (H1N1) 2009 influenza A virus infection in a Pennsylvania domestic cat. *J Zoonoses Pub Health* 2011;58:500-7.
 67. Ostroff SM. Measles: Going, going, but not gone (editorial). *J Infect Dis* 2011;203:1507-9.
 68. Mombouli JV, Ostroff SM. The remaining smallpox stocks: the healthiest outcome. *Lancet* 2012 (Jan 7);379:10-2.
 69. Short VL, Marriott C, Ostroff S, Waller K. Description and evaluation of the 2009-2010 Pennsylvania influenza sentinel school monitoring system. *Am J Public Health* 2011;101:2178-83.
 70. Palumbo, AJ, Loveless PA, Moll ME, Ostroff S. Evaluation of healthcare-associated infection surveillance in Pennsylvania hospitals. *Infect Control Hospital Epidemiol* 2012;33:105-11.
 71. Mombouli JV, Ostroff SM. The remaining smallpox stocks: the wrong debate? (letter). *Lancet* 2011;378;Nov12,e7.
 72. Stark JH, Sharma R, Ostroff S, et al. Local spatial and temporal processes of influenza in Pennsylvania USA: 2003-2009. *PLoS One* 2012;7(3):e35245, March 28.
 73. Stark JH, Cummings D, Ermentrout B, et al. Local variations in spatial synchrony of influenza epidemics. *PLoS One*. 2012;7(8):e43528, Aug 16.
 74. Wong KK, Greenbaum A, Moll ME, et al. Outbreak of novel influenza A (H3N2) variant virus infection among attendees of an agricultural fair, Pennsylvania, 2011. *Emerg Infect Dis*, 2012;18:1937-44.
 75. Thompson ND, Yeh LL, Magill SS, Ostroff SM, Fridkin SK. Investigating systematic misclassification of central line-associated bloodstream infection (CLABSI) to secondary bloodstream infection during healthcare-associated infection reporting. *Am J Med Qual* 2013 Jan-Feb;28:56-9.
 76. Campagnolo ER, Moll ME, Tuhacek K, et al. Concurrent 2009 pandemic influenza A(H1N1) virus infection in ferrets and in a community in Pennsylvania. *J Zoonoses Pub Health* 2013 Mar; 60:117-24.
 77. Miller JR, Short VL, Wu H, et al. Use of non-pharmaceutical interventions to reduce transmission of 2009 pandemic influenza A (pH1N1) in Pennsylvania public schools. *J School Health* 2013;83:281-9.
 78. Longenberger A, Palumbo A, Chu A, Moll M, Weltman A, Ostroff S. *Campylobacter jejuni* infections associated with unpasteurized milk – multiple states, 2012. *Clin Infect Dis* 2013;57:263-6.
 79. Longenberger AH, Gronostaj MP, Yee GY, et al. *Yersinia enterocolitica* infections associated with improperly pasteurized milk, southwest Pennsylvania, March-August 2011. *Epidemiol Infect* 2013;Oct 16;1-11.
 80. Ma ZQ, Kuller LH, Fisher MA, Ostroff SM. Use of interrupted time series method to evaluate tobacco

excise tax increase impact in Pennsylvania, 2000-2009. *Prev Chronic Dis* 2013;Oct 3:E169.

81. Campagnolo ER, Lind LR, Long JH, et al. Human exposure to rabid free-ranging cats: a continuing public health concern in Pennsylvania. *J Zoonoses Pub Health* 2014;61;346-55.
82. Wong KK, Gambhir M, Finelli L, Swerdlow DL, Ostroff S, Reed C. Transmissibility of variant influenza from swine to humans: a modeling approach. *Clin Infect Dis* 2013;57(S1):S16-22.
83. Ostroff SM. West Nile virus – too important to forget (editorial). *JAMA* 2013;310:267-8.
84. Sandt CH, Fedorka-Cray PJ, Tewari D, Ostroff S, Joyce K, M'ikanatha NM. A comparison of non-typhoidal *Salmonella* from humans and food animals using pulsed-field gel electrophoresis and antimicrobial susceptibility patterns. *PLoS One* 2013 Oct 30;8(10): e77836.
85. Hung MA, Epperson S, Biggerstaff M, et al. Outbreak of variant influenza A (H3N2) virus in the United States. *Clin Infect Dis* 2013;57:1703-12.
86. Greenbaum AH, Wong K, Nguyen DB, et al. Assessment for possible healthcare-associated transmission of a new variant influenza virus - Pennsylvania, August 2011. *Infect Control Hosp Epidemiol* 2013;34:1306-9.
87. Beaudoin AL, Torso L, Richards K, et al. Invasive group A *Streptococcus* infections associated with liposuction surgery not subject to state or federal regulation. *JAMA Intern Med* 2014;174:1136-42.
88. Tong W, Ostroff S, Blais B, et al. Genomics in the land of regulatory science. *Reg Toxicol Pharmacol* 2015;72:102-6.
89. Califf RM, Ostroff SM. Sunscreen and the FDA (letter). *N Engl J Med* 2015;373:197.
90. Califf RM, Ostroff SM. FDA as a catalyst for translation. *Science Transl Med* 2015;7:296ed9. doi: 10.1126/scitranslmed.aabb2404.
91. Ostroff S. Remarks of the FDA Commissioner: The Food and Drug Law Institute's 58th Annual Conference. *Food Drug Law J* 2015;70:237-42.
92. Califf RM, Woodcock J, Ostroff S. A proactive approach to prescription opioid abuse. *N Engl J Med* 2016;374:1480-5.
93. Healy MJ, Tong W, Ostroff S, et al. Regulatory bioinformatics for food and drug safety. *Reg Toxicol Pharmacol* 2016, S0273-2300(16)30134-9. doi:10.1016/j.yrtph.2016.05.021.
94. Ostroff S. Remarks by Acting FDA Commissioner: FDLI Annual Conference. *Food Drug Law J* 2017;72;378-85

Book Chapters and Published Reports:

1. Hughes JM, Hatheway C, Ostroff SM. Botulism, in Infections of the Central Nervous System, 2nd ed. Scheld WM, editor. Lippincott-Raven, Philadelphia PA 1997. p. 615-28.
2. Ostroff SM, Hughes JM. Emerging infections, in Maxcy-Rosenau-Last Public Health and Preventive Medicine, 14th ed. Wallace RB, editor. Appleton & Lange, Norwalk CT. 1998. p. 71-5.
3. Ottesen EA, Dowdle WR, Fenner F, et al. How is eradication to be defined and what are the biological criteria?, in The Eradication of Infectious Diseases: Dahlem Workshop Reports, Dowdle WR and Hopkins DR, editors. John Wiley & Sons, Chichester GB 1997. p. 47-59.
4. Ostroff SM, LeDuc JW. Global epidemiology of infectious diseases, in Mandell, Douglas, and Bennett's Principals and Practices of Infectious Diseases, 5th ed. Mandell GL, Bennett JE, Dolin R editors, Churchill Livingstone, New York NY, 1999. p. 167-78.
5. Ostroff SM. New and emerging infectious diseases: the view from the Centers for Disease Control and Prevention, in Mikrobielle Evolution und Infektion - 50 Tagung der DGMH und 25 Jahrestagung der DHI, Göbel UT editor, Einhorn-Press Verlag GmbH, Reinbek Germany, 1998. p. 110-6.
6. LeDuc JW, Ostroff SM, McDade JE, Lillibridge S, Hughes JM. The role of the public health community in

- detecting and responding to domestic terrorism involving infectious agents, in Emerging Infections 3, Scheld WM, Craig WA, Hughes JM, editors, ASM Press, Washington D.C, 1999. p. 219-30.
1. Ostroff SM. Yersinia infections (I. Basic biology, II. Pathogenesis and clinical features, III. Diagnosis and treatment), in UpToDate, Rose BD editor-in-chief, UpToDate, Inc, Wellesley MA, 1999.
 2. Ostroff SM. Emerging infections and travel medicine, in The Textbook of Travel Medicine and Health, DuPont HL, Steffan R editors. B.C. Decker Inc, Pittsburgh PA, 2001, p. 137-50.
 3. Ostroff SM, McDade JE, LeDuc JW, Hughes JM. Emerging and Reemerging Infectious Disease Threats in Mandell, Douglas, and Bennett's Principals and Practices of Infectious Diseases, 6th ed. Mandell GL, Bennett JE, Dolin R editors, Elsevier Churchill Livingston, New York NY, 2004. p. 173-92.
 4. Ostroff SM, Hughes JM. Emerging Microbial Threats to Health and Security, in Maxcy-Rosenau-Last Public Health and Preventive Medicine, 15th ed. Wallace RB, Kohatsu N, editors, McGraw Hill, New York NY, 2007. p. 79-87.
 5. Levitt AM, Drotman DP, Ostroff SM. Control of Infectious Diseases: A Twentieth-Century Public Health Achievement, in Silent Victories: The History and Practice of Public Health in Twentieth-Century America, Ward JW, Warren C, editors, Oxford University Press, New York NY, 2007, p. 3-17.
 6. Ostroff SM. The Spread of Disease in the 20th Century and Lessons for the 21st Century, in Travel Medicine: Tales Behind the Science, Wilder-Smith A, Schwartz E, Shaw M editors, Elsevier Ltd., Amsterdam, The Netherlands, 2007, p. 305-11.
 7. Ostroff SM. Promotion of Quality in the Practice of Travel Medicine, in CDC Health Information for International Travel 2010, Brunette GW, Kozarsky PE, Magill AJ, Shlim DR editors, Elsevier Mosby Inc, Philadelphia PA, 2009, p. 501-4.
 8. Khabbaz RF, Ostroff SM, Leduc JW, Hughes JM. Emerging and Reemerging Infectious Disease Threats in Mandell, Douglas, and Bennett's Principals and Practices of Infectious Diseases, 7th ed. Mandell GL, Bennett JM, Dolin R editors, Elsevier Churchill Livingston, New York, NY, 2009, p. 199-219.
 9. Committee on the Assessment of Future Scientific Needs for Live Variola Virus. Live Variola Virus: Considerations for Continuing Research, Arvin AM, Patel DM, editors, The National Academies Press, Washington DC, 2009.
 10. Ostroff SM. Role of the Traveler in Translocation of Disease, in CDC Health Information for International Travel, 2012, Brunette GW, Kozarsky PE, Magill AJ, Shlim DR editors, Oxford University Press Inc, New York NY, 2011, p.15-9.
 11. Ostroff SM. Promotion of Quality in the Practice of Travel Medicine, in CDC Health Information for International Travel 2012, Brunette GW, Kozarsky PE, Magill AJ, Shlim DR editors, Oxford University Press Inc, New York NY, 2011, p. 584-7.
 12. Committee on Lyme Disease and Other Tickborne Diseases: The State of the Science. Critical Needs and Gaps in Understanding Prevention, Amelioration, and Resolution of Lyme and Other Tickborne Diseases: The Short-Term and Long-Term Outcomes. Workshop Report. The National Academies Press, Washington DC, 2011.
 13. Ostroff SM. Role of the Traveler in Translocation of Disease, in CDC Health Information for International Travel 2014, Brunette GW, Kozarsky PE, Cohen NJ, et al editors, Oxford University Press Inc, New York NY, 2013, p. 14-20.
 14. Ostroff SM. Promoting Quality in the Practice of Travel Medicine, in CDC Health Information for International Travel 2014, Brunette GW, Kozarsky PE, Cohen NJ, et al editors, Oxford University Press Inc, New York NY, 2013, p. 618-21.
 15. Committee on the Evaluation of the Updated Site-Specific Risk Assessment for the National Bio- and Agro-Defense Facility in Manhattan, Kansas. Evaluation of the Updated Site-Specific Risk Assessment for the

National Bio- and Agro-Defense Facility in Manhattan, Kansas. The National Academies Press, Washington DC, 2012.

16. Ostroff SM. Forward, in Concepts and Methods in Infectious Disease Surveillance, Mikanatha N, Iskander J, editors, John Wiley & Sons, Chichester GB, 2014, p. x-xii.
17. Khabbaz RF, Bell BP, Schuchat A, Ostroff SM, Moseley R, Levitt A, Hughes JM. Emerging and Reemerging Infectious Disease Threats, in Mandell, Douglas, and Bennett's Principals and Practices of Infectious Diseases, 8th ed. Blaser MA, et al. editors, Elsevier Churchill Livingston, New York, NY, 2014, p. 158-77.
18. Ostroff SM. Role of the Traveler in Translocation of Disease, in CDC Health Information for International Travel, 2016, Brunette GW, Kozarsky PE, Cohen NJ, et al editors, Oxford University Press, New York NY, 2016, p.15-22.
19. Ostroff SM. Promoting Quality in the Practice of Travel Medicine, in CDC Health Information for International Travel, 2016, Brunette GW, Kozarsky PE, Cohen NJ, et al editors, Oxford University Press, New York NY, 2016, p. 634-7.
20. Forum on Drug Discovery, Development and Translation. Advancing the Discipline of Regulatory Science for Medical Product Development: An Update on Progress and a Forward-Looking Agenda - Workshop Summary. The National Academies Press, Washington DC, 2016.
21. Ostroff SM, Hughes JM. Emerging Microbial Threats to Health, in Maxcy-Rosenau-Last Public Health and Preventive Medicine, 16th ed. Bolton M, et al editors, McGraw Hill, New York NY, submitted Oct 2018.
22. Lee K, Ostroff SM. Appendix A: Promoting Quality in the Practice of Travel Medicine, in CDC Health Information for International Travel, 2020. Brunette GW, Nemhauser JB, Kozarsky PE, et al. editors, Oxford University Press, New York NY, 2019, p. 653-6.
23. Ostroff SM. Regulation of Cannabis-Containing Products in the U.S. Food and Beverage Supply. In Cannabis Law: A Primer on Federal and State Law Regarding Marijuana, Hemp, and CBD. Cohen B, editor. American Bar Association Publishing, Chicago IL, 2021, p. 199-213.

Medical Editor

1. CDC Health Information for International Travel 2014, Brunette GW, Kozarsky PE, Cohen NJ, et al editors, Oxford University Press Inc, New York NY, 2013.
2. CDC Health Information for International Travel 2016, Brunette GW, Kozarsky PE, Cohen NJ, et al editors, Oxford University Press Inc, New York NY, 2015.
3. CDC Health Information for International Travel 2018, Brunette GW, Kozarsky PE, Brown CM, et al editors, Oxford University Press Inc, New York NY, 2017.
4. CDC Health Information for International Travel 2020. Brunette GW, Nemhauser JB, Kozarsky PE, et al editors, Oxford University Press Inc, New York NY, 2019.

Non-Peer Reviewed Publications:

1. Scombroid fish poisoning - Illinois, South Carolina. MMWR 1989;38:147-9.
2. Influenza activity - Worldwide, 1988-89. MMWR 1989;38:817-8.
3. Ebola virus infection in imported primates - Virginia, 1989. MMWR 1989;38:831-7.
4. Update: Ebola-related filovirus infection in nonhuman primates and interim guidelines for handling nonhuman primates during transit and quarantine. MMWR 1990;39:22-4,29-30.
5. Update: Influenza - United States 1989-90. MMWR 1990;39:157-8.

6. Update: Filovirus infection associated with contact with nonhuman primates or their tissues. MMWR 1990;39:404-5.
7. Mycobacterium haemophilum Infections - New York City Metropolitan Area, 1990-1991. MMWR 1991;40:636-7, 643.
8. Outbreak of Acute Illness - Southwestern United States, 1993. MMWR 1993;42:421-4.
9. Update: Outbreak of hantavirus infections. MMWR 1993;42:441-2.
10. Update: Outbreak of hantavirus infection - Southwestern United States. MMWR 1993;42:477-8.
11. Update: Outbreak of hantavirus infection - Southwestern United States. MMWR 1993;42:495-6.
12. Update: Hantavirus infection - United States. MMWR 1993;42:517.
13. Update: Hantavirus disease - Southwestern United States. MMWR 1993;42:570-1.
14. Hantavirus associated illness - North Dakota, 1993. MMWR 1993;42:707.
15. Progress in the development of hantavirus diagnostic assays - United States. MMWR 1993;42:770-1.
16. Hantavirus pulmonary syndrome - United States, 1993. MMWR 1994;43:45-8.
17. Deresinski SC, Khan A, Koster F, Ostroff SM, Stevens DL. Emerging Infections: Beyond the Hype. Patient Care 1995;29:28-55.
18. Ostroff SM. Infectious Diseases in an Age of Change; the Impact of Human Ecology and Behavior on Disease Transmission, book review. Am J Trop Med Hyg 1996;55:577.
19. Ostroff SM. Yellow Fever, Black Goddess: the Coevolution of People and Plagues, book review. Lancet 1997;349:292-3.
20. Ostroff SM. Isolation of *E. coli* O157:H7 from sporadic cases of hemorrhagic colitis - United States. MMWR 1997;46:700-4.
21. Chicken Flu (A H5N1). CID Hot Page, Clin Infect Dis 1998; 26 No. 2.
22. Ostroff SM, Hughes JM. New ways to tackle influenza highlighted at ICAAC. Lancet 1998;352:1123.
23. Ostroff SM, Hughes JM. The changing nature of infectious disease outbreaks in the United States. US Medicine, February 1999;12,15.
24. Ostroff SM. Infectious Disease Epidemiology: Theory and Practice, book review. EpiMonitor 2000; 21-10:10-12.
25. Ostroff SM. CDC's Epidemic Intelligence Service. Eurosurveillance, 2001;6:34-6.
26. Ostroff SM. Public Health Challenges from Emerging Infectious Diseases: Lessons from SARS. State Government News, Feb 2004; 25-7, 38.
27. Ostroff SM. Encyclopedia of Infectious Diseases: Modern Methodologies, book review. Emerg Infect Dis, 2008;14:356.
28. Lind L, Reeser J, Stayman K, et al. *Salmonella Typhimurium* infection associated with raw milk and cheese consumption – Pennsylvania, 2007. MMWR 2007;56:1161-4.
29. Hunt E, Lurie P, Lute J, et al. Multistate measles outbreak associated with an international youth sporting event – Pennsylvania, Michigan, and Texas, August-September 2007. MMWR 2008;57:169-73.
30. Ferraro A, Deasy M, Dato V, et al. Multistate outbreak of human *Salmonella* infections caused by contaminated dry dog food - 2006-2007. MMWR 2008;57:521-4.
31. Deasy M, Moll M, Urdaneta V, et al. Update: Recall of dry dog food and cat food products associated with human *Salmonella Schwarzengrund* Infections – United States, 2008. MMWR 2008;57:1200-2.
32. Safranek T, Leschinsky D, Keyser A, et al. Outbreak of *Salmonella* serotype Saintpaul infections associated with eating alfalfa sprouts – United States, 2009. MMWR 2009;58:500-3.
33. Dato V, Moose C, Rea N, et al. Human vaccinia infection after contact with a raccoon rabies vaccine bait - Pennsylvania, 2009. MMWR 2009;58:1204-7.
34. Imamura T, Suzuki A, Meijer A, et al. Clusters of acute respiratory illness associated with human

- enterovirus 68-Asia, Europe, and the United States, 2008-2010. *MMWR* 2011;60:1301-4.
35. Vorhees R, Casey M, Johnson L, et al. *Yersinia enterocolitica* infections associated with pasteurized milk – Southwestern Pennsylvania, March-August, 2011. *MMWR* 2011;60:1429.
 36. Marsden J, Dettinger L, Fraser G, et al. Invasive group A streptococcus in a skilled nursing facility – Pennsylvania, 2009-2010. *MMWR* 2011;60:1445-9.
 37. Ostroff S. The costs of foodborne illness, product recalls make the case for food safety investments. *Food Safety Magazine* 2018;24(3):14-5.
 38. Bokter S, Ostroff SM. Book review: *Flu Hunter: Unlocking the Secrets of a Virus*. *Emerg Infect Dis*. 2019;25:1994.
 39. Panosian Dunavan C, Ostroff S. Danger in Paradise: Modern Lessons of Rat Lungworm. *The Hill*, July 23, 2019. thehill.com/opinion/healthcare/454364/danger-in-paradise-modern-lessons-of-rat-lungworm & Food Safety News, Aug 19, 2019. <https://www.foodsafetynews.com/2019/08/paradise-parasites-challenges-to-controlling-rat-lungworm-disease/>
 40. Ostroff SM. Romaine has had a tough go. Here's what has to happen to make it safe. *Washington Post*, November 27, 2019. https://www.washingtonpost.com/opinions/romaine-has-had-a-tough-go-heres-what-has-to-happen-to-make-it-safe/2019/11/26/a7f64cc4-1063-11ea-b0fc-62cc38411ebb_story.html Food Safety News, December 2, 2019. <https://www.foodsafetynews.com/2019/12/treat-the-water-then-mitigate-other-romaine-problems/>
 41. Gottlieb S, Ostroff S. How to keep workers safe on the job. *Wall Street Journal*, April 19, 2020. <https://www.wsj.com/articles/how-to-keep-workers-healthy-on-the-job-11587311057>.

Invited Presentations and Lectures

1. *Meningitis Surveillance in Washington* - West Coast Epidemiology Meeting, Oregon (1986)
2. *Outbreak of Bloody Diarrhea in eastern Washington* - Regional EIS Conference, Oklahoma City OK (1987)
3. *Outbreak of *E. coli* O157:H7 Bloody Diarrhea* - EIS Conference, Atlanta GA (1987)
4. *Enteric Disease Case Investigation* - Benton-Franklin Health Department, Richland WA (1987)
5. *Hospital Outbreak Investigations* - Inland Empire Infection Control Practitioners, Spokane WA (1987)
6. *Epidemiologic Investigations* - Indian Health Service Epidemiology Course, Yakima WA (1987)
7. *Source Tracing in an Outbreak of *E. coli* O157:H7 Induced Illness* - International Symposium on Verotoxin Producing Infections, Toronto, Canada (1987)
8. *Necrotizing Enterocolitis in a Neonatal Intensive Care Unit* - International Northwest Conference on Diseases in Nature Communicable to Man, Ellensburg WA (1987)
9. **E. coli* O157:H7 Infections in Washington State - An Overview* - International Northwest Conference on Diseases in Nature Communicable to Man, Ellensburg WA (1987)
10. **E. coli* O157:H7 Surveillance in Washington* - West Coast Epidemiology Meeting, Ashland OR (1987)
11. **E. coli* O157:H7 Surveillance in Washington* - Puget Sound Clinical Microbiology Society, Seattle WA (1987)
12. **E. coli* O157:H7 Disease in Washington* - University of Washington School of Public Health Epidemiology Seminar Series, Seattle WA (1988)
13. *The Quality of Meningitis Reporting in Washington State* - Regional EIS Conference, Tucson AZ (1988)
14. *The Quality of Meningitis Reporting in Washington State* - EIS Conference, Atlanta GA (1988)
15. *An Outbreak of Hepatitis A in a Spokane, Washington Restaurant* - EIS Conference, Atlanta GA (1988)
16. *An Outbreak of *E. coli* O157:H7 in Eastern Washington* - Prevention 88, Atlanta GA (1988)
17. *HIV Family of Seroprevalance Surveys* - USPHS Region IX Monthly Seminar, Seattle WA (1988)
18. *A Cluster of Legionnaires' Disease in Persons With AIDS, Seattle, Washington* - IVth International AIDS Conference - Stockholm, Sweden (1988)
19. **E. coli* O157:H7 Disease in the United States* - National Public Health Institute, Oslo, Norway (1988)

20. *Laboratory Studies of E. coli O157:H7 in Washington State* - 28th Interscience Conference on Antimicrobial Agents and Chemotherapy, Los Angeles CA (1988)
21. *E. coli O157:H7 Surveillance in Washington State* - 28th Interscience Conference on Antimicrobial Agents and Chemotherapy, Los Angeles CA (1988)
22. *E. coli O157:H7 - Seek and Ye Shall Find* - Northwest Medical Laboratory Symposium, Seattle WA (1988)
23. *The Role of Private Foundations in Funding Public Health Initiatives* - Preventive Medicine Seminar, Atlanta GA (1989)
24. *The International Epidemiology of Influenza* - Emory University School of Public Health Seminar, Atlanta GA (1990)
25. *The Epidemiology of E. coli O157:H7: Lessons Learned in the 1st 8 Years* - Society for Industrial Microbiology Annual Meeting, Orlando, FL (1990)
26. *Epidemiologic Aspects of Newly Discovered Filoviruses in the United States* - American Association of Laboratory Animal Scientists Annual Meeting, Milwaukee WI (1990)
27. *Clinical and Epidemiology Aspects of Nontuberculous Mycobacterial Infections*- Laboratory Methods in Medical Mycobacteriology, Atlanta GA (1991)
28. *Clinical and Epidemiologic Features of Nontuberculous Mycobacterial Infections* - American Society of Microbiology New York City Regional Meeting, New York NY (1992)
29. *Clinical and Epidemiologic Aspects of Nontuberculous Mycobacterial Infections* - Laboratory Methods in Medical Mycobacteriology, Atlanta GA (1992)
30. *Recent Issues Regarding Tuberculosis in Nonhuman Primates* - Southeast Branch American Association of Laboratory Animal Scientists, Atlanta GA (1993)
31. *Clinical and Epidemiologic Aspects of Nontuberculous Mycobacterial Infections* - Laboratory Methods in Medical Mycobacteriology, Atlanta GA (1993)
32. *Mycobacterial Species and Drug Resistance Patterns in State Laboratories – 1992* - American Society of Microbiology Annual Meeting, Atlanta GA (1993)
33. Moderator - Session 185 - Drug Resistance in Mycobacteria: Epidemiology and Molecular Genetics. American Society for Microbiology Annual Meeting, Atlanta GA (1993)
34. *Public Health Laboratory Information System* - Council of State and Territorial Epidemiologists/ Association of State and Territorial Public Health Laboratory Directors Annual Meeting, Minneapolis MN (1993)
35. *Pneumococcal Drug Resistance* - Council of State and Territorial Epidemiologist/Association of State and Territorial Public Health Laboratory Directors Annual Meeting, Minneapolis MN (1993)
36. *Emerging Infectious Diseases* - Washington State Department of Health Infectious Disease Conference, Yakima, WA (1993)
37. *National perspective on Hantavirus Infections* - West Coast Epidemiologists Annual Meeting - Yreka, CA (1993)
38. *The Importance of Infectious Diseases to the Public's Health* - Brown University School of Medicine, Providence, RI (1994)
39. *Overview of Emerging Infections* - Society for Epidemiologic Research 27th Annual Meeting, Miami FL (1994)
40. *Antimicrobial Resistance Among Bacteria Causing Pneumonia in Egyptian Children* - ARI International Conference - Cairo, Egypt (1994)
41. *Overview of Emerging Infections* - 49th International Northwest Conference of Diseases in Nature Communiicable to Man, Helena, MT (1994)
42. *Hantavirus Pulmonary Syndrome - A year in the life of an emerging pathogen* - 49th International Northwest Conference of Disease in Nature Communiicable to Man, Helena, MT (1994)
43. *BUGS! What Journalists Should Know from the CDC* - Association for Education in Journalism and Mass Communication, 77th Annual Convention, Atlanta, GA (1994)
44. *Overview of Emerging Infections* - Henry Kaiser Media Fellowship Conference, Atlanta, Georgia (1994)

45. *Nontuberculous Mycobacterial Disease* - Mycobacteriology Laboratory Training Course, Atlanta, GA (1994)
46. *The Epidemiology of Yersiniosis: What We Know and What We Need to Know* - Sixth International Symposium on Yersinia, Rome, Italy (1994)
47. *Communicable Disease Surveillance and Health Care Reform* - First Annual Washington State Joint Conference on Health, Yakima, WA (1994)
48. *Diseases Without Borders* - 1994 Conference of the Oregon Health Forum, Portland, OR (1994)
49. *Emerging Infectious Diseases* - International Epidemiology Training Course, Emory University School of Public Health, Atlanta, GA (1994)
50. *The Challenge of Emerging Infections in the 1990s* - 75th Annual Conference of the Association of Ohio Health Commissioners, Columbus, OH (1994)
51. *The US Centers for Disease Control and Prevention Program on Emerging Microbes* - 1995 American Association for the Advancement of Science (AAAS) Annual Meeting, Atlanta, GA (1995)
52. *E. coli O157:H7 and Other Emerging Causes of Diarrhea* - University of Michigan Annual Update on Infectious Diseases, Captiva Island, FL (1995)
53. *Emerging Infections* - University of Michigan Annual Update on Infectious Diseases, Captiva Island, FL (1995)
54. *Hantavirus Pulmonary Syndrome* - University of Michigan Annual Update on Infectious Diseases, Captiva Island, FL (1995)
55. *Emerging Infections: The Role of the Practicing Internist* - American College of Physicians Annual Meeting, Atlanta, GA (1995)
56. *Overview of Emerging Infectious Diseases* - ChildHealth 2000, Vancouver, Canada (1995)
57. *Update on E. coli Infections* - ChildHealth 2000, Vancouver, Canada (1995)
58. *Nontuberculous Mycobacterial Infections* - Laboratory Medical Mycobacteriology, Atlanta, GA (1995)
59. *Emerging Infections and Surveillance Issues* - National Medical Association 100th Annual Meeting, Atlanta, GA (1995)
60. *Clinical Update: Tales from the Hot Zone* - Emerging Concepts in the Treatment of Serious Infections in the Emergency Department, American College of Emergency Physicians Annual Meeting, Washington, DC (1995)
61. *Emerging Infections* - Foundations of Microbiology Lecture - North Central Branch of the American Society for Microbiology, Iowa City, IA (1995)
62. *Emerging Infetions: Why Now and What's the Latest?* - Foundations of Microbiology Lecture - Southern California Branch of the American Society for Microbiology, San Diego, CA (1995)
63. *Emerging Infectious Diseases* - Ernest Anandham Clinical Microbiology Lecture - Florida Branch of the American Society for Microbiology Annual Meeting, Fort Lauderdale, FL (1996)
64. *Emerging Infections: The Global Village* - Illinois Branch, American Society for Microbiology Annual Meeting, Chicago, IL (1996)
65. *Emerging Infections of Military Significance* - 37th Navy Occupational Health and Preventive Medicine Workshop, Virginia Beach, VA (1996)
66. *Emerging Infections of Clinical Significance* - Medical Grand Rounds, William Beaumont Hospital, Detroit, MI (1996)
67. *Emerging Infections* - Benton-Franklin Medical Society Annual Meeting, Richland, WA (1996)
68. *Update on HIV and Tuberculosis* - Benton-Franklin Medical Society Annual, Meeting, Richland, WA (1996)
69. *Emerging Infectious Diseases* - Infectious Disease Society of Germany 19th Symposium, Reissensburg, Germany (1996)
70. *Emerging Infectious Diseases* - 4th International Conference on the Prevention of Infection, Nice, France.

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71. *Emerging Infectious Diseases and the Pediatrician* - Combined Medical-Pediatrics Grand Rounds, West Virginia University School of Medicine, Morgantown, WV (1996)
72. *New Answers and New Issues from the National Center for Infectious Diseases* - Council of State and Territorial Epidemiologists Annual Meeting, Portland, OR (1996)
73. *Surveillance for Emerging Infections* - Introduction to Public Health Surveillance, Emory University Rollins School of Public Health, Atlanta, GA (1996)
74. *The Coming Plague? A Discussion of Recent Outbreaks* - National Council for International Health 23rd Annual Conference, Washington DC (1996)
75. *Emerging Infectious Diseases* - 22nd Annual University of Michigan Advances in the Management of Infectious Diseases, Mackinac Island, MI (1996)
76. *Emerging Vectorborne Infections* - 22nd Annual University of Michigan Advances in the Management of Infectious Diseases, Mackinac Island, MI (1996)
77. *Emerging Gastrointestinal and Foodborne Diseases* - 22nd Annual University of Michigan Advances in the Management of Infectious Diseases, Mackinac Island, MI (1996)
78. *Resources to Combat Emerging Infections* - International Organization for Mycoplasma Annual Meeting, Orlando, FL (1996)
79. *Clinical Features of E. coli O157:H7 Infections* - Health Sciences Council, Japanese Ministry of Health, Tokyo, Japan (1996)
80. *Emerging Infections: A National Perspective* - American Bar Association 1996 Annual Meeting, Orlando, FL (1996)
81. *Emerging Infectious Diseases* - University of Michigan School of Medicine, Ann Arbor MI (1996)
82. *Infectious Disease Surveillance and Information Systems* - 36th Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) New Orleans LA (1996)
83. *Emerging Infections: Latest Trends and Future Direction* - Suncoast Biomolecular Science Conference, Institute for Biomolecular Science, University of South Florida, Tampa FL (1996)
84. *The Hot Zone: Emerging Infections* - 9th Annual Olive View-UCLA National Conference on Advances in Emergency Medicine, Boston MA (1996)
85. *Emerging Infections, 1996* - Washington DC Branch, American Society for Microbiology Meeting, Washington DC (1996)
86. *Emerging Infections Overview* - American Medical Writers Association Annual Meeting, Chicago IL (1996)
87. *Emerging Infections: What's the Latest?* - Annual Meeting, Hawaii Branch of the American Society for Microbiology, Honolulu, HI (1996)
88. *Addressing the Challenge of Emerging Infectious Diseases: Perspectives from the Centers for Disease Control and Prevention* - 1st International Conference on Emerging Zoonoses, Jerusalem, Israel (1996)
89. *The Global Health Threat of Emerging Infectious Diseases* - Fifth International Conference of Microbiology; AIDS & Emerging Infectious Diseases, Cairo, Egypt (1996)
90. *Emerging Infections in the United States and World Wide: The Role of Human Activity* - 32nd Annual Conference on Occupational Medicine of the Rocky Mountain Academy of Occupational and Environmental Health, Denver, CO (1997)
91. *Emerging Infections* - Distinguished Visiting Scientist Lecture Series, Albany Medical College, Albany NY (1997)
92. *Update on Emerging Infectious Diseases* - Arizona Branch American Society for Microbiology Annual Meeting, Phoenix, AZ (1997)
93. *Control and Prevention of Emerging Diseases: the CDC Agenda* - Global Climate Change & Environmental Health Conference, Society for Occupational and Environmental Health, Washington DC

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94. *Emerging Infections and Their Relation to the Military* - United States Air Force Preventive Medicine Annual Conference, Dallas TX (1997)
95. *Enter the Hot Zone: New and Emerging Infectious Diseases* - New Jersey Chapter American College of Emergency Physicians Scientific Assembly, Atlantic City, NJ (1997)
96. *Hot Infectious Disease Topic(s) from CDC* - New and Reemerging Infectious Diseases Symposium, National Foundation for Infectious Diseases, Atlanta GA (1997)
97. *Imported Tropical Infections in the US & Diagnosis of Hantavirus* - Boehringer Mannheim Workshop on Tropical Medicine, Heidelberg, Germany (1997)
98. *Emerging Infectious Diseases* - U.S. Air Force Annual Public Health Meeting, San Antonio, TX (1997)
99. *E. coli O157:H7 and other Shiga-toxin Producing E. coli* - Pediatric Grand Rounds, West Virginia University School of Medicine, Morgantown, WV (1997)
100. *Emerging Infectious Diseases* - University of Michigan School of Medicine, Ann Arbor, MI (1997)
101. *The Challenge of Infectious Disease Prevention and Control in the Pacific* - Pacific Island Health Officers Association Meeting on Emerging Infectious and Vaccine Preventable Diseases, Tamuning, Guam (1997)
102. *Emerging Infectious Disease Issues* - Sixth European Conference on Clinical Aspects and Treatment of HIV-Infection, Hamburg, Germany (1997)
103. *The Real Story of Ebola: Is It a Threat in Your Emergency Department?* - Current Challenges in Managing Infections in the Emergency Department, American College of Emergency Physicians, San Francisco CA (1997)
104. *Emerging Infectious Diseases* - Danish International Development Agency Policy Seminar, Copenhagen, Denmark (1997)
105. *Emerging Infectious Diseases* - Baseball Team Medicine 12th Annual Conference, Atlanta GA (1998)
106. *Threats from Emerging Infectious Diseases* - Medical Grand Rounds/Visiting Professor, Nassau County Medical Center, East Meadows, NY (1998)
107. *Emerging Infectious Diseases and Travel* - European Conference on Travel Medicine, Venice Italy (1998)
108. *Emerging Pathogens* - 42nd Meeting of the Alabama Public Health Association, Birmingham, AL (1998)
109. *Epidemiologic Factors Associated with Emergence of Infectious Diseases* - Emergence of Infectious Diseases: An Evolutionary Perspective, Scuola Superiore D'immunologia Ruggero Ceppellini, Naples, Italy (1998)
110. *Emerging Infectious Diseases 1997-1998: The Role of Molecular Epidemiology* - 3rd International Meeting on Molecular Epidemiology and Evolutionary Genetics of Infectious Diseases, Rio de Janeiro, Brazil (1998)
111. *International Surveillance of Infectious Diseases - Outbreak Investigation - Emerging Infections* - Summer School in Methods of Infectious Disease Epidemiology, Stockholm, Sweden (1998)
112. *Emerging Infectious Diseases* - University of Michigan School of Medicine, Ann Arbor, MI (1998)
113. *Foodborne Outbreak Coordination and Rapid Assessment Team* - 50 States Meeting Challenges Together Meeting, Kansas City, MO (1998)
114. *Emerging Infectious Diseases: The View from the Centers for Disease Control and Prevention* - Joint Meeting of the German Infectious Disease Society and German Society of Hygiene and Microbiology, Berlin Germany (1998)
115. *CDC's Food Safety Activities & Responding to Emergent Threats to the Food Supply* - National Federal-State Food Safety Conference, Washington DC (1999).
116. *Emerging Infections: What Really Keeps the CDC Up at Night* - Prime Time Summit, West Hollywood, CA (1999).
117. *Surveillance of Infectious Diseases - Outbreak Investigations -Emerging Infectious Diseases* - Summer

- School in Methods of Infectious Disease Epidemiology, Copenhagen, Denmark (1999)
118. *Emerging Infectious Diseases* - University of Michigan School of Medicine, Ann Arbor, MI (1999)
119. *Travel Medicine and the Travel Industry* - American Society of Travel Agents Annual Meeting, Strasbourg, France (1999)
120. *Emerging Infections Update* - 4th Conference on Infectious Diseases, Hospital de Curry Cabral, Lisbon, Portugal (2000)
121. *The CDC Experience in Suspicious Outbreak Investigations* - Seminar in Strengthening the Biologic Toxins Weapons Convention: Recruitment, Training, and Operation of the Inspectorate, Clingendael Institute, Netherlands Ministry of Foreign Affairs, The Hague, Netherlands (2000)
122. *CDC Assistance in Overseas Incidents* - Meeting on A Scientific Evaluation of the Arrangements for Managing Epidemiologic Emergencies Involving More than One European Union Member State - London School of Hygiene and Tropical Medicine, London, England (2000)
123. *Millennium Bugs: Fighting Diseases in 2000 and Beyond* - Conversations at The Carter Center, Atlanta, Georgia (2000)
124. *Emerging Infectious Diseases* - Texas Department of Health, Austin TX (2000)
125. *Public Health Challenges for the 21st Century* - American Mosquito Control Association Legislative Day, Washington DC (2000)
126. *Public Health Laboratories: Addressing Challenges in the New Millennium* - Keynote Address at 43rd Annual Planning Meeting of the Association of Public Health Laboratories, St. Louis MO (2000)
127. *Unraveling the Mystery of West Nile Virus* - The 5th Richard J. Duma/National Foundation for Infectious Diseases (NFID) Annual Press Conference and Symposium on Infectious Diseases, Washington DC (2000)
128. *Disease Surveillance - Outbreak Investigation -Emerging Infections* - Nordic Epidemiology Summer Course, Copenhagen, Denmark (2000).
129. *Emerging Pathogens* - University of Michigan School of Medicine, Ann Arbor MI (2000)
130. *West Nile Virus in the United States, 1999-2000* - Fifth European Programme on Interventional Epidemiology, Veyrier-du-Lac, France (2000)
131. *Emerging Infections Update, 2000* - Clinical Update: Emerging Concepts in the Management of Infections in the Emergency Department, American College of Emergency Physicians Annual Conference, Philadelphia, PA (2000).
132. *Covering Infectious Diseases: What You Don't Know* - Association of Health Care Journalists Second National Conference, Atlanta GA (2001).
133. *The West Nile Virus Outbreak* - 4th Meeting of the Critical Incident Analysis Group, University of Virginia, Charlottesville VA (2001).
134. *Opening Remarks & Planning for 2001* - Symposium on the West Nile Virus, New York Academy of Sciences, White Plains NY (2001).
135. *The U.S. Role in International Surveillance and Response* - International Disease Surveillance and Global Security Conference, Center for International Security and Cooperation at Stanford University, Palo Alto CA (2001).
136. *West Nile Virus* - Infectious Disease Society of Massachusetts, Boston MA (2001).
137. *Emerging Infectious in Europe and the Americas* - 7th Conference of the International Society for Travel Medicine, Innsbruck Austria (2001)
138. *Emerging Infections* - Symposium American Society for Microbiology Annual Meeting, Orlando FL (2001)
139. *CDC Keynote* - 105th Conference of the Association of Food and Drug Officials, Atlanta GA (2001).
140. *CDC Update* - Energy Modeling Forum Summer Workshop on Climate Change and Integrated Assessment, Snowmass CO (2001)

141. *Emerging Infectious Diseases* - University of Michigan School of Medicine, Ann Arbor (2001)
142. *West Nile Encephalitis* - Pediatric Chairman's Conference, Emory University School of Medicine, Atlanta GA (2001)
143. *West Nile Encephalitis* - International Course in Applied Epidemiology, Emory University School of Public Health (2001)
144. *Anthrax-related Bioterrorism* - Public Health Symposium sponsored by Cong. Ralph Regula, Canton OH (2001)
145. *Emerging Infections of the New Millennium* - 2001 Edwin C Yoder Honor Lecture, Tacoma WA (2001)
146. *Homeland Security* - Panel Discussion at National League of Cities Annual Meeting, Atlanta GA (2001)
147. *The Next Big Bug: Beyond Lyme and West Nile* - Society of Environmental Journalists 2002 Boston-to-Baltimore Regional Briefing, Piscataway NJ (2002)
148. *Emerging Infectious Diseases* - Cukarova University School of Medicine, Adana Turkey (2002)
149. *Emerging Infectious Diseases* - Ceyhan Hospital, Adana Turkey (2002)
150. *Vector Borne Diseases* - 7th Linzer Reisemedizinische Tagung, Linz Austria (2002)
151. *Critical Issues in Writing about Bioterrorism* - Writers Guild of America, West Hollywood CA (2002)
152. *Covering Health News in Times of Crisis* - Association of Health Care Journalists Third National Conference, Bethesda MD (2002)
153. *Biological and Chemical Terrorism and Travel: An Overview* - 3rd European Conference on Travel Medicine, Florence Italy (2002)
154. *Emerging and Reemerging Diseases in the 21st Century* - Keynote Address at the Jubilee Celebration of the 100th Anniversary of the Statens Serum Institute, Copenhagen Denmark (2002)
155. *Laboratory Biosecurity* - Bioterrorism Preparedness Symposium in conjunction with 43rd Interscience Conference on Antimicrobial Agents and Chemotherapy, San Diego CA (2002)
156. *Lessons Learned from Last Fall's Bioterrorism Events* - American Society for Healthcare Risk Management Annual Meeting, Seattle WA (2002)
157. *Antibioterrorism: The CDC Strategy and Perspective* - Center for Public Health Preparedness Grand Rounds series, University of Iowa College of Public Health, Iowa City IA (2002)
158. *West Nile Virus: A Pathogen on the Move* - 2002 Robert Fekety Lecture, Medical Grand Rounds, University of Michigan Medical Center, Ann Arbor MI (2002)
159. *New Rules: Possession, Use, and Transfer of Select Agents and Toxins* - Howard Hughes Medical Institute 2003 Environmental Health and Safety Conference, Chevy Chase MD (2003)
160. *Bioterrorism: Lessons Learned and Present/Future Directions from CDC Perspective* - NASA and Uniformed Services University 12th International Continuing Health Education Seminar Series, Washington DC (2003)
161. *SARS: Modes of Transmission and Methods of Control* - 8th Conference of the International Society of Travel Medicine, New York NY (2003)
162. *Bioterrorism: A Concern for Travel Medicine* - 8th Conference of the International Society of Travel Medicine, New York NY (2003)
163. *Regulatory Issues for Research with Select Agents* - American Society for Microbiology 103rd General Meeting, Washington DC (2003)
164. *Lessons Learned from Intentional Anthrax in the United States, 2001* - Bioterrorism Training Module, European Program in Interventional Epidemiology Training (EpiET), Berlin Germany (2003)
- 165-7 *Outbreak Investigation - Public Health Surveillance - Emerging Infections 2002-03* - Nordic Research Foundation Epidemiology Summer Short Course, Skjoldenaesholm Denmark (2003)
168. *The Public Health Rationale for SARS Diagnostic Tests* - FDA Symposium on SARS Diagnostic Testing, Rockville MD (2003)
169. *West Nile Virus* - 8th Annual Richard Duma Honoraria Symposium, National Press Club, Washington DC

- (2003)
170. *The 2001 Intentional Anthrax Attacks* - Forensic Epidemiology Seminar, Sacramento CA (2003)
 171. *The Saga of SARS: Understanding its Origins and Global Reach* - The Council of State Governments Health Policy Forum, Westminster CO (2003)
 172. *CDC Priorities for Bioterrorism Preparedness* - Bioterrorism Preparedness Summit, University of Hawaii, Honolulu HI (2003)
 173. *Emerging Infectious Diseases in 2003* - Consumer Specialty Products Association Annual Meeting, Fort Lauderdale FL (2003)
 174. *The CDC Response to the SARS Outbreak* - International SARS Symposium: A Case Study for Public Health Preparedness, University of Michigan School of Public Health, Ann Arbor (2004)
 175. *Emerging & Re-emerging Epidemics* - Africa-European Conference on Travel Medicine, Cape Town South Africa (2004)
 176. *Emerging Infectious Diseases* - Tygerberg Hospital, University of Stellenbosch, Cape Town, South Africa (2004)
 177. *Emerging Infectious Diseases: An Ongoing Concern for Travel Medicine* - Fourth European Conference on Travel Medicine, Rome, Italy (2004)
 178. *Strategies for Disease Control and Prevention in the USA* - International Conference on Disease Control and Prevention, Seoul, South Korea (2004)
 179. *CDC Activities at Home and Abroad* - Annual Meeting of the Korean Society for Preventive Medicine, Seoul, South Korea (2004)
 180. *Establishing Command, Control, and Management Procedures - CDC Experience* - CSTE Pre-conference Workshop on Influenza Pandemic Preparedness, Boise ID (2004)
 181. *Adapting at Home to the New Global Realities - Challenges and Opportunities* - 2004 Annual Conference of the Council of State and Territorial Epidemiologists, Boise ID (2004)
 182. *Emerging Infectious Diseases of Importance in the U.S.-affiliated Pacific Islands* - Ambassador's Lecture Series, Pohnpei, Federated States of Micronesia (2005)
 183. *Basic Biology of Influenza* - Public Health Emergency Officer training seminar, U.S. Pacific Command, Honolulu HI (2005)
 184. *Pandemic Threat of Influenza* - Pacific Tricare Conference, Tokyo Japan (2005)
 185. *Infectious Diseases and Baseball* - Annual Meeting of Major League Baseball Team Physicians and Trainers Associations, 2005 Major League Baseball Winter Meetings, Dallas TX (2005)
 186. *Pandemic Influenza: Status and Threat - US Government Pandemic Influenza Plans* Pacific Regional Pandemic Preparedness Meeting, Saipan, Commonwealth of the Northern Mariana Islands (2006)
 187. *Planning for Avian Flu: What We Need to Know* - FSM Health Policy Symposium, Pohnpei, Federated States of Micronesia (2006)
 188. *Public Health Preparedness for Avian Influenza in the South Asia Region: Lessons Learned from World Bank Project Development* – Workshop on Avian Influenza, Center for Asia Pacific Strategic Studies, Honolulu HI (2006)
 189. *Preparing for Avian Influenza in the South Asia Region* – National Institute of Public Health, Islamabad, Pakistan (2006)
 190. *Influenza: The Basics* – University of Hawaii John A Burns School of Medicine Preparedness Symposium, Honolulu HI (2006)
 191. *Public Health Preparedness for Avian Influenza in the South Asia Region: Lessons Learned from World Bank Project Development* – Quarterly Epidemiology Meeting – Bureau of Epidemiology, Harrisburg PA (2007)

192. *Update from the Pennsylvania Department of Health on Recent Investigations* – Philadelphia Department of Public Health Annual Public Health Conference, Philadelphia PA (2007)
193. *XDR-TB and Update from the PA Department of Health on Recent Investigations* – Eastern Pennsylvania Branch of American Society for Microbiology workshop, Lionville PA (2007)
194. *Public Health Perspective on MRSA* – Regional MRSA Collaborative Kickoff – Health Care Improvement Foundation, Philadelphia PA (2007)
195. *State Pandemic Influenza Preparedness* - Government Horizon's Preparing for Pandemic Influenza Conference, Washington DC (2007)
196. *Update from the Pennsylvania Department of Health* – Epidemiology Seminar Series – University of Pittsburgh School of Public Health, Pittsburgh PA (2008)
197. *Update from the Pennsylvania Department of Health* – Food Safety Seminar – University of Pennsylvania School of Veterinary Medicine, Kennett Square PA (2008)
198. *Act 52 – Healthcare Associated Infections* – Public Health Update: Emerging Issues in Public Health Preparedness, Philadelphia Department of Public Health, Philadelphia PA (2008)
199. *Overview of Pandemic Influenza Risk* – Business Community Planning for Pandemic Influenza – Danville PA (2008)
200. *Act 52- Implications for Long Term Care Facilities* – Catholic Health Care Services Symposium – Trevoze PA (2008)
201. *Investigation Update from the Pennsylvania Department of Health* – Center for Clinical Epidemiology and Biostatistics, University of Pennsylvania School of Medicine, Philadelphia PA (2008)
202. *Respiratory Infections in Sports and Update on Methicillin-resistant Staph aureus* – 2009 Baseball Team Medicine Conference, Washington DC (2009)
203. *Managing Surge* Panel Discussion – Seasonal and Pandemic Influenza 2009: A Turning Point, Washington DC (2009)
204. *Update on Recent Investigations by the Pennsylvania Department of Health* – Drexel University School of Public Health Epidemiology Seminar Series, Philadelphia PA (2009)
205. *Mandatory Reporting of Healthcare-associated Infections: The Public Health Perspective* – Society of Healthcare Epidemiology of America Annual Meeting, San Diego CA (2009)
206. *Mandatory Healthcare Associated Infections Reporting in Pennsylvania: One Year and Counting* – Academy Health Annual Research Meeting, Chicago IL (2009)
207. *Mandatory Reporting of Healthcare Associated Infections: The View from the Pennsylvania Department of Health* – The Fleming Infection Prevention and Infectious Diseases Symposium, Lehigh Valley Health Network, Allentown PA (2009)
208. *Update on Pandemic Influenza H1N1 from the Pennsylvania Department of Health* – American Public Health Association Annual Meeting – Late Breaker Session, Philadelphia PA (2009)
209. *A State Perspective on Foodborne Diseases* – Centers for Disease Control and Prevention Public Health Grand Rounds – Atlanta GA (2009)
210. *A Year's Worth of Infectious Disease Vignettes in Pennsylvania* – University of Michigan School of Medicine (2010)
211. *Update on Healthcare Associated Infections in Pennsylvania* – Philadelphia Annual Public Health Symposium – Philadelphia PA (2010)
212. *Outbreak Investigations and Emerging Infectious Diseases in Pennsylvania* – Nordic Research Foundation Summer Epidemiology Course – Copenhagen DK (2010)
213. *Public Health Vignettes: Recent Investigations by the Pennsylvania Department of Health* – Public Health Science Seminar Series – Penn State College of Medicine – Hershey PA (2010)

214. *Experience and Future Directions in Public Reporting of Healthcare Associated Infections in the United States* – Meet the Professor Symposium – 47th Annual Meeting of the Infectious Diseases Society of America – Vancouver BC (2010)
215. *Infectious Diseases Epidemiology at the State and Local Level* – University of Michigan School of Medicine (2011)
216. *Public Health Investigations by the Pennsylvania Department of Health* – Division of Infectious Diseases Weekly Conference – University of Pennsylvania School of Medicine – Philadelphia PA (2011)
217. *Healthcare Worker Vaccination for Influenza* – Pennsylvania Patient Safety Symposium – Lancaster PA (2011)
218. *Prevention of Healthcare Associated Infections in Pennsylvania* – Prevention Collaborative Symposium, Pennsylvania Patient Safety Symposium – Lancaster PA (2011)
219. *Update from the Pennsylvania Department of Health on Healthcare Associated Infections* – Pennsylvania Patient Safety Symposium – Lancaster PA (2011)
220. *Risk Communication and Vaccines – Lessons from H1N1* – Research Integrity Challenges in Vaccine Development and Distribution for Public Health Emergencies – Philadelphia PA (2011)
221. *Pennsylvania Department of Health Healthcare Associated Infections Program* – State-Level Partners Collaborating to Eliminate Healthcare-associated Infections Meeting – Dallas TX (2011)
222. *Lyme disease and Other Emerging Public Health Issues* – Penn State: Principals of Public Health – Hershey PA (2011)
223. *Preventing the Spread of Emerging Infectious Diseases through the International Health Regulations- the State Experience* – International Conference on Emerging Infectious Diseases – Atlanta GA (2012)
224. *How to Meet the Needs of State and Local Planners?* - Forum on Medical and Public Health Preparedness for Catastrophic Events – Institute of Medicine – Washington DC (2012)
225. *State Perspective on Multiple National Reporting Systems for Healthcare Associated Infections* – HHS Data Summit – Kansas City MO (2012)
226. *Variant Influenza in Pennsylvania and Proposed Case Definition Revision* – Annual Meeting of the Council of State and Territorial Epidemiologists – Omaha NE (2012)
227. *Federal, State and Local Public Health Relationships and Human Subjects Research* – Orientation Session of CSTE Applied Epidemiology Fellows – Atlanta GA (2012)
228. *Challenges to State and Local Infectious Disease Surveillance and Response* – Sustaining Public Health Capacity in an Age of Austerity – Microbial Threats Forum, Institute of Medicine – Washington DC (2012)
229. *Update from the Pennsylvania Department of Health* – Chester County Hospital Annual Health Symposium – West Chester PA (2012)
230. *Processes and Function of the U.S. Council of State and Territorial Epidemiologists* – First European Centre for Disease Control and Prevention Joint Strategy Meeting – Stockholm Sweden (2012)
231. *Facing the Threat of Bioweapons: The View from State and Locals* – Program for Emerging Leaders – National Defense University – Washington DC (2013)
232. *Activities and Investigations of the Pennsylvania Department of Health* – Principals of Public Health Administration – Penn State University – State College PA (2013)
233. *What Hospital Epidemiologists Should Know About Public Health Surveillance* – Spring 2013 Meeting of the Society of Healthcare Epidemiologists of America – Atlanta GA (2013)
234. *Public Health & Infectious Disease Epidemiology: 2013, a Déjà vu Year* - Northeast Regional Meeting of the American Physician Scientist Association keynote address – Philadelphia PA (2013)
235. *Food for Thought: An FDA Perspective on Food Safety and Regulatory Science* – Keynote address at

- Penn State Public Health Day Symposium – Harrisburg PA (2014)
236. *Fundamentals of Regulatory Science* – Introduction to Regulatory Science – Georgetown University – Washington DC (2014)
 237. *FDA's Views on Scientific Advances and their Impact on Manufacturing of the Future: Connecting Regulatory Science, Quality, and Compliance* – 2014 PDA/FDA Joint Regulatory Conference Keynote Address – Washington DC (2014)
 238. *FDA Potpourri: Selected Topics of Interest to State and Local Epidemiologists* – 2014 Northeast Epidemiology Conference – Philadelphia PA (2014)
 239. *FDA Update on Prescription Opioid-related Activities* – 2015 National Rx Drug Abuse Summit- Atlanta GA (2015)
 240. *Keynote Address* – 2015 Food and Drug Law Institute Annual Conference – Washington DC (2015)
 241. *FDA's Role in Addressing Antimicrobial Resistance Under One Health* – 4th ASM Conference on Antimicrobial Resistance in Zoonotic Bacterial and Foodborne Pathogens – Washington DC (2015)
 242. *International Regulatory Convergence: Collaboration, Cooperation, and Global Governance* – Drug Information Association (DIA) 51st Annual Meeting – Washington DC (2015)
 243. *Priming the Innovation Pump: FDA's Role in Advancing and Using Next Generation Sequencing* – ASM Conference on Rapid NGS Bioinformatic Pipelines for Enhanced Molecular Epidemiologic Investigation of Pathogens – Washington DC (2015)
 244. *Keynote Address* – Missouri Biotechnology Association/BioSTL Life Sciences Event – St. Louis MO (2015)
 245. *Expediting Therapies and Cures to the Patients Who Need Them: The Evolving Role of the FDA* – BioNJ CEO Summit – Bridgewater NJ (2015)
 246. *The Future of Regulatory Science at the FDA* – Workshop on Advancing the Discipline of Regulatory Science for Medical Product Development: An Update on Progress and a Forward-Looking Agenda – National Academy of Medicine – Washington DC (2015)
 247. *Keynote Address* – National Organization for Rare Diseases (NORD) Breakthrough Summit – Washington DC (2015)
 248. *Keynote Address – Comments from the Commissioner on FDA Regulatory Affairs* – Regulatory Affairs Professional Society (RAPS) Annual Meeting “Regulatory Convergence” - Baltimore MD (2015)
 249. *Fireside Chat – Comments from the Acting Commissioner* – Pennsylvania Bio Life Sciences Future Conference – Philadelphia PA (2015)
 250. *Medical Products Containing Marijuana: An FDA Perspective* – Smart Approaches to Marijuana (SAM) 3rd Annual Conference – Atlanta GA (2016)
 251. *Keynote Address* – National Food Policy Conference – Washington DC (2016)
 252. *Keynote Address* – Regulatory Roundup Conference of the International Dairy Foods Association – Washington DC (2016)
 253. *Keynote Address – FDA Food and Veterinary Medicine Update: Things You Can Do as a Regulator That You Can't as an Epidemiologist* – Annual Meeting of the Council of State and Territorial Epidemiologists – Anchorage AK (2016)
 254. *Change of Leadership in FDA's Food and Veterinary Medicine Program* – Association of Food and Drug Officials (AFDO) 120th Annual Educational Conference – Pittsburgh PA (2016)
 255. *Keynote Address* – The Food Defense Conference 2016 – Minneapolis MN (2016)
 256. *U.S. Regulatory Update on Food Safety* – 2016 Annual Meeting of the International Association of Food Protection – St. Louis MO (2016)
 257. *Update from the Food and Drug Administration* – North American Millers Association Annual Meeting –

Middleburg VA (2016)

258. *Update from the Food and Drug Administration – American Frozen Food Institute Meeting – Washington DC (2016)*
259. *Keynote Address – Food and Drug Administration Food Safety Update – 2016 National Association of State Departments of Agriculture (NASDA) Annual Meeting – Lincoln NE (2016)*
260. *Keynote Update from the Food and Drug Administration – American Spice Trade Association Regulatory Meeting – Arlington VA (2016)*
261. *Update from the Food and Drug Administration – National Chicken Council Annual Meeting – Washington DC (2016)*
262. *Food Safety Modernization in the United States: A Work in Progress – China International Food Safety and Quality Conference (CIFSQ) – Shanghai China (2016)*
263. *Food Safety Update from the FDA – Annual Regulatory Meeting of the Apple Processors Association – Washington DC (2016)*
264. *Keynote Address – Update on Food Safety Activities from the Food and Drug Administration – 4th Annual Food Safety Consortium Conference – Schaumburg IL (2016)*
265. *Keynote Address – Update from the Food and Drug Administration – Dairy Forum 2017 – Orlando FL (2017)*
266. *Keynote Address – Update from the Food and Drug Administration – National Association of State Departments of Agriculture Winter Policy Meeting – Washington DC (2017)*
267. *Implementing the 21st Century Cures Act – Forum on Regenerative Medicine, National Academy of Medicine – Washington DC (2017)*
268. *A Regulatory Perspective on Preventing and Mitigating Food Fraud – Food Fraud 2017: Global Understanding – Quebec City Canada (2017)*
269. *FDA: Using Science and Teamwork to End the Opioid Crisis – National Rx Drug Abuse and Heroin Summit – Atlanta GA (2017)*
270. *FDA Keynote Address – 2017 FDLI Annual Conference: Exploring Advanced Topics in Food and Drug Law – Washington DC (2017)*
271. *Town Hall: A Candid Conversation with Top Regulators – 19th Food Safety Summit – Rosemont IL (2017)*
272. *FDA's Scientific Approaches to New Mosquito Control Technologies – 19th Annual Washington Conference of the American Mosquito Control Association – Washington DC (2017)*
273. *Trust and Transparency in the Food and Beverage Industry – FoodBevForum3 – Savannah GA (2017)*
274. *Keynote Address – Regulatory Roundup Conference of the International Dairy Foods Association – Washington DC (2017)*
275. *Update from U.S. Regulatory Food Safety Agencies – International Association for Food Protection 2017 Annual Meeting – Tampa FL (2017)*
276. *The Food Safety Modernization Act – Agriculture Task Force, National Council of State Legislatures Annual Meeting – Boston MA (2017)*
277. *FSMA/GAP: The Alphabet Soup to Safe and Healthy Produce for All Consumers – Hawaii Agricultural Conference – Honolulu HI (2017)*
278. *Keynote Address: FDA Priorities for Dietary Supplements & Functional Food – Council for Responsible Nutrition's Annual Symposium for the Dietary Supplement Industry – Tucson AZ (2017)*
279. *Towards a Global Approach for the Prevention of Economically Motivated Adulteration – Global Understanding of Food Fraud: Towards Global Action for Prevention and Mitigation of Food Fraud – Beijing China (2017)*

280. *The Food Safety Modernization Act: From Concept to Reality* – 2017 China International Food Safety & Quality Conference – Beijing China (2017)
281. *2017 Food Safety Consortium Opening Remarks Keynote Address* – 2017 Food Safety Consortium – Schaumburg IL (2017)
282. *FDA Update* – 2018 Legislative Agriculture Chairs Summit – State Agriculture and Rural Leaders (SARL) – Kansas City MO (2018)
283. *Food and Veterinary Medicine Update* – Winter Policy Meeting of the National Association of State Directors of Agriculture (NASDA) Food Safety Committee – Washington DC (2018)
284. *Keynote Address* – Annual Policy Meeting of the National Cotton Ginners Association – Fort Worth TX (2018)
285. *FDA Activities* – U.S. Apple Association Annual Leadership Meeting – Washington DC (2018)
286. *Keynote Address* – Grocery Manufacturers of America Science Policy Forum – Washington DC (2018)
287. *Keynote Address* – Food Enforcement and Compliance Conference – Washington DC (2018)
288. *Keynote Address* – 2018 Conference for Food Protection – Richmond VA (2018)
289. *Keynote Address* – 2018 Legislative Update, United Egg Producers – Washington DC (2018)
290. *Keynote Address* – 2018 Food Defense Conference, University of Minnesota – Minneapolis MN (2018)
291. *Food Update from the US Food and Drug Administration* – 122nd Annual Education Meeting of the Association of Food and Drug Officials (AFDO) – Burlington VT (2018)
292. *US Regulatory Update on Food Safety* – International Association of Food Safety 2018 Annual Meeting – Salt Lake City UT (2018)
293. *Global Perspectives on Strengthening Food Safety Performance: How to Keep Up with a Changing World* – International Association of Food Safety Annual Meeting – Salt Lake City UT (2018)
294. *FDA Update* – 14th Annual Commissioner's Food Safety Forum – North Carolina Department of Agriculture – Raleigh NC (2018)
295. *FDA Food Safety Update* – American Frozen Food Institute Government Action Summit – Washington DC (2018)
296. *FDA Priorities and FSMA* – 2018 National Association of State Departments of Agriculture (NASDA) Annual Meeting – Hartford CT (2018)
297. *Keynote Address* - 2018 Annual Meeting of the Institute for Food Safety and Health (IFSH) – Chicago II (2018)
298. *Food Safety at Home and Abroad in an Era of a Changing Food Supply* – Wellness Week Lecture – Penn State University College of Medicine – Hershey PA (2018).
299. *Assuring the Safety of Imported Food: A U.S. FDA Perspective* – China International Food Safety and Quality Conference – Shanghai, China (2018)
300. *Food Safety Going Forward: Focus on Technology and Transparency* – Dairy Forum 2019 International Dairy Foods Association – Orlando FL (2019)
301. *Navigating Regulations for Novel Foods and Technologies* – IDFA Regulatory Roundup – Washington DC (2019)
302. *Food Safety Update* – Independent Bakers Association 45th Annual Convention – Washington DC (2019)
303. *Commercializing Alternative Proteins* – BIO World Congress on Industrial Biotechnology – Des Moines IA (2019)
304. *Food Safety and Foodborne Disease: The More Things Change, the More They Stay the Same* – Food Science Seminar – Penn State University Department of Food Science – State College PA (2019)
305. *Vaccine Development: Lessons for the Next Pandemic*. 17th Conference of the International Society for Travel Medicine – Virtual (2021)

U.S. Congressional Testimony

1. *Biological Weapons: the Threat Posed by Terrorists* - Senate Select Committee on Intelligence and Senate Judiciary Committee, Subcommittee on Technology, Terrorism, and Government (joint hearing), March 4, 1998.
2. *Shortages of Immune Globulins in the United States* - House Government Reform and Oversight Committee, Human Resources Subcommittee May 7, 1998.
3. *The Safety of Food Imports: From the Farm to the Table: A Case Study of Tainted Imported Fruit* - Senate Committee on Governmental Affairs, Permanent Subcommittee on Investigations July 9, 1998.
4. *Assessing the Adequacy of Federal Law Relating to Dangerous Biological Agents* - House Committee on Commerce, Subcommittee on Oversight and Investigations, May 20, 1999.
5. *Combating Terrorism: Management of Medical Stockpiles* - House Committee on Government Reform, Subcommittee on National Security, Veterans Affairs, and International Relations, March 8, 2000.
6. *Microbial Risks to Food Safety* - Senate Committee on Agriculture, Nutrition, and Forestry, September 20, 2000.
7. *Emergency Preparedness for the Elderly and Disabled* - Senate Special Committee on Aging, Field Hearing in New York City, February 11, 2002.
8. *The SARS Threat: Is the Nation's Public Health Network Ready for the Next Epidemic?* - House Committee on Government Reform, April 9, 2003.
9. *Public Health and Exotic Animal Importation* - Senate Environment and Public Works Committee, July 17, 2003.
10. *Combating the Flu: Keeping Seniors Alive* - Senate Special Committee on Aging, September 28, 2004.
11. *Combating West Nile Virus* - House Committee on Government Reform, Subcommittee on Energy Policy, Natural Resources and Regulatory Affairs, October 6, 2004.
12. *Pandemic Flu – Closing the Gaps* – Senate Committee on Homeland Security and Governmental Affairs, Ad Hoc Subcommittee on State, Local, and Private Sector Preparedness and Integration, June 3, 2009.
13. *FDA Food Supply Safety Efforts* – Senate Appropriations Committee Subcommittee on Agriculture, Rural Development & FDA, September 16, 2015.
14. *Fiscal Year 2017 Budget Hearing – Food and Drug Administration* – House Committee on Appropriations Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies, February 25, 2016.

Exhibit 2

Recommendations from the Healthy Sail Panel

Advice to cruise operators to advance their public health
response to COVID-19,
improve safety, and
achieve readiness for the safe resumption of operations

September 21, 2020

TABLE OF CONTENTS

INTRODUCTION	(1)
I. BACKGROUND	(2)
II. PANEL OVERVIEW	(3)
III. METHODS	(4)
IV. GUIDING PRINCIPLES	(5)
GATING CRITERIA	(7)
I. RECOMMENDATIONS SUMMARY	(9)
RECOMMENDATIONS	(16)
I. HEALTH: TESTING, SCREENING & EXPOSURE REDUCTION	(16)
i. <i>Assessing the Health Status of Guests and Crew</i>	(16)
Testing	(16)
Health Screening	(20)
Denial of Boarding	(22)
Policy on Guests at Increased Risk of Severe Illness	(23)
Guest Information & Education	(23)
Onboard Symptom Tracking and Monitoring	(24)
ii. <i>Protective Measures for Guests and Crew</i>	(25)
Personal Protective Equipment (PPE) Usage	(25)
iii. <i>Physical Distancing</i>	(27)
Capacity Restrictions	(27)
General Distancing Guidelines	(28)
Terminal, Boarding, Debarkation Controls	(29)
II. SANITATION AND VENTILATION	(29)
i. <i>Sanitation</i>	(30)
Hand Hygiene	(32)
ii. <i>Ventilation, HVAC, Filtration Controls</i>	(34)
III. RESPONSE, CONTINGENCY PLANNING, & EXECUTION	(37)
i. <i>Onboard Medical Capabilities</i>	(37)
Medical Personnel	(38)
Onboard Clinic Design & Operations	(39)
ii. <i>Case Management</i>	(42)
Treatment Plan	(42)
Contact Tracing	(43)
Isolation/Quarantine	(46)
iii. <i>Evacuation Scenarios</i>	(47)
Debarkation Scenarios	(48)
IV. DESTINATION & EXCURSION PLANNING	(51)
i. <i>Destinations and Itinerary Planning</i>	(51)
ii. <i>Guest Excursions</i>	(54)
V. MITIGATING RISKS FOR CREW MEMBERS	(56)

TABLE OF CONTENTS

i. *Prevention*..... (56)

ii. *Training & Culture* (57)

VI. VALIDATION OF IMPLEMENTATION..... (58)

VII. THE PATH FORWARD (59)

CONCLUSION (61)

Introduction

The COVID-19 pandemic has had an immense public health impact and has caused significant death and suffering. Our collective response to the pandemic has also, in turn, created substantial economic effects across many sectors of our economy. The cruise industry is among the hospitality sectors that have been especially impacted by these events. The industry has been nearly shuttered since mid-March, with hundreds of ships in the world's fleets idled, crews sent home, employees furloughed or let go, and Americans left with less opportunity to enjoy leisure activities that are important to them.

While the cruise industry, and the connected industries and nations that are economically linked to the industry, are keenly interested in resuming sailing, their leaders recognize that the economic impact of suspending operations cannot be addressed until the public health risks associated with the pandemic are appropriately mitigated in a shipboard environment.

The following document represents the findings of a four-month effort by a panel of experts in public health, infectious disease, biosecurity, epidemiology, hospitality, and maritime operations. The Healthy Sail Panel (the Panel; the Expert Panel) was convened at the request of cruise industry leaders Royal Caribbean Group and Norwegian Cruise Line Holdings Ltd. The Panel was given the charge to closely examine every aspect of the cruise ecosystem, and recommend the most effective, scientifically sound ways to make the cruise experience healthier and safer. The paramount goal and guiding principle of our work was to define a set of protocols and procedures that would protect guests, crews, and the communities cruise ships visit from SARS-CoV-2¹ and reduce the risk of transmission below the level people would experience in other normal activities.

Our recommendations are rooted in the best scientific and public health information available, and offer guidance that we believe will be valuable to the cruise industry, and perhaps to other industries seeking to better protect the health and safety of their customers and employees. We look forward to sharing these recommendations with the overall cruise industry as well as with the public. We also recognize that our understanding and knowledge of SARS-CoV-2 is evolving daily, and that these plans will need to evolve to incorporate new science and practices.

The pandemic presents serious challenges, but we believe that with the ongoing advances in areas such as testing and therapies, our recommendations provide cruise operators with a robust set of thoughtful preparations, innovations, strengthened protocols, and enhanced facilities preparedness that will enable them to safely resume sailings.

These recommendations rely on the ability of the cruise operators to implement them with determination, care, and a strong commitment to protect the health and safety of guests and crew. Fortunately, the Expert Panel's experience over the past four months has been that cruise operators are approaching the challenges presented by the COVID-19 pandemic in a thoughtful, positive, and aggressive manner and, to ensure they have the highest levels of execution, are planning to employ appropriate auditing, verification, and continuous learning systems.

¹ SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2) is the virus that causes the disease COVID-19.

I. Background

On January 31, 2020 the United States Centers for Disease Control and Prevention (CDC) declared that COVID-19 constitutes a public health emergency under the Public Health Service Act.² Since early 2020, public health authorities across the country have been working to contain the spread of this disease.³

The early months of 2020 were marked by a number of COVID-19 clusters and outbreaks associated with cruise ship travel.⁴ As CDC has noted, “the initial stages of the COVID-19 epidemic were marked by the outsized role of a single cruise ship...in Yokohama, Japan.” In the United States, the “Federal government engaged in a massive effort to disembark and quarantine American passengers” from one cruise ship on four military bases to help prevent further spread to passengers’ home communities. Therefore, with the concern and recognition that “cruise ship travel markedly increases the risk and impact of the COVID-19 disease outbreak within the United States,” on March 14, 2020, the CDC Director issued a No Sail Order for cruise ships. It was subsequently renewed and updated on April 15, 2020⁵ and again on July 21, 2020.⁶ The order remains in effect until one of the following occurs: the expiration of the Secretary of Health and Human Services’ declaration that COVID-19 constitutes a public health emergency, the CDC Director rescinds or modifies the order based on specific public health or other considerations, or we reach September 30, 2020.⁷

Recognizing the new health and safety risks posed by the continued spread of SARS-CoV-2, the cruise industry has focused on additional measures to protect the health of passengers and crew and on implementing the necessary ship upgrades and risk mitigation protocols to enable their services to safely resume in an environment that significantly mitigates the potential for spread of SARS-CoV-2.

Since issuance of the CDC No Sail Order in March, the cruise industry has been seeking advice from some of the world’s leading experts to inform their plans and pathways back to a “new normal” of sailing. Specifically, Royal Caribbean Group and Norwegian Cruise Line Holdings Ltd. have dedicated the last several months to deploying all of the resources necessary to make their ships ready to safely resume guest operations at the appropriate time. These cruise operators have engaged in a collaborative effort to develop new and enhanced cruise health and safety standards informed by the Healthy Sail Panel.

² U.S. Dept. of Health and Human Services, Assistant Secretary for Preparedness and Response, “Determination that a Public Health Emergency Exists,” published January 31, 2020, accessed September 18, 2020, <https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx>.

³ U.S. Dept. of Health and Human Services, Centers for Disease Control and Prevention, “No Sail Order and Other Measures Related to Operations,” published March 14, 2020, accessed September 18, 2020, https://www.cdc.gov/quarantine/pdf/signed-manifest-order_031520.pdf.

⁴ Id.

⁵ U.S. Dept. of Health and Human Services, Centers for Disease Control and Prevention, “No Sail Order and Suspension of Further Embarkation; Notice of Modification and Extension and Other Measures Related to Operations,” *Federal Register* 85, no. 73 (April 15, 2020): 21,004-21,008.

⁶ U.S. Dept. of Health and Human Services, Centers for Disease Control and Prevention, “No Sail Order and Suspension of Further Embarkation; Second Modification and Extension of No Sail Order and Other Measures Related to Operations,” *Federal Register* 85, no. 140 (July 21, 2020): 44085-44094.

⁷ U.S. Dept. of Health and Human Services, Centers for Disease Control and Prevention, “Cruise Ship Guidance,” CDC website, last updated July 16, 2020, accessed September 18, 2020, <https://www.cdc.gov/quarantine/cruise/index.html>.

The Panel was tasked with developing recommendations for cruise operators to advance their public health response to COVID-19, improve safety, and achieve readiness for the safe resumption of operations. Royal Caribbean Group and Norwegian Cruise Line Holdings Ltd. have leveraged ongoing feedback from the Panel to craft plans and protocols that appropriately address the challenges of the current public health environment due to SARS-CoV-2.

II. Panel Overview

The Healthy Sail Panel is comprised of a group of globally recognized experts with diverse backgrounds, including in public health, infectious disease, biosecurity, hospitality, and maritime operations. It is co-chaired by Governor Mike Leavitt, former Secretary of the U.S. Department of Health and Human Services (HHS), and Dr. Scott Gottlieb, former Commissioner of the U.S. Food and Drug Administration (FDA). Panel members were selected with input from several sources, including cruise operators, but ultimate selection of the Expert Panel was carried out by the Panel's co-chairs. Members of the Expert Panel include:

- **Helene Gayle**, MD, MPH – CEO of the Chicago Community Trust, former Director of CDC Center for HIV, TB and STD Prevention
- **Julie Gerberding**, MD, MPH – Executive Vice President and Chief Patient Officer for Merck; Former Director of the Centers for Disease Control and Prevention
- **Steven Hinrichs**, MD – Professor and Chair in the Department of Pathology and Microbiology at the University of Nebraska Medical Center in Omaha; Former Director of the Nebraska Public Health Laboratory (NPHL); Director of the University of Nebraska Center for Biosecurity
- **Michael Osterholm**, MD, PhD – Director of the Center for Infectious Disease Research and Policy at the University of Minnesota
- **Stephen Ostroff**, MD – Former Acting Commissioner of the Food and Drug Administration
- **William Rutala**, PhD, MS, MPH – Professor in the Division of Infectious Diseases at the University of North Carolina's School of Medicine; Director, Statewide Program for Infection Control and Epidemiology; Former Director, Hospital Epidemiology, Occupational Health and Safety Program, UNC Hospitals
- **Kate Walsh**, PhD – Dean of the School of Hotel Administration at Cornell University
- **Captain Patrik Dahlgren** – Senior Vice President of Global Marine Operations and Fleet Optimization for Royal Caribbean Group
- **Robin Lindsay** – Executive Vice President of Vessel Operations for Norwegian Cruise Line Holdings Ltd.

Full biographies of all Panel members are included in Appendix A. The Expert Panel also benefited from the advice and experience of key public health advisors:

- **Phyllis Kozarsky**, MD – Professor Emerita in Medicine and Infectious Diseases at Emory University, Co-Founder of the International Society of Travel Medicine
- **Caitlin Rivers**, PhD – Assistant Professor in the Department of Environmental Health and Engineering at the Johns Hopkins Bloomberg School of Public Health

All panelists and advisors participated in this work in their personal capacities. Recommendations do not represent endorsement by their other institutional affiliations.

The work of the Expert Panel was designed and intended to be fully transparent to both industry leaders and regulators so that its work could be freely adopted by any company or industry that would benefit from the group's scientific and medical insights. As such, the Panel welcomed observers from:

- Centers for Disease Control and Prevention
- Cruise Line International Association (CLIA)
- Carnival Cruise Line & plc
- MSC Cruises

The Panel's discussions were focused on developing a core set of recommendations for cruise operators on developing plans for resuming operations that protect the public health and safety of guests, crew, and the communities cruise ships visit by leveraging the best available insights from public health, science, and engineering expertise. The Panel discussions and deliberations were highly collaborative and benefited from robust participation from the diverse group of experts and the cruise operators. While the Panel included leading experts with depth of experience in a variety of relevant areas of science, hospitality, and public health, the experts relied on the cruise operators on the Panel to contribute the necessary expertise around the operational constraints and unique considerations of cruise travel.

The varied and deep expertise of all Panel members, conveners, advisors, and observers was a source of critical insight during the framing of these recommendations. The Panel members' areas of knowledge span preventive testing, surveillance and safety measures, environmental and engineering controls, case management and evacuation protocols, and destination and itinerary planning. As we believe will be evident in these recommendations, the Panel aimed to achieve the appropriate balance between addressing business needs and operational realities, with the paramount goal of creating enhanced health and safety standards.

We came away convinced of both companies' determination and commitment to create best practices for mitigating the risk of SARS-CoV-2, to ensure the safety of passengers, crew, and destination communities, and to implement a best-in-class set of standards for safety.

III. Methods

Once formed, the Panel created work groups to discuss and propose recommendations around four key areas:

- Work Group 1: Health: Screening & Exposure Reduction
- Work Group 2: Environmental, Operations & Engineering Controls
- Work Group 3: Response, Contingency Planning & Execution
- Work Group 4: Destination & Itinerary Planning

The work groups met at least every other week to identify and answer key questions for each topic, including questions identified in the CDC's "Request for Information Related to Cruise Ship Planning and Infrastructure, Resumption of Passenger Operations, and Summary Questions" (CDC's RFI) issued on July

21, 2020.⁸ The Panel leveraged the two cruise operators' return to service planning and discussions as a starting point for our final recommendations. The cruise operators also joined work group calls to provide guidance and information on the specifics of cruise ship operations, layouts, and technology, and to provide an understanding of whether proposed recommendations could be operationally feasible and how the Panel's proposals relate to current practices.

We reviewed multiple proposed protocols and action plans that the cruise operators had developed to address key issues. We interacted with dozens of representatives from Royal Caribbean Group and Norwegian Cruise Line Holdings Ltd., as well as with representatives from other cruise lines and associations, and we recognized their commitment to the health and safety of their guests, crew, and communities they visit. In addition, we reviewed materials that had been jointly produced by both companies with the focus on creating best practices across the industry and a determination to exceed the standards that have been adopted in many other areas on land, sea, and air.

Following discussion with the cruise operators, thorough consideration of the most up-to-date scientific and public health knowledge, and formation of recommendations, each work group brought their recommendations to the full Expert Panel for further discussion and ratification.

In each biweekly meeting, the full Panel discussed all four work groups' recommendations, modified them as necessary, and reached a consensus on whether they should be incorporated into the final set of recommendations (detailed here). In circumstances where a full consensus was not reached, the work groups revisited the topic to answer any outstanding questions identified by the Panel and to revise its recommendations. Furthermore, given the unique considerations for crew members that were continuously discussed across all four work groups, the Panel convened an additional ad-hoc work group to focus on mitigating risks related to crew members.

IV. Guiding Principles

As members of the Panel, we view our work as an ambitious, cross-disciplinary, public health, problem-solving endeavor. In developing our recommendations, our main objectives were to improve health and safety, advance public health goals, and help inform the cruise industry's efforts to achieve the objectives listed by the CDC's No Sail Order:

- Preservation of human life;
- Preventing the further introduction, transmission, and spread of COVID-19 into and throughout the United States;
- Preserving the public health and other critical resources of federal, state, and local governments;
- Preserving hospital, healthcare, and emergency response resources within the United States; and
- Maintaining the safety of shipping and harbor conditions, including safety of personnel.

In undertaking this task, several important principles, as outlined below, guided our work.

⁸ U.S. Dept. of Health and Human Services, Centers for Disease Control and Prevention, "Request for Information Related to Cruise Ship Planning and Infrastructure, Resumption of Passenger Operations, and Summary Questions," *Federal Register* 85, no. 140 (July 21, 2020): 44,083-44,085.

Risk can never be fully eliminated, but with appropriate measures in place, it can be substantially reduced, and many layers of risk reduction are needed since each alone is insufficient.

When we embarked on this collaborative effort, we acknowledged at the start that risk can never be fully eliminated. This concept came up repeatedly in our conversations, and we strived to focus on minimizing risks wherever possible and mitigating risks that cannot be fully eliminated. An important principle underlying our effort was to create multiple layers of prevention. Both early detection of infected individuals and risk mitigation strategies are needed in order to reduce the risk of an outbreak. No single measure is sufficient, but all should be interconnected with other measures. If one particular strategy is not as effective as expected or is not faithfully implemented, having redundant layers of protection is expected to provide additional risk mitigation. We believe that taken together, the totality of measures being recommended will enable cruise operations to resume operations prudently.

Risk mitigation strategies must be practical and balanced with operational feasibility.

The Panel's recommendations balance what is best from an infection control and medical perspective with what is operationally feasible and practical to implement on a cruise ship. Recommendations that are not possible to implement or that are unlikely to gain full compliance will not be effective in reducing risk. Recommendations were made wherever activities could be modified to improve safety without a major impact on the guest experience. In certain areas this was a particularly challenging task. Some recommendations, such as improvements to the air filtration systems and enhanced sanitation protocols, will happen largely behind the scenes and will have no negative impact on the guest experience. Others, such as social distancing, mask use, and modification or even cancellation of certain activities during the cruise will directly impact the guest experience. The Panel paid special attention to these areas, and we believe our recommendations strike the appropriate balance between safety and practicality.

Aggressive measures to minimize or prevent SARS-CoV-2 from entering a ship are the single most important step that can be taken to reduce risk of an outbreak on board.

The Panel recognizes that people will be arriving to the cruise ship with varying levels of individual risk due to personal activities and exposures, including arriving from communities with varying levels of SARS-CoV-2 prevalence. While many of the recommendations included here are aimed at preventing the spread of SARS-CoV-2 among guests and crew once on board cruise ships, preventing the virus from coming onto the cruise ship in the first place is the top priority. Aggressive testing, health screenings, and exclusion policies will be critical.

Despite all the measures put in place, SARS-CoV-2 infections may still occur on cruise ships. If they do, cruise operators' goals should be to (1) minimize risk of transmission among individuals and prevent a widescale outbreak, (2) provide appropriate care on board for those infected, and (3) arrange in advance for appropriate transfers of impacted guests or crew.

Despite all of the measures cruise operators will take to prevent SARS-CoV-2 from being introduced into the ship environment, infections may still occur because, as previously mentioned, there is no way to eliminate risk entirely. It is important to minimize consequences if the virus is identified on board through proper contact tracing and quarantine/isolation procedures to stop transmission and prevent an outbreak. Furthermore, cruise operators will need to be prepared with the proper medical

equipment, expertise, and training to treat severely ill people who contract COVID-19 while on board until they can be safely transferred to onshore medical facilities. The ultimate measure of success will be having robust protocols that are faithfully implemented and improved upon over time to prevent outbreaks and negative outcomes.

Previous incidents (such as the situations in Yokohama and San Francisco) provide important lessons to enable cruise operators to avoid similar situations in the future.

At an early stage in the outbreak, the industry experienced incidents where entire ships were quarantined. Such incidents were traumatic for passengers and in some cases resulted in unfortunate and unnecessary spread of illness. In addition, such incidents involved significant burdens on the governments involved. Cruise industry knowledge of the virus and ways to control the spread of disease have improved dramatically since those early days, and lessons learned from those experiences, as well as the new tools available, were considered by the Panel. The Panel recognizes the necessity of avoiding such incidents in the future and has recommended steps to do so. In particular, cruise operators should establish in advance a robust, pre-approved program, that includes the use of third-party operators, to handle the logistics in the event of illness.

There is an opportunity to train and learn from a phased-in return to sailing before full guest operations resume.

The cruise industry has a history of conducting test sailings when they introduce a new product. These are normally several cruises of short duration with selected invited guests and limited itineraries, which gives the operator the opportunity to train the crew and refine its procedures. We believe that such a process could be helpful in the introduction of these protocols and procedures, giving the operators the opportunity to ensure that their programs are well understood and work appropriately. This concept is described in further detail later in this document.

Vigilance in implementation, continuous improvement, and innovation will be needed.

Cruise operators should commit to vigilance in implementing protocols and continuously assess their success in doing so. As they resume operations, it should be with a spirit of iterative learning and improvement as they adjust to sailing under new procedures. Particularly in regard to surveillance for SARS-CoV-2 on board, cruise operators should be proactive and forward-thinking, in addition to being reactive whenever an infection is discovered. As scientific understanding of SARS-CoV-2 rapidly evolves, new information, technologies, treatments, and preventive measures may call for adjustments in procedures. These recommendations are intended to be the initial steps, and we expect that they will continue to be revised and improved as knowledge of the virus and ways to control it continue to evolve.

Gating Criteria

The Healthy Sail Panel was convened to provide a set of recommendations for SARS-CoV-2 risk-mitigation strategies and protocols that, if implemented appropriately, will provide regulators, cruise operators, guests, and crew with confidence that cruise ships can begin to sail again in a way that appropriately protects the safety of all persons on board and those at the destinations they visit. What became clear in our discussions almost immediately was that this exercise requires a holistic view of

risk. The Panel contemplates a scenario where cruise travel can be resumed most safely by creating as much of a “bubble” as possible, by preventing SARS-CoV-2 from coming on board a ship. In the event that the virus does enter the ship environment, the goal is to prevent severe COVID-19 outcomes for individuals who contract the illness and to prevent transmission that could result in an outbreak on board. Under this construct, there are three main categories of risk to consider:

- 1) What is the risk of a guest or crew member boarding the ship while infected with SARS-CoV-2?
- 2) What is the risk of an individual acquiring SARS-CoV-2 infection while visiting a destination on the cruise?
- 3) What is the risk of either of those situations resulting in widespread transmission of SARS-CoV-2 onboard the ship?

This section on “gating criteria” addresses the first question: “What is the risk of a guest or crew member boarding the ship while infected with SARS-CoV-2?”

We started with the assumption that, independent of what the cruise lines would be able to do to mitigate risks, the external factors (*i.e.*, the epidemiology of the disease) would substantially affect risk. Thus, the Panel initially set out to craft recommendations for “gating criteria” or a set of parameters that would lie above all of the Panel’s recommendations to provide advice about what conditions must be met to resume sailing and how to plan for which destinations to visit. These criteria could also be used, eventually, to understand when it would be appropriate to scale down or phase out some of the risk mitigation protocols recommended to cruise operators.

We initially assumed that these gating criteria would be heavily dependent on the status of the COVID-19 pandemic (*i.e.*, the global, regional, and local prevalence and burden of SARS-CoV-2). We intended to decide on a metric or combination of metrics (*e.g.*, disease incidence, prevalence, test positivity rate) and certain ranges for each metric, to develop the gating criteria. However, after substantial thought and discussion, the Panel determined that the up-front assumption that we had made—that the decision about when to resume sailing and which risk mitigation protocols should be employed should be driven by the status of the global pandemic—was imperfect.

While the current status of the pandemic is a legitimate factor in determining an individual’s risk of infection, that risk is significantly influenced by an individual’s behavior and exposures before they board the ship. We believe there is a high likelihood that regardless of the SARS-CoV-2 prevalence and burden in a given locality or region, the activities and exposures of the individuals from that region will be far more predictive of their likelihood of contracting the virus and bringing it to the ship than the fact that they traveled from a given location. Further, the quality of epidemiologic data varies across regions and localities, so it is not possible to confidently attribute the metrics of a region to the relative risk of infection of individuals from that area.

After assessing the shortcomings in these metrics and the importance of individual variability in risk, we came back to the question of why we were trying to develop these measures. The value in using any of these factors is to attempt to quantify the risk that someone infected with SARS-CoV-2 will board the ship. But throughout our discussions, we acknowledged that the best way to mitigate this risk is with an aggressive testing regimen, regardless of where an individual is from. Specifically, we believe that the preboard testing protocol that we have recommended can greatly reduce the risk of infected individuals boarding the ship.

As such, we are unable to suggest specific parameters (*e.g.*, local incidence of SARS-CoV-2) that would indicate that it is “safe enough” to begin sailing again. There is no moment when we will definitively know we have reached that threshold. Instead, we would like to reiterate our confidence in the ability of the proposed preboard testing strategy, in conjunction with onboard risk-mitigation measures and controls, to maintain a healthy “bubble” within which cruises can operate. It is our firm belief that evaluation of a cruise operator’s ability to identify cases prior to boarding through testing and individual health screening, and the implementation of appropriate safety protocols and protective measures on board, will be a more instructive measure of whether sailing can safely resume than metrics regarding the status of the pandemic. Therefore, the Panel believes that ultimately, the thoroughness of a cruise operator’s testing plan and implementation of onboard mitigation measures should be the driving factor in creating a safe environment for cruising.

I. Recommendations Summary

Because the COVID-19 pandemic is ever-changing and the future is unpredictable, the Panel’s recommendations reflect the current state and science of the COVID-19 pandemic. The Panel acknowledges that SARS-CoV-2 will likely continue to spread, at variable levels, for some period of time. While we can’t predict exactly how or when control measures like a vaccine or advances in treatment will reduce risk, common sense tells us that certain measures will need to continue to be in place to address SARS-CoV-2 and other infectious diseases, while other measures that we are recommending to cruise operators may be modified over time.

Because, as noted above, societal prevalence rates are an imperfect indicator of risk, we are unable to point to specific parameters that would determine at which point those control measures could be modified from the criteria that we have outlined here. However, the Panel felt comfortable with suggesting which recommendations may be able to be modified over time, even without specifically defining the threshold of when we have reached a “new normal” of this pandemic where it remains a public health concern but does not pose the same threat as it does today. The following chart summarizes our recommendations and indicates which of them can be scaled down, modified, or discontinued over time (M) and which should continue to be implemented to address SARS-CoV-2 and other infectious diseases (K).

#	Recommendations	M	K
	Modify (M): Recommendations that can be scaled down, modified, or discontinued over time Keep (K): Recommendations that should continue to be implemented to address SARS-CoV-2 and other infectious diseases		
	Testing		
1	All crew should be tested for SARS-CoV-2 between 5 days and 24 hours prior to leaving their home location to join the ship and receive a negative result, quarantine for seven days on board the ship upon arrival, and take a test at the end of that seven-day period and receive a negative result, before beginning their duties. Additionally, if feasible based on cost and available technology, cruise operators should consider administering an additional test and requiring a negative result shortly prior to boarding.	X	

2	Cruise operators should implement a crew surveillance program, including periodic testing for SARS-CoV-2, to provide a reasonable level of assurance that the virus is not circulating among crew.	X	
3	Other employees and ancillary staff (<i>e.g.</i> , luggage porters and transportation providers) should undergo daily symptom screening but do not need to be regularly tested like crew or guests.		X
4	All guests joining a ship, regardless of method of travel to the ship, should be tested for SARS-CoV-2 between 5 days and 24 hours before boarding and receive a negative result that is shared with the cruise operator, before coming on board.	X	
Health Screening			
5	At embarkation, all guests and crew boarding the ship should undergo health screening to identify any symptoms consistent with COVID-19 (or other infectious diseases) and any contact with individuals suspected or confirmed to have a SARS-CoV-2 infection prior to the cruise.		X
6	All individuals should have their temperature taken via contactless device as part of the boarding process.	X	
7	Any individual who discloses symptoms of possible SARS-CoV-2 infection or close contact with an individual with suspected infection, or who displays a temperature of 100.4 degrees or above, should undergo secondary screening by medical personnel to determine whether they may board the ship or whether they will be denied boarding.		X
Denial of Boarding			
8	Cruise operators should not allow an individual to sail if they do not affirmatively state their willingness to comply with current safety and public health protocols.		X
9	Individuals who have received a positive SARS-CoV-2 test or who have in the last 14 days been in close contact with an individual with <u>confirmed</u> infection should not be permitted to board the ship.		X
Policy on Guests at Increased Risk of Severe Illness			
10	Cruise operators should rely on CDC guidelines to determine who is at an increased risk of severe illness and who may be at an increased risk of severe illness.		X
11	Cruise operators should recommend that guests who are or may be at increased risk of severe illness consult with their health care provider before traveling.		X
Guest Information & Education			
12	In addition to the information typically communicated at booking, guests should be provided sufficient information on SARS-CoV-2 to assess their individual risk, to fully understand the safety precautions being taken by the cruise line to address SARS-CoV-2, and to agree to comply with the necessary safety protocols while traveling.		X
Onboard Symptom Tracking and Monitoring			
13	Cruise operators should conduct once-daily temperature checks for guests and crew on board.	X	
14	Cruise operators should employ routine symptom screening methodologies to help ensure that potential SARS-CoV-2 infections are identified as quickly as possible.		X

15	Cruise operators should ensure education efforts are in place to help guests understand the importance of reporting symptoms and potential repercussions of failure to report symptoms.		X
Personal Protective Equipment (PPE) Usage			
16	To prevent the spread of SARS-CoV-2, cruise operators should require guests and crew to wear cloth face coverings/face masks in accordance with CDC recommendations.	X	
17	Crew members with prolonged contact (<i>i.e.</i> , contact that may result in exposure by CDC's definition) with guests on board the ship should be required to utilize complementary PPE, in addition to wearing a face mask/face covering.	X	
Capacity Restrictions			
18	When returning to sailing, cruise operators should adjust guest and crew load factors in a manner that allows for appropriate physical distancing on board in accordance with applicable guidance, taking into consideration the size and design of each ship.	X	
General Distancing Guidelines			
19	Cruise operators' facilities on board the ship, at terminals, and at cruise line-owned and operated destinations should be modified to promote and facilitate physical distancing in accordance with the CDC recommendation of a distance of at least six feet.	X	
20	Abundant signage and floor markers should be utilized to communicate physical distancing requirements in the terminal, at cruise line-owned destinations, and on board the ship, with a particular emphasis on high-traffic areas (<i>e.g.</i> , gangways, elevators, ship common areas).	X	
Terminal, Boarding, Debarkation Controls			
21	Cruise operators should utilize processes and protocols for touchless check-in and speedier boarding to reduce contact and potential congestion in the terminal.		X
Sanitation			
22	Cruise operators should educate guests in advance of travel about the sanitation measures that are being used preboard, on board, and at private, cruise line-owned and operated destinations.		X
23	Enhanced sanitation protocols should be employed to protect against the risk of SARS-CoV-2 transmission via inanimate surfaces or objects, with attention to both high- and low-touch areas of the ship, terminal, and cruise line-owned and operated destinations.		X
24	Cruise operators should ensure that all disinfectants used for cleaning and disinfection are on the EPA's List N: Disinfectants for Use Against SARS-CoV-2 or national equivalent for terminals located outside the U.S., which must also comply with local government regulations.		X
Hand Hygiene			
25	Cruise operators should follow CDC recommendations regarding the use of hand sanitizers and hand washing with soap and water to craft their recommendations for guests.		X
26	Cruise operators should ensure that hand sanitizer stations, wipes, or hand washing stations are conveniently placed around the ship for guests' and crew members' usage.		X

27	Cruise operators should ensure that crew members are thoroughly trained on all aspects of infection control with emphasis on proper hand hygiene techniques.		X
28	In addition to providing hand sanitizer and hand washing stations on board, cruise operators should encourage hand washing or use of hand sanitizer before and after guests participate in recreational activities.		X
Ventilation, HVAC, Filtration Controls			
29	Transmission of SARS-CoV-2 through the air is sufficiently likely that airborne exposure to the virus should be controlled for.		X
30	Cruise operators should use a variety of indoor air management strategies aimed at reducing occupant exposure to infectious droplets/aerosols.		X
31	All cruise operators should upgrade the HVAC systems on their ships to, ideally, MERV 13 filters to minimize pathogen dispersal from infected guests and crew.		X
32	Cruise operators' indoor air management strategies should be optimized given the constraints of ship age and ventilation type.		X
33	When considering air management strategies, cruise operators should have a primary focus on reducing exposures in the core set of areas where guests and crew would be most vulnerable to droplet/airborne exposure to virus.		X
Medical Personnel			
34	As a part of augmenting onboard medical capacity to ensure preparedness for potential COVID-19 cases, cruise operators should increase their existing ratios of medical personnel to guests and crew.	X	
35	Cruise operators should ensure redundancy and back-up for onboard medical personnel.		X
36	Cruise operators should ensure there is sufficient onboard medical leadership on all ships, including the designation of a crew member with responsibility for infectious disease prevention and response who will inform and oversee execution of components of the response to an outbreak. Cruise operators should also ensure they have a doctor on board with intensivist training to manage the medical care of severely ill patients.		X
Onboard Clinic Design & Operations			
37	Cruise operators should increase the capacity in their onboard medical facilities to treat patients who may become critically ill from SARS-CoV-2 infection or other unrelated illnesses.	X	
38	Cruise operators should amplify the varieties and amount of equipment in the onboard medical facilities, including the ability to test for SARS-CoV-2 infection on board.		X
39	Cruise ship facilities should be arranged to accommodate care for patients presenting with suspected infectious disease separately from care for those presenting with non-infectious diseases.		X
40	Rather than a patient having an in-person appointment at the medical facility to receive a diagnosis or care, medical appointments should be scheduled virtually/remotely and/or medical staff members should hold appointments in the patient's stateroom when possible.		X
Treatment Plan			

41	A cruise line's medical treatment plan should be responsive to the current understanding of COVID-19 and optimal treatment protocols, as well as to the specific clinical needs of each patient.		X
42	Cruise operators should have established relationships with onshore medical institutions that can provide telemedicine consultations in the event of a more serious COVID-19 case.		X
Contact Tracing			
43	Cruise operators should use CDC guidance as a general guide regarding exposure (< 6 feet for ≥ 15 minutes), pending updates based on emerging scientific evidence.	X	
44	Cruise operators should define high-, medium-, and low-risk exposures such that recommendations for each exposure level can be efficiently operationalized.		X
45	Cruise operators should employ a variety of contact tracing methodologies to ensure that all potential SARS-CoV-2 infections are identified as quickly as possible.		X
46	Cruise operators should collect metrics on the effectiveness of contact tracing.		X
47	Cruise operators should be transparent in their communication with guests about what information is being collected and how it will be used for contact tracing.		X
Isolation/Quarantine			
48	Cruise operators should designate certain cabins on the ship as isolation and quarantine spaces.		X
49	Cruise operators should provide guidelines for the determination of whether, when, and where an individual should be isolated or quarantined based on their exposure risk, symptoms, etc.		X
Debarcation Scenarios			
50	Cruise operators should have a thorough mobilization response plan in place prior to sailing to address the various scenarios that may require individuals with confirmed SARS-CoV-2 infection (guests or crew), and their close contacts, to debark from the ship.		X
51	Cruise operators should define the criteria for small-, moderate-, and large-scale debarkation scenarios in advance of cruising, including a clear decision-making process to guide thinking about when the threshold has been met for each risk level.		X
52	Cruise operators should establish offsite incident management with designated medical professionals' advice to respond rapidly and to aid in decision-making.		X
53	In any debarkation scenario, individuals with confirmed SARS-CoV-2 infection, close contacts, and persons under investigation should be kept separate from any healthy individuals (<i>i.e.</i> , those not identified through contact tracing or those who have tested negative).		X
54	Cruise operators should establish a communications plan, and assign a communications lead in advance, to share timely, relevant information with crew and guests on board the ship in the event of a SARS-CoV-2 infection during or after the cruise. Additionally, cruise operators should have systems in place to coordinate information about SARS-CoV-2 infections to relevant health authorities.		X
Destination & Itinerary Planning			

55	There are two essential prerequisites that need to be satisfied in order for a ship to sail to a given port: 1) Approval from the local government to visit a port. 2) Agreement to allow safe passage to SARS-CoV-2-infected individuals and their close contacts to debark and travel home.		X
56	Cruise operators should rely primarily on three key parameters when determining whether to travel to a given port: 1) Current burden of SARS CoV-2 as defined by testing rate, positivity rate, and death rate. 2) Local testing capacity. 3) Local/regional/national implementation of SARS CoV-2 mitigation protocols.		X
57	In the startup phase, cruises itineraries should be as simple as possible, utilizing private, cruise line-owned and operated destinations or ports where there can be tight control of the onshore experience.	X	
58	Cruise operators should initially return to service with shorter length trips.	X	
Guest Excursions			
59	During the initial return to sailing, cruise operators should only allow guests debarking from a ship at a destination port to participate in cruise line-sponsored or verified excursions as a way of limiting potential exposures in the destinations they visit.	X	
60	Cruise operators should establish expectations of the vendors at the destinations they visit to ensure that they are taking recommended steps to reduce the transmission of SARS-CoV-2.		X
61	Cruise operators should incorporate verification of compliance with SARS-CoV-2 protocols into their routine ongoing monitoring guidelines for excursion vendors.		X
62	Cruise operators should ensure that guests are thoroughly informed about potential exposure risks and how to minimize their risk of contracting SARS-CoV-2 at the planned destination.		X
63	Cruise operators should offer indoor excursions only if physical distancing, use of masks, and other recommended protective measures can be implemented.	X	
Prevention (Crew)			
64	Cruise operators should manage the population density of crew areas of the ship.	X	
65	Cruise operators should provide opportunities for crew to debark from the ship at destinations while maintaining reasonable limitations on their movement to reduce risk of exposure to SARS-CoV-2.	X	
66	Crew should be placed in single-occupancy crew cabins whenever possible to minimize extended periods of close contact with other crew members.	X	
67	Cruise operators should limit crew members' close contact with guests over extended periods of time wherever possible. When distancing isn't possible, crew should be provided with additional PPE appropriate to their job type.	X	
68	Cruise operators should include crew in the surveillance, contact tracing, quarantine, isolation, and debarkation protocols that will be employed in the event that a SARS-CoV-2 infection is discovered on board.		X
Training & Culture			

69	Crew should be provided with regular training on protocols to reduce transmission of SARS-CoV-2 and empowered to take action to ensure these protocols are followed by guests and fellow crew members.		X
70	Cruise operators should reinforce a culture of honesty and collective responsibility among crew for following protocols and creating a safer environment.		X
Validation of Implementation			
71	Cruise operators should have measures and metrics in place to perform continual self-assessment of compliance with all updated health and safety protocols as well as methods for third-party verification of compliance.		X
72	Cruise operators should perform an “after-action review” following a cruise on which a SARS-CoV-2 infection was detected to assess gaps and make improvements prior to the next trip.		X
The Path Forward			
73	In their return to sailing, cruise operators should use a phased approach to demonstrate that protocols can be successfully implemented on board their ships before returning to full operations with guests on board.	X	
74	Cruise operators should implement a formal process to review health and safety experiences related to COVID-19 on cruises to enhance best practices and shared learnings for continuous improvement.		X

Recommendations

I. Health: Testing, Screening & Exposure Reduction

Key to preventing an outbreak on board a ship will be developing and implementing several layers of protection—beginning before crew and guests arrive to the ship, continuing through the time when they are on board, and lasting until they eventually debark. The best way to prevent an outbreak on board is through robust testing prior to embarkation, supported by preboard education and health screening for guests and crew. If diligently followed, these steps will greatly reduce the likelihood of the introduction of SARS-CoV-2 on cruise ships. Once individuals are on board, a variety of measures can be employed to identify SARS-CoV-2 infections and reduce the risk of person-to-person transmission. Each measure alone is insufficient, but a multi-layered approach, with careful planning and implementation, is much more likely to reduce the risk that the virus will spread among passengers and crew.

i. Assessing the Health Status of Guests and Crew

Prior to boarding, cruise operators should provide the necessary educational information for all crew members and guests to understand the risks inherent in cruise travel during the ongoing pandemic and to guide their decision-making about their own individual health risk factors, risk tolerance, and comfort with cruising. Additionally, guests and crew should understand prior to booking their trip, and be reminded about prior to boarding, the measures that cruise operators will take to protect them, as well as their individual obligations to follow relevant protocols and to seek medical attention if they are ill.

Testing, screening, and onboard symptom tracking will be essential components of prevention and early detection of any illness.

Testing

Preboard testing for SARS-CoV-2 infection for guests, crew, and employees at private, cruise line-owned and operated destinations is the single most important step that can be taken to prevent disease introduction on board. Given the congregate nature of cruise travel and global prevalence of SARS-CoV-2, the Panel recommends universal testing prior to boarding as cruise ships return to service. As is described more fully below, the Panel recommends a minimum of 1 and preferably 2 preboard negative SARS-CoV-2 test results for guests and a minimum of 2 preboard and 1 post-quarantine negative SARS-CoV-2 test results for crew members, presuming feasibility of rapid testing at the pier.

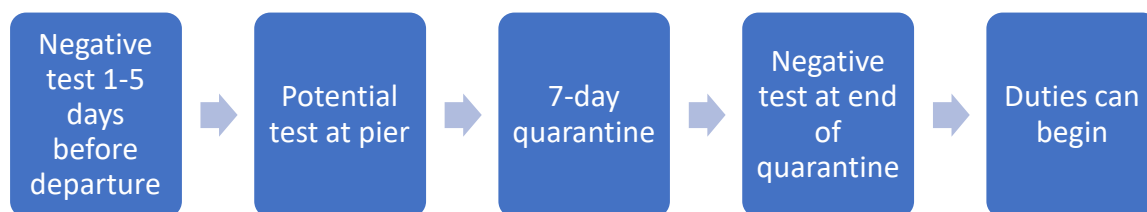
For the purposes of this testing section only, the term “guest” will be used to refer to all guests listed on the guest manifest and short-term vendors, contractors, startup employees and shoreside employees who might be listed in both the guest and crew manifests. The term “crew” refers to all individuals listed on the crew manifest who are crew under contract for the ship and the cruise lines’ private destinations manifest. A final term “other employees and ancillary staff” refers to a category of staff who may have brief contact with guests but generally are not boarding the ship (*e.g.*, luggage porters and transportation providers).

The Panel acknowledges that its recommendations regarding testing may change over the coming months as the testing landscape evolves, and particularly once an effective vaccine is widely available. However, given the uncertainties around the timing, availability, and performance of a vaccine, the Panel recommends waiting until there is more certainty about these issues before recommending changes to the testing protocols based on vaccine availability.

Testing for crew

Recommendation 1: All crew should be tested for SARS-CoV-2 between 5 days and 24 hours prior to leaving their home location to join the ship and receive a negative test result, quarantine for seven days on board the ship upon arrival, and take a test at the end of that seven day period and receive a negative result, before beginning their duties. Additionally, if feasible based on cost and available technology, cruise operators should consider administering an additional rapid test and requiring a negative result shortly prior to boarding.

Figure 1: Crew testing protocol



Recognizing that crew on a cruise ship arrive from all over the world, remain on board the ship for extended periods of time, and may come in contact with a large number of other crew and guests on multiple sailings during this time, the Panel spent significant time discussing an appropriate testing

regimen to mitigate the risk of crew with a SARS-CoV-2 infection from boarding the ship. When first resuming sailing, cruise operators will need to increase staffing, so this is a particularly important point in the process to ensure that the new crew members coming on board are not infected with SARS-CoV-2.

The Panel recommends that all crew should be tested in their home location and shown to be negative before boarding an airplane or other commercial or private transportation method to travel to board the ship. Using a network of preferred, validated providers for testing would be the best option since the quality and reliability of testing may vary worldwide. The initial test should take place as close as possible to departure from the home location while allowing enough time for results to be returned before the crew member begins to travel. Thus, the Panel recommends a window of no less than 24 hours and no more than 5 days before departure. If a crew member receives a positive result, they should not commence travel to the ship; if a negative result is received, they can begin their journey to the ship. It should be noted that a crew member must receive a negative test result for this first test and every subsequent test taken in order to begin their duties.

As noted above, the Panel recommends that a second test be administered as part of the sign-on process for crew (*e.g.*, at the pier immediately before boarding or nearby the location where the ship is embarking), if it is feasible. This would provide a valuable second layer of protection to help assure that the earlier test result was not a false negative and that the individual did not acquire SARS-CoV-2 since the first test. Taking into consideration cost and feasibility, pooled testing or new rapid testing technologies may make this type of testing possible in the short window before boarding. If the results of this test are positive, the crew member should not board the ship, and should instead be isolated and treated on shore.

Once on board the ship, newly arriving crew members should enter a 7-day quarantine period in individual cabins. According to CDC, “quarantine separates and restricts the movement of people who were exposed to a contagious disease to see if they become sick;”⁹ therefore, inherent in the Panel’s quarantine recommendations are the parameters of such quarantine: crew will remain in their individuals cabins to maintain separation from others, meals should be delivered to them, crew will monitor their own health and report symptoms as soon as possible, and crew will follow all other quarantine instructions from the cruise operator.

Given that every crew member boarding the ship will have tested negative at least once, and twice if an additional test is added, the purpose of the onboard quarantine period is to identify any crew with SARS-CoV-2 infection who were not accurately identified through testing because they were too early in their infection, received a false negative test result, and/or acquired the virus during travel to the pier. During this period of time, any individuals who develop symptoms of COVID-19 can be identified, tested, isolated, and treated on board or debarked from the ship if necessary.

The Panel spent significant time discussing the appropriate length of quarantine for crew, and specifically whether a 14-day quarantine, the length of time recommended by CDC for an individual who has been exposed to someone with a SARS-CoV-2 infection, was needed. The Panel was cognizant of the

⁹ U.S. Dept. of Health and Human Services, Centers for Disease Control and Prevention, “Quarantine and Isolation,” CDC website, last updated September 29, 2017, accessed September 18, 2020, <https://www.cdc.gov/quarantine/index.html>.

operational challenges for cruise operators of such a quarantine length as well as the mental health effects on crew of being confined to their cabins for this length of time. Ultimately, the Panel decided that, based on current scientific understanding of the disease and when coupled with exit testing, a 7-day quarantine will be nearly as effective as a 14-day quarantine in detecting infected individuals¹⁰ and will greatly reduce the burden for cruise operators and crew alike. Exit testing at the conclusion of quarantine provides an opportunity to identify any infected individuals not identified during a first and possibly second round of testing and who remained asymptomatic for the duration of the onboard quarantine period. From a disease transmission perspective, the Panel believes that a 14-day quarantine without an exit test is a reasonable alternative that cruise operators may also choose to implement.

Polymerase chain reaction (PCR) diagnostic testing is the most accurate and reliable form of testing available. However, the options for testing are rapidly evolving and faster, less expensive, but still reliable testing options are becoming available as an alternative to PCR. In late August 2020, FDA granted an Emergency Use Authorization to a low-cost rapid SARS-CoV-2 diagnostic test using lateral flow technology, which can return a result within 15 minutes.¹¹ Soon, other reliable point of care tests are likely to become available, opening up the possibility of widespread, less invasive and inexpensive testing as well as further surveillance or re-screening opportunities that cruise operators deem appropriate. As access to such testing improves, it is important that cruise operators rely on high-quality testing that has been independently verified and received regulatory authorization or approval.

The Panel also emphasizes that antibody testing is not a substitute for a diagnostic test, which identifies current infection. The CDC provides further information on this topic in its interim guidance for rapid antigen testing for SARS-CoV-2 that was released on August 29, 2020.¹²

Taken together, these layers of testing and quarantine for new crew members should be highly effective in preventing SARS-CoV-2-infected crew members from boarding the ship or from exposing others once on board the ship. As part of its evaluation of options, the Panel discussed the return to sail experiences for the small number of ships in other jurisdictions that have resumed operations. Recent problems with COVID-19 on these ships demonstrate the importance of crew testing. When a preboard crew testing regimen has been followed, it has successfully identified infected crew and prevented them from boarding. In contrast, where protocols were not adopted or implemented, it has led to the introduction of virus onto ships and subsequent outbreaks.

Recommendation 2: Cruise operators should implement a crew surveillance program, including periodic testing for SARS-CoV-2, to provide a reasonable level of assurance that the virus is not circulating among crew.

One of the most critical yet challenging issues for cruise operators will be developing robust surveillance programs to identify any ill or asymptomatic individuals on board. Regular testing of crew is an important component of this surveillance regimen. The Panel spent time discussing whether individual

¹⁰ Stephen Lauer et al., “The Incubation Period of Coronavirus Disease 2019 (COVID-19) from Publicly Reported Confirmed Cases: Estimation and Application,” *Annals of Internal Medicine* 172, no. 9. (May 5, 2020): 577-582.

¹¹ U.S. Food & Drug Administration, letter of EUA authorization for BinaxNOW COVID-19 Ag Card, published August 26, 2020, accessed September 18, 2020, <https://www.fda.gov/media/141567/download>.

¹² U.S. Dept. of Health and Human Services, Centers for Disease Control and Prevention, “Interim Guidance for Rapid Antigen Testing for SARS-CoV-2,” CDC website, last updated September 4, 2020, accessed September 18, 2020, <https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html>.

crew members should be tested at differing intervals based on the number of guests they are likely to be in contact with, the nature of that contact, or the type of work they perform. Ultimately, the Panel felt that there is a wide variety of factors that may increase risk, and that even crew whose positions do not entail much guest contact may be exposed through contact with other crew members. Therefore, all crew members should be included in a SARS-CoV-2 surveillance program and be tested periodically.

The Panel recommends that the cruise operators develop their own program for regular testing of all crew members for surveillance purposes, and update it over time as the cruise operators gain real-world experience regarding the efficacy of the testing regimen in identifying SARS-CoV-2 infected crew members in a timely fashion. The testing regimen should be robust enough to provide a reasonable degree of assurance that the virus is not circulating among crew. One screening protocol that could be considered is testing 10% of the crew every week and oversampling the crew with high-touch/high-exposure jobs. Alternatively, cruise operators could choose to test all crew on a rotating cycle so that everyone is tested every other week.

Recommendation 3: Other employees and ancillary staff (e.g., luggage porters and transportation providers) should undergo daily symptom screening but do not need to be regularly tested like crew or guests.

There is a category of staff such as terminal agents, luggage porters, and transportation providers who may have brief contact with guests and crew, but generally do not have regular prolonged interactions with guests and will not be boarding the ship. Such employees and ancillary staff should undergo daily symptom checks and self-assessment, but do not require regular SARS-CoV-2 testing given the lower risks they pose.

Testing for Guests

Recommendation 4: All guests joining a ship, regardless of method of travel to the ship, should be tested for SARS-CoV-2 between 5 days and 24 hours before boarding and receive a negative result that is shared with the cruise operator, before coming on board.

As discussed throughout this document, testing for all individuals boarding cruise ships is a critically important step in reducing the likelihood of virus introduction on board the ship. All guests and short-term vendors, contractors, startup employees, and shoreside employees boarding a cruise ship should be tested 24 hours to 5 days before the cruise, so that they are able to receive a negative result prior to beginning their travel via land or air transportation to the port for embarkation. If a guest receives a positive result, they and their close contacts should not travel to the embarkation point.¹³

As discussed in the crew testing recommendation, if rapid, reliable, and clinically valid testing options become widely available, the addition of a second test at the pier or immediately before boarding would improve confidence in the testing regimen's ability to prevent SARS-CoV-2 from entering the ship. Using adequately sensitive testing methods, the likelihood of missing a SARS-CoV-2 infection in an individual because of false negatives is extremely low under this double testing scenario. Therefore, if logistically

¹³ Individuals who are unable to submit to testing due to a disability, or for whom testing is medically contraindicated, should be referred to a secondary medical screening where a case-by-case assessment of the individual's fitness for travel will be made, and a recommendation to allow or deny boarding will be based on the fitness-for-travel determination.

and financially feasible, the Panel recommends this as the standard protocol. However, the Panel emphasizes that a single test at the point of embarkation is not a substitute for an initial test performed before a guest departs their home location; rather, the second test supplements and provides additional confidence in the ability of cruise operators to identify infected guests prior to boarding.

Health Screening

While diagnostic tests are one method of reducing the risk of SARS-CoV-2 from coming on board, preboard health screening measures are not only useful for identifying individuals who may have COVID-19 (*i.e.*, an individual displaying symptoms); they can also identify at-risk individuals in ways that a diagnostic test cannot (*e.g.*, identifying individuals who have been exposed to SARS-CoV-2 prior to arrival). Combined with testing, preboard health screening provides another layer of protection against an individual infected with SARS-CoV-2 entering the ship. However, the effectiveness of preboard screening relies on individuals truthfully disclosing their symptoms as well as past exposures and having knowledge of those exposures. CDC estimates that 40 percent of infected individuals are asymptomatic,¹⁴ so it is a known and unavoidable weakness that health screening based on symptoms will not be able to detect these individuals. With the benefits and weaknesses of health screening in mind, the Panel recommends that anyone boarding a ship undergo health screening.

Recommendation 5: At embarkation, all guests and crew boarding the ship should undergo health screening to identify any symptoms consistent with COVID-19 (or other infectious diseases) and any contact with individuals suspected or confirmed to have a SARS-CoV-2 infection prior to the cruise.

It is already regular practice that individuals boarding a cruise ship undergo screening, aimed primarily at identifying gastrointestinal illness or pregnancy. To add to the information gleaned through the testing process, the Panel recommends that all individuals boarding the ship complete a self-assessment questionnaire to identify symptoms consistent with COVID-19. Since knowledge of the disease presentation has been changing as more is learned about the disease, the Panel does not recommend a specific set of questions but rather recommends that the cruise operators base their screening questionnaires on the latest CDC guidance regarding signs and symptoms of COVID-19.¹⁵ The assessment should also include questions to identify any contact prior to boarding with individuals diagnosed with, or displaying symptoms of, COVID-19. Given that many symptoms of COVID-19 are consistent with symptoms of influenza or other viral respiratory illnesses, the Panel emphasizes that health screening should be performed in conjunction with the testing regimen noted above. Health screening alone is insufficient to determine whether an individual should board the ship.

To encourage truthful reporting, cruise operators should make guests and crew aware that identification of symptoms or potential exposures does not automatically result in denial of boarding. An individual who reports a symptom that may indicate COVID-19 should go to a secondary screening area for further

¹⁴ U.S. Dept. of Health and Human Services, Centers for Disease Control and Prevention, "COVID-19 Pandemic Planning Scenarios," CDC website, last updated September 10, 2020, accessed September 18, 2020, <https://www.cdc.gov/coronavirus/2019-ncov/hcp/planning-scenarios.html>.

¹⁵ U.S. Dept. of Health and Human Services, Centers for Disease Control and Prevention, "Symptoms of Coronavirus," CDC website, updated May 13, 2020, accessed September 18, 2020, <https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html>.

medical evaluation. Individuals reporting recent, prior contact with an individual with suspected COVID-19 should also be referred to secondary medical screening.

The Panel's discussion reflected that the effectiveness of screening is limited in that it may not identify mild or atypical symptoms, asymptomatic individuals, or those travelers who are within the incubation period or concealing symptoms (*e.g.*, with use of antipyretics). Nonetheless, it is an important step to take toward both identifying risk and signaling to guests and crew that the cruise operator is taking every reasonable measure to prevent SARS-CoV-2 from entering a ship.

Recommendation 6: All individuals should have their temperature taken via contactless device as part of the boarding process.

Temperature screening to detect infections has been implemented in airports, workplaces, and childcare settings in response to COVID-19. Scientific evidence to support the practice of temperature screening for facility entry is limited and based mostly on experience screening for SARS (2003), H1N1 (2009), and Ebola (2014) at airports. Studies have not shown this to be a highly effective method of identifying individuals with these diseases. In one study, over 12 million people were screened in and around Beijing in 2003 using infrared thermometers and only 12 probable cases of SARS were detected.¹⁶ The Panel expects temperature screening to be of limited value in identifying individuals with SARS-CoV-2 infections as well, since many infected individuals have no fever, or have a transient fever. Nonetheless, the Panel supports the use of temperature screening as it is a simple, quick, and low-cost step that can be taken as part of an overall strategy to prevent SARS-CoV-2 from entering a ship. It is also another demonstration to guests that all reasonable measures are being taken to limit the chance the virus will come aboard since presence of a fever could indicate a SARS-CoV-2 infection or infection with another contagious pathogen.

Recommendation 7: Any individual who discloses symptoms of possible SARS-CoV-2 infection or close contact with an individual with suspected infection, or who displays a temperature of 100.4 degrees or above, should undergo secondary screening by medical personnel to determine whether they may board the ship or whether they will be denied boarding.

When an individual is identified as potentially at risk of having COVID-19 through primary screening, they and their boarding party should be escorted away from other guests to a private location to undergo assessment by medical personnel. As noted above, some symptoms of COVID-19 (*e.g.*, persistent cough) occur in other medical conditions and would not necessarily prevent the person from boarding. In other instances, though, secondary SARS-CoV-2 testing or other evaluation may be needed to determine whether the individual should be denied boarding. If rapid testing is done at the pier, it may aid the medical staff in making an assessment of whether the individual is healthy to sail.

The Panel discussed whether close contact with someone with suspected SARS-CoV-2 infection should be a reason to automatically deny boarding. Because of potentially variable understandings of the terminology "suspected" SARS-CoV-2 infection, the Panel felt that secondary screening was an appropriate next step so that medical personnel could make a judgement based on the specific

¹⁶ Xinghuo Pang et al., "Evaluation of Control Measures Implemented in the Severe Acute Respiratory Syndrome Outbreak in Beijing, 2003," *JAMA* 290, no. 24 (December 2003): 3215-3221.

circumstances. However, as noted below, if the guest reports close contact with someone with confirmed SARS-CoV-2 infection, they should be denied boarding.

Denial of Boarding

The Cruise Ticket Contract is a customary part of the guest experience. In reviewing and agreeing to the terms of the contract, guests are agreeing to various terms and conditions of the cruise experience, including an understanding of the cruise operator's policy for denial of boarding—for example, age restrictions would result in a denial of boarding for children under a certain age.

In addition to existing guest restrictions, the Panel believes that it is important that guests formally agree to follow the safety policies and protocols set forth to specifically reduce the risk of contracting SARS-CoV-2 for both guests and crew. Additionally, guests must be made aware that the results of their preboard testing or screening could result in a denial of boarding. Under the current circumstances, it would not be appropriate for cruise operators to have anything less than strict adherence to a no-tolerance policy toward allowing individuals to board if they are confirmed or suspected of being infected with SARS-CoV-2.

Recommendation 8: Cruise operators should not allow an individual to sail if they do not affirmatively state their willingness to comply with current safety and public health protocols.

As discussed throughout this document, cruise operators will take numerous precautions to prevent the spread of SARS-CoV-2 on cruise ships, and guests also have a role to play in preventing potential person-to-person spread. It is essential that cruise operators require guests to affirmatively state their willingness to comply with protocols to prevent the spread of SARS-CoV-2, as well as other health and safety requirements. Cruise operators may choose to incorporate the acknowledgment of compliance into existing attestations at the time of booking and/or boarding. Guests should be made aware far in advance of their cruise about mask wearing requirements, social distancing requirements, and changes in other cruise operations so they are prepared to comply with these policies on board.¹⁷ For example, mask wearing requirements have become the norm and expectation in many areas of society, and on cruise ships they will play an important role in protecting everyone on board. Further details about mask wearing recommendations are included in the Personal Protective Equipment (PPE) section of this document.

Recommendation 9: Individuals who have received a positive SARS-CoV-2 test or who have in the last 14 days been in close contact with an individual with confirmed infection should not be permitted to board the ship.

As noted above, there are several circumstances that warrant secondary screening to determine whether the individual is deemed by the medical personnel in charge to be fit to board the ship (*e.g.*, any individual who discloses symptoms of possible COVID-19 infection or close contact with an individual with suspected SARS-CoV-2 infection, or who displays a temperature above 100.4 degrees). These are cases where a medical judgement must be made based on the totality of information

¹⁷ Individuals for whom wearing a mask is medically contraindicated should be directed to a secondary medical screening (to be conducted in person or as a telehealth consult) where a case-by-case assessment of the individual's fitness for travel will be made, and a recommendation to allow or deny boarding will be based on the fitness for travel determination.

available. There are, however, a few circumstances that merit an automatic denial of boarding. These include a positive test result or known close contact with an individual with confirmed SARS-CoV-2 infection in the preceding two weeks. As noted earlier in the recommendations, if a group is traveling together to a cruise, if any one of them has tested positive for SARS-CoV-2 in the previous two weeks, all members of that party who are close contacts of the infected individual should not travel to the pier and all will be denied boarding.

Policy on Guests at Increased Risk of Severe Illness

CDC guidance details factors that are related to an increased risk of severe illness once an individual has contracted SARS-CoV-2.¹⁸ As science evolves, so does the current understanding of which factors are associated with an increased risk of severe disease. Therefore, the Panel recommends that cruise operators stay apprised of any updates to CDC guidance and rely on the most recent information regarding risk groups to inform their guest education and policies related to health risk.

Recommendation 10: Cruise operators should rely on CDC guidelines to determine who is at an increased risk of severe illness and who may be at an increased risk of severe illness.

While the Panel does not recommend that cruise operators have special policies or requirements in place for guests at a high or increased risk of severe COVID-19, the Panel does think that cruise operators should make sure guests are informed about who is, or may be, at increased risk so they can make an informed decision about whether to book or take the cruise. Guests should also be informed that there is a difference between an increased risk of becoming infected and an increased risk of developing severe disease if infected. Further, cruise operators can and should recommend that those with an increased risk of severe illness consult with their health care provider to help them assess and attest to their fitness to sail.

Recommendation 11: Cruise operators should recommend that guests who are or may be at increased risk of severe illness consult with their health care provider before traveling.

Ultimately, an individual is in the best position to determine whether they are fit to cruise. However, the Panel's view is that cruise operators should provide educational information to guests and recommend that any guests who are or may be at increased risk of severe illness consult with their health care provider before sailing. A conversation between the individual and their provider will aid them in determining their own risk factors and risk tolerance.

Guest Information & Education

Sailing amidst an ongoing threat of COVID-19 requires increased attention and cooperation of all individuals involved. It is essential that guests are fully informed about policies or protocols for reducing the spread of SARS-CoV-2, how these protocols will impact their cruise experience, and why their

¹⁸ U.S. Dept. of Health and Human Services, Centers for Disease Control and Prevention, "People at Increased Risk," CDC website, last updated September 11, 2020, accessed September 18, 2020, <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/index.html>.

attention to, and compliance with, these protocols is critical to ensuring a safe and enjoyable sailing experience for all.

Recommendation 12: In addition to the information typically communicated at booking, guests should be provided sufficient information on SARS-CoV-2 to assess their individual risk, to fully understand the safety precautions being taken by the cruise line to address SARS-CoV-2, and to agree to comply with the necessary safety protocols while traveling.

Cruise operators should sufficiently educate guests prior to sailing that they will be required to provide informed self-attestation that:

- they are knowledgeable about their individual risk of developing severe illness if they are infected with SARS-CoV-2;
- they have made an informed decision about cruising based on their individual risk;
- they have decided whether to consult with a health care provider based on their individual risk; and
- they will follow policies on board to minimize the spread of disease.

As indicated above, cruise operators should reserve the right to deny boarding to guests who will not affirmatively attest to their compliance with SARS-CoV-2 safety protocols, including current requirements for mask wearing and physical distancing. However, it is the responsibility of the cruise operator to provide the necessary information to guests in an easy-to-understand format so that guests are aware of their obligations before deciding to purchase a ticket for a cruise.

Further, the Panel believes that it is incumbent upon cruise operators to foster a culture of caring and compliance for guests. Cruise lines should take care in their communication with guests to help create a collective understanding of responsibility for the health of one's fellow guests and the crew who are essential to the cruise experience. This includes education around the need for honesty and timeliness in reporting of COVID-19 symptoms or exposure without fear of negative repercussions.

Onboard Symptom Tracking and Monitoring

Being able to efficiently and accurately detect and track SARS-CoV-2 infections on board is a significant aspect of the cruise operator's risk mitigation strategy. Even though many individuals infected with SARS-CoV-2 will be asymptomatic, the Expert Panel recommends that cruise operators perform symptom screenings, including temperature checks, on a regular basis.

Recommendation 13: Cruise operators should conduct once-daily temperature checks for guests and crew on board.

While temperature checks can be performed at any time during the day, it is recommended that checks be performed in the later part of the day, if operationally feasible, as that is when individuals are more likely to present with a fever (defined by CDC as a measured temperature of 100.4 degrees Fahrenheit).¹⁹ The Panel does not recommend that cruise operators perform temperature checks more frequently than once a day. As noted previously, temperature checks will miss many individuals with

¹⁹ U.S. Dept. of Health and Human Services, Centers for Disease Control and Prevention, "Definitions of Symptoms for Reportable Illnesses," CDC website, last updated June 30, 2017, accessed September 18, 2020, <https://www.cdc.gov/quarantine/air/reporting-deaths-illness/definitions-symptoms-reportable-illnesses.html>.

SARS-CoV-2 infection, and there is marginal added benefit to multiple temperature checks per day. In addition, multiple daily temperature checks would impose a significant operational burden and implications for the guest experience.

Given that an elevated temperature is not a consistently present marker of a SARS-CoV-2 infection, the Panel recommends that cruise operators also screen on a daily basis for COVID-19 symptoms. The CDC recommends that employers consider symptom screening as an optional strategy to use when identifying potential COVID-19 cases, and notes that it should be used in conjunction with PPE and other protective measures.²⁰

Recommendation 14: Cruise operators should employ routine symptom screening methodologies to help ensure that potential SARS-CoV-2 infections are identified as quickly as possible.

Potential symptom screening methodologies include guests self-reporting through a mobile application or in-person symptom screenings performed by a stateroom attendant or other ship personnel. Similarly, crew could self-report symptoms daily through electronic means or to their supervisor or other designated personnel. The Panel discussed the attributes of various methods of screening and ultimately decided that cruise lines should employ whatever method they believe is likely to produce the most timely, accurate, and consistent reporting of symptoms.

The Panel also discussed more passive measures of onboard surveillance such as wastewater testing. While not specific enough to assist with contact tracing, wastewater testing could be an effective way for cruise operators to monitor if SARS-CoV-2 is on board the ship, and it may provide an early indication of infection prior to any symptom expression.

Recommendation 15: Cruise operators should ensure education efforts are in place to help guests understand the importance of reporting symptoms and potential repercussions of failure to report symptoms.

Education is a key part of ensuring that all guests and crew members recognize the importance of being transparent if they develop any COVID-19-like symptoms. Similar to informing guests about the mask requirements on board, this education should begin at the time of booking so that the guests fully understand cruise operators' expectations far in advance of boarding the ship. Education should also continue throughout the guest journey.

ii. Protective Measures for Guests and Crew

Personal Protective Equipment (PPE) Usage

Spread of SARS-CoV-2 is significantly reduced through appropriate use of PPE. As such, cruise operators must require PPE use among their crew members and guests. While some crew members with prolonged guest contact (*i.e.* contact that may result in exposure by CDC's definition) may be required to utilize multiple, complementary forms of PPE (*e.g.*, spa staff coming in close contact with guests will be

²⁰ U.S. Dept. of Health and Human Services, Centers for Disease Control and Prevention, "Interim Guidance for Businesses and Employers Responding to Coronavirus Disease 2019 (COVID-19), May 2020," CDC website, last updated June 30, 2020, accessed September 18, 2020, <https://www.cdc.gov/coronavirus/2019-ncov/community/guidance-business-response.html>.

required to wear masks and additional PPE), the Panel recommends that guests utilize face masks/cloth coverings in accordance with CDC recommendations while on board the ship.

The Panel discussed the benefits to widespread and consistent usage of face masks on board a cruise ship as well as consumer preferences about mask usage. There is increasing evidence that cloth face coverings help prevent people who are infected with SARS-CoV-2 from spreading the virus to others. According to CDC, cloth face coverings are a critical tool in the fight against COVID-19 that could reduce the spread of the virus, particularly when used universally within communities.²¹ In July 2020, the Lancet published a systematic review of 172 observational studies in health care and non-health care settings across 16 countries and six continents that found a reduced risk of infection with the use of face masks.²²

Consumer insight surveys conducted by the cruise industry show that some guests are unwilling to cruise if face coverings are required, while other consumers are unwilling to cruise if face masks are not required. The limited experience this summer aboard European cruises has revealed that a significant portion of guests wear face masks in public areas, even when they are not mandated. Therefore, in the interest of limiting potential spread of virus, the Panel recommends that face coverings are a simple and effective strategy that should be employed. The Panel recognizes that as disease prevalence goes down, face covering requirements may be loosened over time based on the latest available scientific data, public health agency recommendations, and risk modeling. However, in the initial period of sailing, they are an important tool that should be regularly used.²³

Recommendation 16: To prevent the spread of SARS-CoV-2, cruise operators should require guests and crew to wear cloth face coverings/face masks in accordance with CDC recommendations.²⁴

Specifically, guests should wear face coverings in any indoor, congregate setting regardless of physical distancing measures, but should not be required to wear face coverings in their own cabins. A notable exception is indoor dining. Seating in restaurants and bars/lounges should allow for physical distancing, so guests can eat and drink without needing face coverings while seated.

Face coverings are not required in outdoor settings as long as physical distancing is feasible. However, if physical distancing is not feasible in certain outdoor settings, masks/face coverings among guests should be required in those locations.

For crew members, masks should be worn any time they are engaging with other crew members or guests (*i.e.*, in all public settings, both indoors and outdoors).

²¹ U.S. Dept. of Health and Human Services, Centers for Disease Control and Prevention, "CDC Calls on Americans to Wear Masks to Prevent COVID-19 Spread," CDC website, published July 14, 2020, accessed September 18, 2020, <https://www.cdc.gov/media/releases/2020/p0714-americans-to-wear-masks.html>.

²² Derek Chu et al., "Physical Distancing, Face Masks, and Eye Protection to Prevent Person-to-Person Transmission of SARS-CoV-2 and Covid-19: A Systematic Review and Meta-Analysis," *Lancet* 395 no. 10,242 (June 27, 2020): 1973-1987.

²³ Case-by-case exceptions may be granted for individuals for whom wearing a mask is medically contraindicated.

²⁴ U.S. Dept. of Health and Human Services, Centers for Disease Control and Prevention, "Use of Masks to Help Slow the Spread of COVID-19," CDC website, last updated June 28, 2020, accessed September 18, 2020, <https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/diy-cloth-face-coverings.html>.

CDC recommends that masks have two or more layers, be worn over the nose and mouth, be worn by individuals two years of age and older, and should not be worn by children younger than two, people who have trouble breathing, or people who cannot remove the mask without assistance.²⁵ CDC does not recommend that non-health care workers wear masks intended for health care workers and also does not recommend the use of gaiters or face shields at this time. Cruise operators should ensure that requirements for face masks are in accordance with the most up-to-date CDC guidelines.

Recommendation 17: Crew members with prolonged contact (*i.e.*, contact that may result in exposure by CDC's definition) with guests on board the ship should be required to utilize complementary PPE, in addition to wearing a face mask/face covering..

There are several scenarios on board where crew members may come in close contact with guests for longer periods of time (*e.g.*, spa staff giving guests a spa treatment), where it is impossible for crew members to maintain physical distancing from each other or guests to perform their job function and/or maintain the safety of the ship (*e.g.*, watch standing officers, mooring stations). In such scenarios, cruise operators should ensure that crew members are equipped with the necessary and additional PPE, such as gloves, to prevent transmission of SARS-CoV-2 and other infectious illnesses.

The Panel also recommends educating guests and crew members on how to properly clean and wear their face masks/face coverings as appropriate, in adherence with CDC recommendations.²⁶

iii. Physical Distancing

Physical distancing is key to reducing the spread of SARS-CoV-2 given that transmission is typically related to prolonged, close contact with another individual who is infected with SARS-CoV-2. According to CDC, "to practice social or physical distancing, stay at least 6 feet (about 2 arms' length) from other people who are not from your household in both indoor and outdoor spaces."²⁷ As such, cruise operators should take precautions to both facilitate (*e.g.*, reduced capacity, facilities modifications) and require appropriate physical distancing for guests and crew.

Capacity Restrictions

One way that cruise operators can facilitate physical distancing is by reducing overcrowding on board the ships. Therefore, the Panel believes that it is appropriate for cruises to sail at reduced capacity once sailing resumes as a way to facilitate physical distancing, especially as procedures are being tested to ensure they are working properly. Capacity can be gradually increased as conditions permit.

²⁵ U.S. Dept. of Health and Human Services, Centers for Disease Control and Prevention, "How to Select, Wear, and Clean Your Mask," CDC website, last updated August 27, 2020, accessed September 18, 2020, <https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/about-face-coverings.html>.

²⁶ U.S. Dept. of Health and Human Services, Centers for Disease Control and Prevention, "How to Wash Masks," CDC website, last updated May 22, 2020, accessed September 18, 2020, <https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-to-wash-cloth-face-coverings.html>.

²⁷ U.S. Dept. of Health and Human Services, Centers for Disease Control and Prevention, "Social Distancing," CDC website, last updated July 15, 2020, accessed September 18, 2020, <https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/social-distancing.html>.

Recommendation 18: When returning to sailing, cruise operators should adjust guest and crew load factors in a manner that allows for appropriate physical distancing on board in accordance with applicable guidance, taking into consideration the size and design of each ship.

The Panel recommends that returning to cruising with a reduced population of guests and crew will significantly aid cruise operators in reducing overcrowding and promoting physical distancing. Furthermore, it ensures there is ample space to allow other SARS-CoV-2 controls such as adequate isolation spaces for symptomatic or potentially infected individuals and single-occupancy crew rooms for crew members. Cruise operators can consider gradually increasing the load factor on ships over time in accordance with how well other control measures are working. Of note, a reduction in load factor should not apply to medical staff, as the ratio of medical personnel to guests and crew will be purposefully increased.

Capacity reductions should also be applied to all ship and terminal venues (*e.g.*, restaurants, retail, casinos, lounges, fitness centers), as well as transportation vehicles and shore excursions, to allow for appropriate distancing practices.

General Distancing Guidelines

As a general rule, cruise operators should do everything they can to facilitate and promote social distancing in accordance with CDC guidelines.

Recommendation 19: Cruise operators' facilities on board the ship, at terminals, and at cruise line-owned and operated destinations should be modified to promote and facilitate physical distancing in accordance with the CDC recommendation of a distance of at least six feet.

Should CDC physical distancing guidelines change, cruise operators should be prepared to respond accordingly. At this time, however, there are no settings on board where it would be appropriate for cruise operators to suspend the general physical distancing recommendations. As such, seating should be modified across the ship, wherever feasible, to promote distancing. The specific modifications that can be made will vary by ship. The Panel defers to each cruise operator to take on the specific planning for each of their vessels. The kinds of modifications that the Panel discussed include spacing out loungers at the pool, separating tables at restaurants or leaving some empty, blocking off certain seats in the theaters, blocking off some slot machines to allow space between guests, and moving activities outdoors where possible (*e.g.*, holding yoga class on the ship deck rather than in the gym). While many of the specific modifications may vary by cruise operators and ship, the Panel believes that removal of, and substitution for, self-service buffets during this time will help to maintain these general distancing guidelines and avoid overcrowding, and should therefore be implemented across all ships.²⁸

In addition, guests should be frequently reminded about their responsibility to physically distance via appropriate signage and floor markers.

The requirement to maintain physical distancing will require cruise operators to modify or in some cases cancel certain activities. For example, a muster drill is required early in the cruise to ensure guests understand safety evacuation procedures. This often leads to significant crowding, so innovative

²⁸ Suzanne Rowan Kelleher, "Watch: Viral Japanese Video Shows How Quickly COVID-19 Can Spread at a Buffet," *Forbes* (May 11, 2020), <https://www.forbes.com/sites/suzannerowankelleher/2020/05/11/watch-viral-japanese-video-shows-how-quickly-covid-19-can-spread-at-a-buffet/#33f3b2e924a5>.

solutions should be employed to alter the flow of people. Some recreational events like poolside dance parties may need to be cancelled or significantly altered from their previous form. The Panel understands that some of these modifications may negatively impact the guest experience. Whenever activities can be preserved through additional spacing, smaller groups, moving activities outdoors, or other innovations, the Panel supports their continuation. At the same time, the Panel recognizes that some activities cannot be safely conducted and may need to be postponed until a time when risks have been reduced.

Recommendation 20: Abundant signage and floor markers should be utilized to communicate physical distancing requirements in the terminal, at cruise line-owned destinations, and on board the ship, with a particular emphasis on high-traffic areas (e.g., gangways, elevators, ship common areas).

The only exception to the general distancing guidelines is for guests traveling together or immediate family members. Guest traveling together from the same household or immediate family members should be encouraged to remain together while traveling and to physically distance themselves not from each other, but from other guests/groups when in public spaces.

Terminal, Boarding, Debarkation Controls

Protocols and procedures for increased physical distancing should be implemented along every step of the guest journey. Essential to appropriate distancing is reducing the need for face-to-face interactions between guests and crew. Therefore, the Panel recommends that cruise operators leverage the appropriate technology and procedures to allow for touchless boarding and debarkation.

Recommendation 21: Cruise operators should utilize processes and protocols for touchless check-in and speedier boarding to reduce contact and potential congestion in the terminal.

Reducing the need for face-to-face interactions at check-in is an improvement that will reduce the likelihood of crowding and creation of a choke point in the boarding process. Wherever possible, touchless processes should be used to reduce the amount of time at boarding and the level of interaction between terminal personnel and guests. Additional controls that can help to facilitate physical distancing throughout the guest journey include:

- Restricting visitor access to the terminal and ship;
- Arrival by appointment to the terminal;
- Access to preboard wellness screening materials in advance of arrival; and
- Aligning terminal hours of operation with ship arrival and debarkation times to reduce unnecessary traffic in the terminal.

II. Sanitation and Ventilation

According to CDC, SARS-CoV-2 “is thought to spread mainly from person-to-person, mainly through respiratory droplets produced when an infected person coughs, sneezes, or talks.”²⁹ While the risk of spread can be mitigated through strategies such as physical distancing and mask wearing, a specific

²⁹ U.S. Dept. of Health and Human Services, Centers for Disease Control and Prevention, “Frequently Asked Questions: Spread,” CDC website, last updated September 16, 2020, accessed September 18, 2020, <https://www.cdc.gov/coronavirus/2019-ncov/faq.html#Spread>.

focus on reducing transmission via sanitation of surfaces and objects and through air management strategies is warranted to reduce the risk of an onboard outbreak.

Stringent sanitation protocols and hand hygiene measures for guests and crew can reduce the risk of transmission of SARS-CoV-2 via surfaces. Since other infectious illnesses like norovirus and influenza are also likely to be transmitted via contaminated surfaces, enhanced sanitation protocols will help mitigate the risk of contracting various pathogens via contaminated surfaces, not just SARS-CoV-2.³⁰ Additionally, recent evidence has shown that airborne particles may play a role in virus transmission. Ensuring that a ship is equipped with appropriate heating, ventilation, and air conditioning (HVAC) systems and other air control measures will also help prevent an outbreak on board a ship.

The full list of the Expert Panel's recommendations around appropriate ventilation and sanitation protocols are described below. It is important to note that while the strategies discussed in this section may help reduce transmission of a variety of infectious diseases on board cruise ships, the Panel's recommendations are specifically geared toward prevention of the spread of SARS-CoV-2.

i. Sanitation

Comprehensive cleaning protocols will mitigate the risk of disease transmission on board. Through the Vessel Sanitation Program, the CDC already provides significant guidance on sanitation protocols focused on preventing and controlling the introduction, transmission, and spread of gastrointestinal illness on cruise ships. All requirements of the Vessel Sanitation Program (VSP) Operations Manual are assumed to be part of the baseline requirements cruise ships will operate under,³¹ and the Panel's recommendations regarding SARS-CoV-2 mitigation make additional suggestions or modifications for implementation in tandem with existing protocols.

Recently published data on the survival of SARS-CoV-2 on environmental surfaces suggest that SARS-CoV-2 is stable on plastic and stainless steel for about two to three days, compared to on copper or on cardboard, where SARS-CoV-2 is only stable for 4 hours and 24 hours, respectively.³² Overall, these data suggest that potential transmission of SARS-CoV-2 via inanimate surfaces and objects is possible.

The Panel discussed the relative risk of transmission of SARS-CoV-2 via different methods. CDC advises that the primary and most important mode of transmission for SARS-CoV-2 is through close contact from person to person. Based on previously mentioned data from lab studies on SARS-CoV-2 and what is known about similar respiratory diseases, it may be possible that a person can become infected by touching a surface or object that has the virus on it and then touching their own mouth, nose, or possibly their eyes, but this isn't thought to be a major mode of transmission. Therefore, the Panel recommends that sanitation procedures should be followed along with other risk-mitigation protocols that reduce the chances of person-to-person contact.

³⁰ World Health Organization, "Transmission of SARS-CoV-2: Implications for Infection Prevention Precautions," WHO website, published July 9, 2020, accessed September 18, 2020, <https://www.who.int/news-room/commentaries/detail/transmission-of-sars-cov-2-implications-for-infection-prevention-precautions>.

³¹ U.S. Department of Health and Human Services, U.S. Public Health Service, and CDC National Center for Environmental Health, "Vessel Sanitation Program 2018 Operations Manual," published 2018, accessed September 18, 2020, https://www.cdc.gov/nceh/vsp/docs/vsp_operations_manual_2018-508.pdf.

³² G. Kampf et al., "Persistence of Coronaviruses on Inanimate Surfaces and Their Inactivation with Biocidal Agents," *Journal of Hospital Infection* 104, no. 3 (March 1, 2020): 246-251.

The focus on sanitation should begin before the guests board the ship by providing educational information on enhanced ship sanitation and cleanliness protocols at the time of booking and ensuring the terminal is appropriately cleaned and disinfected.

Recommendation 22: Cruise operators should educate guests in advance of travel about the sanitation measures that are being used preboard, on board, and at private, cruise line-owned and operated destinations.

Surveys of consumers have indicated that enhanced sanitation protocols are a significant factor in guests' comfort with cruising. Educating guests about the upgraded protocols will make them aware of the cruise operator's commitment to addressing this issue and increase their comfort with cruising, without necessitating that all prevention and safety measures are regularly apparent or visible to guests. Cleaning and disinfection are important precautions to take, but guests should understand that cleaning and disinfection alone are not sufficient to prevent the possibility of SARS-CoV-2 transmission on board and that they will need to continue to follow other precautions like social distancing and mask wearing. While visibly observing constant cleaning and disinfecting may be comforting to some guests, that may not be the case for other guests. As such, cruise operators should avoid excessive sanitation measures that may give the false impression of enhanced safety or that could negatively impact the guests' cruise experience (*e.g.*, constant smell of disinfectants, general feeling of being in a medical space).

Additionally, when educating guests about the upgraded protocols, the Panel supports cruise operators describing their sanitation measures as "hospital-like" and referencing the CDC's recommendations.

Overall, sanitation methods employed by cruise operators should be consistently employed across their onboard locations, terminals, and cruise line-owned and operated destinations, and should focus on reduced use of communal and shared items and employing traditional cleaning methods to properly sanitize surfaces.

Recommendation 23: Enhanced sanitation protocols should be employed to protect against the risk of SARS-CoV-2 transmission via inanimate surfaces or objects, with attention to both high- and low-touch areas of the ship, terminal, and cruise line-owned and operated destinations.

Cruise operators should evaluate their sanitation protocols and consider areas of the ship that require a higher frequency of disinfecting or the addition of new methods of cleaning to prevent against the risk of SARS-CoV-2 transmission via surfaces. Cruise operators should apply the disinfectants to frequently touched surfaces or objects for an appropriate contact time as indicated on the product label. Contact cleaning and disinfecting methods (*e.g.*, wiping) should be employed alongside passive cleaning methods (*e.g.*, electrostatic spraying, UV lights).

When possible, single use items should be used instead of shared items (*e.g.*, disposable menus or digital codes rather than paper menus, having guests purchase snorkels rather than sharing). In many cases this will not be feasible, so items shared between guests (*e.g.*, salt and pepper shakers, sporting equipment, massage tables) should be adequately sanitized at intervals consistent with the cruise operator's surface sanitation protocols.

Additionally, cruise operators should ensure that there is sufficient time between sailings to thoroughly clean and sanitize the ship to protect against the risk of SARS-CoV-2 passing from guests from one cruise to the next.

Recommendation 24: Cruise operators should ensure that all disinfectants used for cleaning and disinfection are on the EPA’s List N: Disinfectants for Use Against SARS-CoV-2 or national equivalent for terminals located outside the U.S., which must also comply with local government regulations.³³

As cruise operators evaluate the disinfectants that they will use and recommend for use across their properties, they should ensure that all of the disinfectants are listed on “List N.”

EPA’s List N contains more than 450 products with 32 active ingredients that meet criteria for use against SARS-CoV-2. When using these EPA registered disinfectants, the label directions should be followed for safe and effective use, including the necessary contact time. If products on this list are going to be used in conjunction with a cleaning device (e.g., electrostatic sprayer) the cruise operator should assess the effectiveness of the combination of the product and device together before including in their overall sanitation strategy.

While cruise operators can generally abide by consistent use of sanitation protocols, products, and technologies across settings, there may be situations where enhanced sanitation efforts are warranted. The Panel recommends that cruise operators continuously consider settings where additional disinfection may be necessary. In addition, if a SARS-CoV-2 infection is identified on board, cruise operators should step up their internal compliance checks to ensure that all sanitation procedures are being properly implemented. The protocols should already be designed to be protective against SARS-CoV-2 transmission, so more cleaning and disinfecting is not necessarily warranted. However, verification that the specified procedures are actually being implemented across the ship is prudent.

Hand Hygiene

As with all infections, hand hygiene remains a key aspect of preventing transmission of SARS-CoV-2. For this reason, it is important that all guests and crew members on board practice good hand hygiene, that cruise operators provide all guests and crew members with sufficient education and training to understand what proper hand hygiene entails, and that all settings (ships, terminals, cruise line-owned and operated destinations) are equipped with the appropriate tools and facilities to ensure safe and convenient access for all.

Recommendation 25: Cruise operators should follow CDC recommendations regarding the use of hand sanitizers and hand washing with soap and water to craft their recommendations for guests.

Based on current CDC recommendations, to protect from COVID-19 and other infectious illnesses,³⁴ guests and crew members should practice frequent and appropriate hand hygiene using soap and water for at least 20 seconds or an alcohol-based hand rub (or equivalent product, as described below). CDC also provides a list of scenarios in which it is particularly helpful to practice hand washing, such as before eating or preparing food and after leaving a public place or restroom. If hands are visibly dirty or soiled, washing hands with soap and water should be prioritized over use of hand sanitizer.

³³ U.S. Environmental Protection Agency, “List N: Disinfectants for Use Against SARS-CoV-2 (COVID-19),” EPA website, last updated September 17, 2020, accessed September 18, 2020, <https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2-covid-19>.

³⁴ U.S. Dept. of Health and Human Services, Centers for Disease Control and Prevention, “Your Health: How to Protect Yourself & Others,” CDC website, last updated September 11, 2020, accessed September 18, 2020, <https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html>.

When procuring hand sanitizers, cruise operators should ensure that they contain 60-95% alcohol. Further, as per the CDC's recommendations, the manufacturer's recommendations should be followed when determining the volume of alcohol-based hand rub to use for maximum effectiveness.

Non-alcohol-based hand sanitizer products are commercially available. If cruise operators are considering use of these products, they should ensure that they are non-irritating to human skin and demonstrated to be effective against viruses based on peer reviewed literature. At this time, the CDC's guidance for health care providers about hand hygiene and COVID-19 says, "CDC does not have a recommended alternative to hand rub products with greater than 60% ethanol or 70% isopropanol as active ingredients. Benzalkonium chloride, along with both ethanol and isopropanol, is deemed eligible by FDA for use in the formulation of healthcare personnel hand rubs. However, available evidence indicates benzalkonium chloride has less reliable activity against certain bacteria and viruses than either of the alcohols."³⁵

Recommendation 26: Cruise operators should ensure that hand sanitizer stations, wipes, or hand washing stations are conveniently placed around the ship for guests' and crew members' usage.

By providing hand sanitizer and hand washing stations throughout the ship, guests and crew members are consistently reminded to be practicing hand hygiene to minimize the risk of transmission of SARS-CoV-2 and other infectious pathogens. Furthermore, convenient placement of such stations (*e.g.*, at entrances of restaurants, guest services, outside elevators) will also increase the likelihood that guests and crew members use them.

In addition to ensuring that hand sanitizer and hand washing stations are placed around the ship, terminals, and cruise line-owned and operated destinations, cruise operators should add signage in all of these settings to direct guests and crew to the nearest station, as well as provide signage at the stations informing guests and crew on how to properly practice hand hygiene (*e.g.*, wash the hands with soap and water for at least 20 seconds or use an approved hand sanitizer).

Recommendation 27: Cruise operators should ensure that crew members are thoroughly trained on all aspects of infection control with emphasis on proper hand hygiene techniques.

All crew members should be thoroughly trained and educated on the best methods to use when practicing hand hygiene to reduce risk of transmission of SARS-CoV-2 and other infections. Cruise operators should also ensure that crew members coming in close contact with guests or serving food and drinks be instructed on the frequency of practicing hand hygiene, and in accordance with CDC recommendations.³⁶

Recommendation 28: In addition to providing hand sanitizer and hand washing stations on board, cruise operators should encourage hand washing or use of hand sanitizer before and after guests participate in recreational activities.

³⁵ U.S. Dept. of Health and Human Services, Centers for Disease Control and Prevention, "Hand Hygiene Recommendations: Guidance for Healthcare Providers About Hand Hygiene and COVID-19," CDC website, last updated May 17, 2020, accessed September 18, 2020, <https://www.cdc.gov/coronavirus/2019-ncov/hcp/hand-hygiene.html>.

³⁶ *Id.*

Various sports and activities are offered to guests on board cruise ships; however, many of these activities can increase risk of contracting SARS-CoV-2 or other infections due to equipment, toys, games, etc. that are commonly used by other guests. To decrease this risk of transmission, cruise operators should not only ensure that all equipment, toys, games, etc. be sanitized after each use, but should also require that all guests sanitize their hands before and after participating in such activities.

ii. Ventilation, HVAC, Filtration Controls

Pathogen dissemination through the air occurs through droplets and aerosols typically generated by coughing, sneezing, shouting, breathing, toilet flushing, singing, talking, and during some medical procedures. It takes about 8 minutes for a 10 μ particle to settle 5 feet in still air, while a 1 μ particle would take 12 hours to settle 5 feet in still air.³⁷ Although direct exposure to respiratory droplets is the main transmission route of SARS-CoV-2, some investigators have suggested that SARS-CoV-2 may be transmitted via aerosols. These studies that suggest that SARS-CoV-2 behaves like influenza and RSV, and that transmission via airborne droplets is an important pathway.³⁸ These studies suggest that 1) a number of respiratory droplets generate microscopic aerosols (< 5 μ m) by evaporating, and 2) normal breathing and talking results in exhaled aerosols. Thus, a susceptible person could inhale aerosols, and could become infected if the aerosols contain the virus in sufficient quantity to cause infection within the recipient. The proportion of exhaled droplet nuclei or of respiratory droplets that evaporate to generate aerosols, and also the infectious dose of viable SARS-CoV-2 required to cause infection in another person, are not known; however, this issue has been studied for other respiratory viruses.

The World Health Organization (WHO) has acknowledged that “airborne transmission of [SARS-CoV-2] can occur in health care settings where specific medical procedures, called aerosol generating procedures, generate very small droplets called aerosols. Some outbreak reports related to indoor crowded spaces have suggested the possibility of aerosol transmission, combined with droplet transmission, for example, during choir practice, in restaurants or in fitness classes.”³⁹ This acknowledgement followed an open letter signed by 239 scientists from 32 countries urging WHO and other public health organizations to address airborne transmission of COVID-19.⁴⁰

³⁷ Renat Manassypov, “Evaluating Virus Containment Efficiency of Air-Handling Systems,” *ASHRAE* (July 2020): 17-23.

³⁸ Rajat Mittal, Rui Ni, and Jung-Hee Seo, “The Flow Physics of COVID-19,” *Journal of Fluid Mechanics* 894 (July 10, 2020): F2; Lydia Bourouiba, “Turbulent Gas Clouds and Respiratory Pathogen Emissions: Potential Implications for Reducing Transmission of COVID-19,” *JAMA* 323, no. 18 (May 12, 2020): 1837-1838; Sima Asadi et al., “The Coronavirus Pandemic and Aerosols: Does COVID-19 Transmit Via Expiratory Particles?” *Aerosol Science and Technology* 54, no. 6 (2020): 635-638; Lidia Morawska and Junji Cao, “Airborne Transmission of SARS-CoV-2: The World Should Face the Reality,” *Environment International* 139 (2020): 105730; Jan Gralton et al., “Respiratory Virus RNA Is Detectable in Airborne and Droplet Particles,” *Journal of Medical Virology* 85, no. 12 (2013): 2151-2159; Valentyn Stadnytskyi et al., “The Airborne Lifetime of Small Speech Droplets and Their Potential Importance in SARS-CoV-2 Transmission,” *Proceedings of the National Academy of Sciences of the United States of America* 117, no. 22 (2020): 11875-11877.

³⁹ World Health Organization, “Transmission of SARS-CoV-2: Implications for Infection Prevention Precautions,” WHO website, published July 9, 2020, accessed September 18, 2020, <https://www.who.int/news-room/commentaries/detail/transmission-of-sars-cov-2-implications-for-infection-prevention-precautions>.

⁴⁰ Lidia Morawska and Donald Milton, “It is Time to Address Airborne Transmission of COVID-19,” *Clinical Infectious Diseases*, accepted manuscript (July 6, 2020).

Given the evidence noted above, and with an acknowledgement of the limitations of current studies and the remaining questions regarding infectious dose, etc., the Panel concluded that air management strategies are an important part of a cruise operator's return to sail plan.

Recommendation 29: Transmission of SARS-CoV-2 through the air is sufficiently likely that airborne exposure to the virus should be controlled for.

Specifically, the Panel believes that it is important that cruise operators develop air management strategies that minimize the risk of aerosol transmission and ease the concerns of guests and crew regarding airborne pathogen dispersal. To achieve this goal, cruise operators should consider deploying a number of different air management strategies.

The University of Nebraska Medical Center & National Strategic Research Institute recently conducted a bioaerosol assessment on Royal Caribbean's "Oasis of the Seas" vessel. This study involved releasing billions of 1 μ aerosol-sized microspheres, each containing uniquely DNA barcoded inert virus surrogate, throughout the ship at certain pre-selected spaces (*i.e.*, crew cabins, guest staterooms, and adjacent public spaces including the casino, Studio-B & Disco/Lounge) to determine the efficiency and effectiveness of the vessel's indoor air management strategies, as well as to understand the spread of the aerosols through the HVAC system and in between the adjacent private and public spaces. Unpublished data from this assessment highlights that an HVAC system equipped with MERV 13 filtration⁴¹ and an energy recovery wheel did not transport a significant number of aerosols into adjacent rooms and spaces served by the same air handling unit, and in most cases the airborne contamination was undetectable. Furthermore, study results show that in public areas, guest staterooms, and crew cabins, airborne contamination disappeared or microspheres were not detectable in less than an hour from the space they were released. This was accomplished by the combination of $\geq$ 6 air changes in the room and filtration of air through the MERV 13 filters. While not yet published, the results of this study provide confidence that a variety of indoor air management strategies, appropriately managed, can reduce presence and transmission of SARS-CoV-2 through the air.

Recommendation 30: Cruise operators should use a variety of indoor air management strategies aimed at reducing occupant exposure to infectious droplets/aerosols.

The Panel supports the use of the following strategies:

- 1) **Enhance filtration** – The Panel recommends that HVAC filters be upgraded to the highest level possible for each ship given the constraints of ship age and ventilation type (*e.g.*, MERV 8 to MERV 13; see below).
- 2) **Optimize airflow patterns** – For example, the Panel recommends that cruise operators optimize airflow so that air is not recirculated; should air recirculation exist, given the HVAC system design, then the recirculated air must be filtered through a high-grade filter (*i.e.*, MERV 13 or higher).
- 3) **Use negative pressurization** – The Panel recommends that cruise operators ensure that SARS-CoV-2 isolation rooms are consistently at negative pressure. This means that cruise operators

⁴¹ MERV stands for Minimum Efficiency Reporting Value, a system used to evaluate the efficiency of an air filter based on how effective it is at catching particles of various sizes. The higher the MERV rating, the higher the air filtration capabilities of a particular filter. MERV ratings range from 1-20, with 1 being the lowest level of filtration and 20 being the highest. Additional detail on MERV filter recommendations is provided later in this document.

should ensure that there is sufficient negative pressure that will not be affected by doors opening and closing or people walking by. This should be optimized given the constraints of ship age and ventilation type.

- 4) **Minimize unfiltered, recirculated air** – Cruise operators should provide air exhausted to the outside and maximize air changes per hour and filtration of air in staterooms, crew rooms, and public areas.
- 5) **Increase number of air changes per hour in certain areas** – The Panel recommends that cruise operators pay special attention to areas where individuals would be most vulnerable to airborne transmission, and that they should prioritize increasing the number of air changes per hour in those areas. More specifically, isolation rooms in medical facilities on board should have 6-12 air changes per hour, be at a negative pressure to the adjacent area, and have 100% air exhausted to the outside.
- 6) **Use portable HEPA filters (or other proven air cleaning systems) in congregate areas, as needed** – Portable HEPA units have been shown to help reduce the level of airborne particles. This technology or other technologies that reduce the risk of airborne infection transmission may be used to augment other air management strategies.⁴²
- 7) **Maximize outdoor functions and physical distancing** – The Panel recommends an overall emphasis on reducing indoor functions whenever possible, given that dilution is most achievable in outdoor settings. Further, cruise operators should ensure that guests understand that air management strategies do not negate the importance of following physical distancing protocols.

The Panel also recommends that, wherever feasible, cruise operators upgrade the HVAC systems (e.g., enhanced filtration from MERV 8 to MERV 13) on their ships to minimize pathogen dispersal from potentially infected guests and crew.

Recommendation 31: All cruise operators should upgrade the HVAC systems on their ships to, ideally, MERV 13 filters to minimize pathogen dispersal from infected guests and crew.

HVAC upgrades can drastically improve filtration of pathogens and therefore reduce the risk that SARS-CoV-2 particles are transmitted through the air. As the MERV rating increases, fewer airborne contaminants and dust particles can pass through the filter. For example, MERV 8 HVAC filters are 30% efficient in removing 3.0-10.0 μ particle size, while MERV 13 filters are 90% efficient in removing 0.3-1 μ particle size. Therefore, cruise operators should make every possible effort to upgrade the HVAC filters throughout their ships to MERV 13 filters.

Recommendation 32: Cruise operators' indoor air management strategies should be optimized given the constraints of ship age and ventilation type.

The Panel understands that ships vary in age, size, layout, ventilation type, etc. (sometimes significantly). As such, the Panel did not feel comfortable recommending minimum levels of protection for each air management strategy. However, the Panel does feel strongly that MERV 13 HVAC filters should be utilized. If that is infeasible, the Panel strongly believes that cruise operators should optimize the air management strategies used to the greatest extent possible on each of their ships, which would include upgrading HVAC filtration to as close to a MERV 13 filter as possible.

⁴² William Rutala et al., "Efficacy of Portable Filtration Units in Reducing Aerosolized Particles in the Size Range of Mycobacterium Tuberculosis," *Infection Control & Hospital Epidemiology* 16, no. 7 (July 1995): 391-398.

Further, given the evolving science around transmission of SARS-CoV-2, cruise operators should continue to evaluate new air management strategies that will further assess and reduce guest and crew risk of exposure to droplet/airborne pathogens. Specifically, the Panel encourages cruise operators to focus on reducing exposure in areas where guests and crew would be most vulnerable to droplet/airborne exposure to virus (*i.e.*, critical control points).

Recommendation 33: When considering air management strategies, cruise operators should have a primary focus on reducing exposures in the core set of areas where guests and crew would be most vulnerable to droplet/airborne exposure to virus.

Being able to accurately address the areas considered critical control points, and ensuring minimums are met are in those areas, is a key aspect in mitigating risk of airborne transmission of SARS-CoV-2. On ships, examples of specific hazards include circumstances where airborne exposure to the virus might be uncontrolled (or less controlled) for such as areas where crowding is common, areas subject to heavy guest movement, areas with the lowest air change rate, or areas where cruise operators have discerned that guests or crew likely became exposed or infected with SARS-CoV-2 during recent ship outbreaks.

As cruise operators evaluate various strategies that could be employed to reduce the risk of airborne exposure to SARS-CoV-2, they should evaluate each effort in the context of the other efforts being performed in tandem. Further, before employing any new technologies/strategies on board, cruise operators should determine the effectiveness of complementary enhancements and systems in reducing microbial contamination before employing them on board (*e.g.*, air ionizers).

Finally, it is important to note that even with the important upgrades described above, and even with the most robust ventilation systems, it will be impossible for cruise operators to control all airflows and completely prevent dissemination by droplets. Therefore, all sanitation and ventilation controls should be leveraged within the context of additional SARS-CoV-2 transmission mitigation tactics.

III. Response, Contingency Planning, & Execution

Essential to preparing to sail during an evolving pandemic is an appropriate plan for responding in the event of a SARS-CoV-2 outbreak on board a ship. There are three key components to an effective mobilization plan in the event that a SARS-CoV-2 infection is identified on a cruise ship: (1) appropriately augmented medical capabilities to effectively treat symptomatic patients, (2) a case management plan that will enable cruise operators to quickly identify symptomatic and asymptomatic individuals and use isolation and quarantine to stop the spread of infection, and (3) a plan for evacuating individual guests and impacted crew, or in the most extreme circumstances a whole ship, should an outbreak reach a sufficient level that the risk to guests and crew, and the risk of exceeding onboard medical capacity, is high enough to merit cruise cancellation. The recommendations of the Expert Panel around appropriate preparations for an onboard SARS-CoV-2 response are described below.

i. Onboard Medical Capabilities

Overall, cruise operators should aim to bolster their onboard medical capabilities such that care provided on board a ship is sufficiently robust to stabilize and treat guests and crew until they can be transitioned safely to a shore-based facility to continue their care. In particular, ships will need to be

equipped to address the rare situation where multiple patients are experiencing severe illness. This means that cruise operators will need to have sufficient clinicians and supplies to treat patients, and also sufficient supplies to maintain the safety of the medical staff (*i.e.*, appropriate PPE). Augmentations to the tools, spaces, and protective equipment at a clinician's disposal to treat a COVID-19 patient, together with appropriate medical staffing, form the backbone of effective outbreak preparedness.

Medical Personnel

Having sufficient medical staffing on board is a key aspect of enhanced medical planning for potential COVID-19 cases. Should guests or crew on board a ship exhibit symptoms of COVID-19, it is essential that cruise operators have sufficient medical personnel to care for all symptomatic individuals in addition to guests experiencing medical emergencies unrelated to COVID-19. Therefore, the Expert Panel recommends that cruise operators increase their medical staffing ratios for the duration of the pandemic.

Recommendation 34: As a part of augmenting onboard medical capacity to ensure preparedness for potential COVID-19 cases, cruise operators should increase their existing ratios of medical personnel to guests and crew.

During the initial sailing period, the Panel expects that cruise operators will decrease the overall capacity of their ships. Therefore, it may be possible for cruise operators to sufficiently increase medical staffing ratios without increasing the absolute number of medical staff on board (*e.g.*, if a cruise operator maintains the number of medical staff normally on board for a full ship, sailing with a load factor of 50% would effectively double the medical staffing ratio). As cruise operators scale operations over time, medical staffing ratios should remain appropriately proportional to the guest/crew count until prevailing evidence suggests that SARS-CoV-2 is no longer a significant threat. Another way to ensure that medical staffing is appropriately augmented to respond in the unlikely but potential event that there is a surge in guests or crew requiring medical attention, is to establish redundancy and onshore back-up staff for the onboard medical personnel.

Recommendation 35: Cruise operators should ensure redundancy and back-up for onboard medical personnel.

Even as cruise operators increase their onboard medical staffing ratios, there still exists the possibility that there could be an influx of guests or crew requiring medical attention or medical staff who are incapacitated due to illness or otherwise unable to provide care for patients. In this unlikely event, cruise operators should ensure that they can quickly increase the number of medical staff on board. This will require a staffing structure in the cruise operator's organization that ensures the safety and availability of onshore staff to join the ship on short notice should the need arise.

Essential to a quick and effective mobilization response in the event of an outbreak is having the appropriate leadership and oversight for the team of professionals providing necessary care to patients. Therefore, the Expert Panel recommends that cruise operators designate a specific individual whose sole role would be to manage the medical team (*i.e.*, Senior Doctor). Cruise operators should also designate an individual to manage the ship's outbreak response (*i.e.*, the individual with responsibility for infection control described below) who would be an essential member of the medical team and would report to the Senior Doctor.

Recommendation 36: Cruise operators should ensure there is sufficient onboard medical leadership on all ships, including the designation of a crew member with responsibility for infectious disease prevention and response who will inform and oversee execution of components of the response to an outbreak. Cruise operators should also ensure they have a doctor on board with intensivist training to manage the medical care of severely ill patients.

The designated crew member with responsibility for infectious disease prevention and response should be an individual who is able to manage execution of public health and infection control protocols and ensure that onboard operations continuously meet or exceed the cruise operator's public health and infection control standards. Further, cruise operators should ensure that their onboard medical staff includes at least one intensivist doctor who has training in acute respiratory care. This will ensure that the medical team has the appropriate expertise to respond to patients with more complex COVID-19 symptoms, in addition to caring for patients with less severe illness.

Onboard Clinic Design & Operations

Across the world, medical providers have had to modify their facilities in response to the global pandemic; hospital bed capacity has needed to be expanded wherever possible to handle the influx of patients exhibiting COVID-19 symptoms. Further, structural changes have been needed to ensure that the COVID-19 patient population is isolated from other patients and to protect those caring for them to the greatest extent possible.

Cruise operators will need to modify or enhance their medical facilities by taking steps similar to those seen among medical providers around the world. For example, the Panel recommends that cruise operators significantly increase their onboard capacity to care for critically ill patients.

Recommendation 37: Cruise operators should increase the capacity in their onboard medical facilities to treat patients who may become critically ill from SARS-CoV-2 infection or other unrelated illnesses.

The Panel spent significant time developing this recommendation about the required critical care capacity on board ships. The Panel noted that in a hospital on land, a patient may spend a significant length of time (*i.e.*, days or weeks) in an Intensive Care Unit (ICU) when critically ill. In contrast, on a cruise ship, a patient would spend limited time in an intensive care bed, with the goal of transferring the patient to an appropriate onshore care facility as soon as reasonably possible.

However, it is important that cruise operators have sufficient onboard critical care capacity because a patient may not be able to be immediately transferred to a shore-based facility depending on the location of the ship and other factors. Further, the severity of symptoms in a patient with SARS-CoV-2 infection is highly variable, and some patients require mechanical ventilation.⁴³ Driving our recommendations is the principle that in the worst case scenario, cruise operators need to be prepared to treat multiple seriously ill patients simultaneously. Additionally, while increasing capacity to address

⁴³ U.S. Dept. of Health and Human Services, Centers for Disease Control and Prevention, "Interim Clinical Guidance for Management of Patients with Confirmed Coronavirus Disease (COVID-19)," last updated September 10, 2020, accessed September 18, 2020, <https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-guidance-management-patients.html>; Erin Stokes et al., "Coronavirus Disease 2019 Case Surveillance—United States, January 22–May 30, 2020," *Morbidity and Mortality Weekly Report* 69, no. 24 (June 19, 2020): 759–765.

patients critically ill because of SARS-CoV-2 infection, cruise ships must also maintain capability to deal with other unrelated emergencies that may also require this level of care.

The American College of Emergency Physicians (ACEP) currently recommends that cruise ship medical facilities have at least 1 ICU room and at least 1 inpatient bed per 1,000 guests and crew, among other requirements.⁴⁴ The Panel felt that given the known risks of SARS-CoV-2 infection, the standard of a single ICU bed, regardless of the size of the ship, should be reexamined. The cruise lines we are advising presented us with the following proposal they intend to adopt to increase critical care capacity onboard their ships:

Capacity to care for critically ill patients onboard will be increased as follows:

- *Ships carrying between 250 and up to 1,000 persons (meaning guests and crew) will have at least 1 Intensive Care capable bed, and 1 inpatient bed.*
- *Ships carrying more than 1,000 and up to 3,000 persons will have at least 1 inpatient bed per 1,000 persons, of which 2 are Intensive Care capable beds.*
- *Ships carrying more than 3,000 and up to 5,000 persons will have at least 1 inpatient bed per 1,000 persons, of which 3 are Intensive Care capable beds.*
- *Ships carrying more than 5,000 and 6,000 persons will have at least 1 inpatient bed per 1,000 persons, of which 4 are Intensive Care capable beds.*
- *Ships carrying more than 6,000 and up to 8,000 persons, will have at least 1 inpatient bed per 1,000 persons, of which 5 are Intensive Care capable beds.*
- *Ships carrying more than 8,000 persons will have at least 1 inpatient bed per 1,000 persons, of which 6 are Intensive Care capable beds.*

The Panel reviewed this proposal and viewed it as responsive to the need to increase intensive care capacity. We recognize that some regular inpatient beds may also be “Intensive Care capable” beds, meaning that they could be converted to meet critical care needs during a surge. As cruise operators increase the available space to treat symptomatic guests and crew, they must also increase the treatment supplies accessible to onboard clinicians. Due to the fact that SARS-CoV-2 infection can result in severe lung complications, it is important that cruise operators have sufficient access to medical equipment such as Bilevel Positive Airway Pressure (BiPAP) machines and hospital-grade ventilators to support a patient’s oxygen levels. Furthermore, it is imperative that cruise operators comply with CDC-recommended personal protective equipment for medical staff caring for confirmed or suspected COVID-19 patients.⁴⁵

In the course of many discussions on this topic, it became clear that the needs and capacities across the industry, and even within a specific cruise operator, are not uniform. Cruise operators may have

⁴⁴ American College of Emergency Physicians, “Cruise Ship Health Care Guidelines: Policy Resource and Education Paper (PREP),” ACEP website, <https://www.acep.org/globalassets/new-pdfs/preps/cruise-ship-health-care-guidelines---prep.pdf>.

⁴⁵ U.S. Dept. of Health and Human Services, Centers for Disease Control and Prevention, “Infection Control Guidance for Healthcare Professionals About Coronavirus (COVID-19),” CDC website, last updated June 3, 2020, accessed September 18, 2020, <https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control.html>.

different limitations on their ability to convert space based on their current facilities design, as well as different anticipated care needs on various ships. In determining the appropriate ratio of Intensive Care capable beds, consideration should be made for the number of persons who may need care on board and the time period in which they are expected to need care before they can be debarked, among other factors.

The Panel recommends that this is an area where close monitoring is warranted once cruising resumes to determine if these ratios are appropriate. Once the pandemic subsides, cruise operators may opt to reduce Intensive Care capable bed capacity.

The Panel also encourages further discussion on this topic with ACEP which sets industry wide standards.

Recommendation 38: Cruise operators should amplify the varieties and amount of equipment in the onboard medical facilities, including the ability to test for SARS-CoV-2 infection on board.

Cruise operators should ensure redundancy and back-up for medical equipment, as there is always the chance of an outbreak causing a quick influx of patients into medical units that would require a supply of back-up equipment on hand. Additionally, complex medical equipment can malfunction, so redundancy for vital equipment is important.

The Panel's surveillance and case management recommendations rely on the ability of cruise operators to conduct onboard testing for SARS-CoV-2. Cruise operators should therefore equip their ships with testing capabilities, including sensitive, specific methods such as PCR testing or other accurate and reliable testing methods that can confirm whether an individual who presents with symptoms is infected with SARS-CoV-2. In the event that the need for testing exceeds the capacity to do so rapidly on board, the cruise operators should have prearranged capability to use onshore providers to quickly conduct tests and return results.

In the potential scenario where a patient with an infectious disease must be evacuated from the ship while on a stretcher (*i.e.*, the patient is not able to walk/utilize appropriate PPE), the cruise operators should utilize negative pressure isolation stretchers to prevent transmission to other individuals during the disembarkation process. As such, all cruise operators should ensure that they have an appropriate supply of these isolation stretchers.

As noted above, in addition to increasing capacity, cruise operators will need to take great care to ensure that individuals being treated for COVID-19 are isolated from other patients as well as healthy guests and crew.

Recommendation 39: Cruise ship facilities should be arranged to accommodate care for patients presenting with suspected infectious disease separately from care for those presenting with non-infectious diseases.

While COVID-19 is a newer illness to the cruise industry, there are several other conditions that cruise ship operators are prepared to address and that have previously been handled on board cruise ships. Examples include strokes, injuries, gastrointestinal illnesses, and respiratory infections. Given the likelihood that some of those other conditions may occur at the same time as COVID-19, it is important

that cruise operators are able to physically separate the facilities in which guests and crew who require non-COVID-19 care so these individuals are not exposed to the virus, if it is present on board.

One way to ensure that non-infectious patients are not exposed to infectious patients is to modify the standard operation of the onboard medical clinic to educate and encourage guests to call in if they have concerns prior to presenting to the clinic in person. In addition, the clinic space should be separated, including with appropriate ventilation measures, so that isolation of suspected or confirmed cases is possible. Appropriate personnel and supplies will need to be available in the infectious and non-infectious zones. All persons presenting to the medical clinic must wear a face covering.

Recommendation 40: Rather than a patient having an in-person appointment at the medical facility to receive a diagnosis or care, medical appointments should be scheduled virtually/remotely and/or medical staff members should hold appointments in the patient's stateroom when possible.

Combined with appropriate isolation and quarantine facilities and procedures (see below), reducing the flow of guests through the medical facility to the maximum extent possible will help to maintain the health of guests and crew and reduce the likelihood that someone will acquire SARS-CoV-2 by visiting the onboard clinic itself. Many people with SARS-CoV-2 infection are asymptomatic or only mildly ill and do not require inpatient-level care. These individuals may be able to be isolated and visited regularly by the onboard medical staff in their isolation room, or remotely, rather than staying for long periods of time in the ship's medical facility. This will conserve space in the medical facility to care for the sickest patients.

ii. Case Management

Once one person with a SARS-CoV-2 infection is identified on board, staff will need to mobilize quickly to appropriately treat infected patients, identify all potential cases on board using robust contact tracing, and segregate potentially infected guests and crew from healthy guests and crew. It is critical that cruise operators have the appropriate case management plans and protocols in place to respond to confirmed and potential SARS-CoV-2 infections on board.

Treatment Plan

Due to the novel nature of the SARS-CoV-2 virus and the varying clinical profiles of patients, treatment guidelines must be adjusted to conform with prevailing scientific evidence, best practices, and patient needs. Cruise operators should ensure that their medical personnel are armed with the most up-to-date recommendations for treatment of COVID-19.

Recommendation 41: A cruise line's medical treatment plan should be responsive to the current understanding of COVID-19 and optimal treatment protocols, as well as to the specific clinical needs of each patient.

Depending on the presentation of the patient and results of testing, including repeat testing for SARS-CoV-2 and/or influenza, as appropriate, protocols should be in place for management and treatment of a variety of illnesses, including COVID-19. Each ship needs to have appropriate diagnostic capacity, medications, equipment, and PPE as well as medications to treat SARS-CoV-2, influenza, and secondary bacterial infections.

It will be up to the onboard physicians to use treatment guidelines to inform, rather than dictate, patient care. The National Institutes of Health (NIH) and the Infectious Diseases Society of America (IDSA) have up-to-date treatment guidelines published on their websites.⁴⁶

In the event that an individual's care needs exceed the expertise of the onboard medical staff, cruise operators should ensure that COVID-19 experts are available for consultation.

Recommendation 42: Cruise operators should have established relationships with onshore medical institutions that can provide telemedicine consultations in the event of a more serious COVID-19 case.

Knowledge of treatment protocols and best practices for caring for those infected with SARS-CoV-2 are quickly evolving, and there are a limited number of COVID-19 medical experts. While onboard clinicians should be well trained and capable of treating patients with SARS-CoV-2 infections that follow more common or predictable trajectories, the Expert Panel recommends having on-call physicians who could provide clinical advice, if needed, for more serious or complex patient needs. These telemedicine arrangements should be made in advance to assure both the medical staff and patients on board that high quality care will be available.

An additional factor the Panel discussed is the potential need for telemedicine consultations for mental health conditions. The Panel does not recommend that a mental health specialist needs to be part of the medical clinic staffing. The doctor on board would be able to prescribe medication in certain situations (e.g., extreme anxiety). However, if additional mental health support services are needed, these could be provided via telemedicine consultations, which is another reason to establish relationships with onshore providers in advance.

Contact Tracing

As soon as a SARS-CoV-2 infection is identified, contact tracing should be initiated to identify close contacts of the individual. Cruise operators should be prepared to employ several methods of identifying close contacts to ensure that all exposed individuals are identified. If any close contacts are not identified, quarantined, and monitored in a timely fashion, a ship could risk an outbreak due to further transmission of the virus. Additionally, when a guest or crew member presents as the index case, cruise operators should activate their mobilization protocols immediately, starting with the presumption that there is likely more than one SARS-CoV-2 infection on board because of the possibility that exposed or infected individuals are pre-symptomatic or asymptomatic. Contact tracing is one of the critical methods of identifying who these individuals might be.

Therefore, cruise operators should provide clear guidance to onboard crew that will aid in operationalizing appropriate contact tracing protocols. First and foremost, cruise operators should ensure that staff conducting contact tracing are aligned in their understanding of what constitutes an

⁴⁶ COVID-19 Treatment Guidelines Panel, "Coronavirus Disease 2019 (COVID-19) Treatment Guidelines," NIH website, last updated September 1, 2020, accessed September 18, 2020, <https://files.covid19treatmentguidelines.nih.gov/guidelines/covid19treatmentguidelines.pdf>; Infectious Diseases Society of America, "Infectious Diseases Society of America Guidelines on the Treatment and Management of Patients with COVID-19," IDSA website, published April 11, 2020, last updated September 15, 2020, accessed September 18, 2020, <https://www.idsociety.org/practice-guideline/covid-19-guideline-treatment-and-management/>.

exposure. The Expert Panel recommends that cruise operators adhere to the definition of exposure provided by CDC.⁴⁷

Recommendation 43: Cruise operators should use CDC guidance as a general guide regarding exposure (< 6 feet for ≥ 15 minutes), pending updates based on emerging scientific evidence.

Emerging scientific evidence has shown that a small percentage of individuals with COVID-19 infect many others, while the majority of individuals with COVID-19 infect very few, if any, other individuals.⁴⁸ In addition, while a variety of factors influence exposure risk, proximity and duration are prevailing factors in assessing the risk level of a particular exposure. Given current scientific knowledge (further research on the infectious dose of SARS-CoV-2 is ongoing), the Expert Panel agrees that the CDC guidance of exposure to an infected individual within less than 6 feet for at least 15 minutes is a reasonable and acceptable benchmark that should be used by cruise operators until new evidence necessitates an updated CDC guideline.

In addition, cruise operators should clearly define exposure risk levels. The Expert Panel believes that 3 exposure risk levels (above “no identifiable risk”) are appropriate. Cruise operators should leverage these same risk levels to determine which individuals should receive a diagnostic test for SARS-CoV-2. Ultimately, the onboard medical staff, using the risk levels as a guide, will determine which individuals should be tested.

Recommendation 44: Cruise operators should define high-, medium-, and low-risk exposures such that recommendations for each exposure level can be efficiently operationalized.

Examples of appropriate contact risk profiles include:

- High Risk: someone sharing a stateroom or cabin with an individual with SARS-CoV-2 infection; someone providing care in a non-health care setting for a symptomatic individual without using recommended precautions for infection control; or someone who had close contact (within 6 feet) with an individual with SARS-CoV-2 infection for greater than 15 minutes. Examples include spa treatment, close-proximity bar gatherings, sitting within 6 feet on a tour bus.
- Medium Risk: someone located in proximity to an individual with SARS-CoV-2 infection (*e.g.*, shared bathroom); someone who was in a semi-closed environment (*e.g.*, game room, restaurant, infirmary waiting room) with an individual with SARS-CoV-2 infection for longer than 15 minutes; someone providing care in a non-health care setting for a symptomatic individual while consistently using recommended precautions. Examples include working out at the gym, children playing at the playground.
- Low Risk: someone located in a large or outdoor venue with more than 10 people where social distancing was not achievable or adhered to with an individual with SARS-CoV-2 infection. Examples include being in the pool, playing slots at the casino.

⁴⁷ U.S. Dept. of Health and Human Services, Centers for Disease Control and Prevention, “Public Health Guidance for Community-Related Exposure,” CDC website, last updated July 31, 2020, accessed September 18, 2020, <https://www.cdc.gov/coronavirus/2019-ncov/php/public-health-recommendations.html>.

⁴⁸ Max Lau et al., “Characterizing Super-Spreading Events and Age-Specific Infectiousness of SARS-CoV-2 Transmission in Georgia, USA,” *medRxiv* draft compiled July 14, 2020 (not yet published).

- **No Identifiable Risk:** Interactions that do not meet the other risk criteria. Examples include walking by an infected person, briefly being in the same room as an infected person.

There are several factors that impact level of risk. These include, but are not limited to, location (indoor versus outdoor); proximity (within or outside of 6 feet); exposure time (greater than or less than 15 minutes); compliance with precautionary measures (*e.g.*, face coverings); and personal risk (*e.g.*, underlying health conditions). An effective contact tracing program will incorporate these various components of risk to ensure that all close contacts are identified. Appropriate and meaningful guidelines for exposure risk will aid across contact tracing methodologies whether a cruise line is utilizing onboard camera monitoring systems or guest interviews to identify potential cases.

As noted above, there is no single contact tracing method that cruise operators could employ to confidently identify all close contacts. In fact, the prevalence of asymptomatic SARS-CoV-2 infection as well as the lengthy incubation period⁴⁹ make timely identification of infected persons quite challenging. As such, the use and effectiveness of contact tracing to identify and quarantine potentially infected individuals becomes increasingly important. While the Expert Panel does not have specific recommendations around preferred contact tracing methodologies, given the general difficulty in quarantining close contacts, the Panel believes that the best contact tracing program will employ a variety of different tactics to be sure that infected persons do not go unidentified.

Recommendation 45: Cruise operators should employ a variety of contact tracing methodologies to ensure that all potentially exposed people with SARS-CoV-2 infection are identified as quickly as possible.

Potential contact tracing methodologies include, but are not limited to: identifying guest location/exposure by pulling transaction data, collecting information about potential exposure from applications utilizing Bluetooth technology, collecting potential exposure data from cruise line-provided wearable devices, using video analytics and facial recognition to determine exposure risk, and conducting interviews with suspected cases.

Over time, cruise operators may be able to eliminate or modify certain contact tracing methodologies if they are deemed ineffective. However, cruise operators should rely on quantitative evidence to inform contact tracing decisions. The Expert Panel suggests that cruise operators formally evaluate the success of the contact tracing protocols whenever they are employed. Additionally, the Panel notes that since contract tracing is happening all across the country, there are ample educational opportunities that cruise operators can take advantage of to ensure their protocols cover the necessary elements and include skills-based training, such as effective interview skills.

Recommendation 46: Cruise operators should collect metrics on the effectiveness of contact tracing.

The purpose of contact tracing protocols is to identify and isolate individuals with SARS-CoV-2 infections as quickly as possible. Therefore, cruise lines should track metrics such as time from onset of symptoms in an index case to identification of close contacts and/or percentage of new cases arising from individuals in quarantine, to ensure that the contact tracing program is effective. In addition, as part of the after-action review of any SARS-CoV-2 spread on board, cruise lines should retrospectively examine

⁴⁹ Daniel Oran and Eric Topol, "Prevalence of Asymptomatic SARS-CoV-2 Infection: A Narrative Review," *Annals of Internal Medicine* 173, no. 5: 362-367.

whether contact tracing protocols were effective in identifying individuals who later developed illness. In addition, appropriate metrics would allow cruise lines to assess the utility of each of the various contact tracing methodologies to determine which are most useful and effective.

Given that some contact tracing methods could be seen as invasive, the Expert Panel believes that cruise operators should take care to manage expectations and increase education and awareness around contact tracing efforts so that guests feel comfortable with the methods that may be employed.

Recommendation 47: Cruise operators should be transparent in their communication with guests and crew about what information is being collected and how it will be used for contact tracing.

While contact tracing is a key component of an outbreak prevention plan, guests and crew may be uncomfortable with specific contact tracing methodologies. While the Expert Panel does not recommend that guests or crew be allowed to opt out of contact tracing methodologies, the Panel believes that upfront transparency about the use of guest and crew data, combined with education around the importance and utility of contact tracing in the current environment, could both improve the comfort level of guests and crew and boost their overall understanding and support for the outbreak prevention measures that cruise lines have put in place.

Isolation/Quarantine

Ideally, appropriate case management on board a ship will stop a COVID-19 outbreak by containing the spread of the virus. Integral to containing spread is reducing the chance that uninfected guests and crew will be exposed to infected guests and crew. Therefore, it is critical that cruise operators have the capacity and facilities to allow for quarantine of exposed individuals and isolation of infected individuals.

The decision about whether an individual has been in contact or close contact with someone with SARS-CoV-2 infection will drive the decision about whether they need to quarantine. In making the decision about when and where to quarantine, medical staff should assess an individual's symptoms, exposure risk level, stateroom occupancy, preexisting conditions, and a variety of other factors. Any infected person must be isolated. As such, the Expert Panel believes that cruise operators should provide clear guidance in advance that can be used to make these decisions when the need arises.

Recommendation 48: Cruise operators should designate certain cabins on the ship as isolation and quarantine spaces.

Cruise operators should dedicate a number of cabins to remain open in case individuals need to be isolated or quarantined. In some cases it may be appropriate for SARS-CoV-2 exposed guests or crew to remain in their own staterooms to quarantine. However, availability of some dedicated quarantine space is advisable so that individuals can adequately separate from their traveling companions or other crew in shared living quarters. Food and beverage should be delivered, and medical personnel should check on them by phone or in-person visits at least once daily.

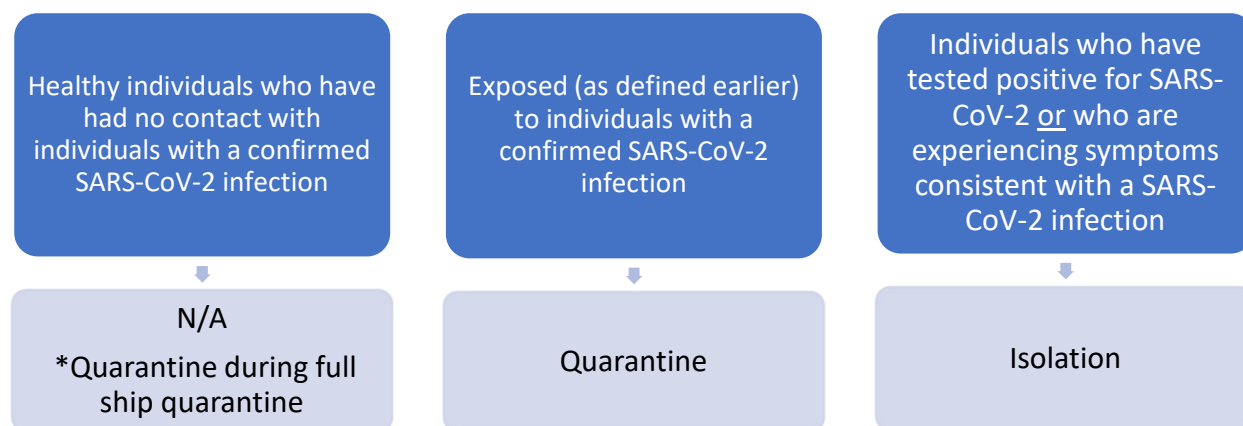
For isolation, cruise operators will need dedicated space that has been configured for this purpose. The Panel recommends that isolation rooms be redesigned to limit the risk of transmission through surfaces (*e.g.*, remove carpets so floors can be sanitized, remove throw pillows that can't be easily washed, use disposable items where possible). Additionally, the ventilation of these rooms should have increased filtration and a negligible risk of contamination for adjacent spaces (*see full ventilation*

recommendations). The decision about whether individuals need to enter isolation or quarantine will be made based on assessment of several factors.

Recommendation 49: Cruise operators should provide guidelines for the determination of whether, when, and where an individual should be isolated or quarantined based on their exposure risk, symptoms, etc.

With the appropriate guidelines in place, cruise operators can rely on the expert medical opinion of the leading medical officer on board to ultimately determine whether an individual should be isolated or quarantined. The following is an example of acceptable guidelines for isolation/quarantine of guests and crew in specific zones:

Figure 2. Isolation/Quarantine Zones



- Individuals who have tested positive for SARS-CoV-2 or individuals who are experiencing symptoms consistent with a SARS-CoV-2 infection will be isolated in designated isolation cabins within close proximity to the medical ward. A set of protocols apply to isolation including periodic health checks, cleaning, and meal delivery.
- Individuals who were exposed to an individual with a confirmed SARS-CoV-2 infection will be quarantined in a single occupancy cabin with a private bathroom (unless quarantining with family members or close contacts with the same exposure history), no interconnection with an adjoining room, door closed, and preferably with a balcony.

iii. Evacuation Scenarios

All cruise operators should have a well-thought-out and detailed plan for the unplanned debarkation of individual guests or crew that allows them to travel quickly and safely to their appropriate destination (e.g., hotel, home, onshore medical facility). In a confined outbreak, the individuals affected could be debarked while the cruise continues. However, in the unlikely but most concerning situation where an outbreak has reached a sufficient level that there is a high risk of exceeding onboard medical capacity, or there is uncertainty about the level of community spread or a lack of confidence in the ability to contain the outbreak, cruise operators must have a plan in place to debark all guests and impacted crew.

In any of the scenarios above, specific plans and protocols should be in place to swiftly and safely execute the required evacuation. Crew members who will be responsible for executing these debarkations should be well-trained in these protocols to ensure safe debarkation for all involved, and specifically to make sure that debarkation events and processes do not undo the good work of the isolation and quarantine measures described previously.

Debarkation Scenarios

In the event that an individual or group of individuals needs to debark from the ship, robust plans should be put in place in advance. Many potential SARS-CoV-2 infections can likely be detected, contained, and treated on board the ship, given the plans for enhanced medical capabilities and staffing, until infected individuals can be safely transported home or to a medical facility. Detailed planning and exercises to test debarkation protocols are highly recommended well in advance of any individuals needing to debark. These kinds of exercises are critically important in testing whether evacuation plans are operationally feasible and responsive to the issues likely to arise in these scenarios. Additionally, they create the opportunity for cruise operators to work through as many of the unknowns and unclear areas as possible in advance of actually needing to use the plan, and also to practice making decisions and pivoting quickly when needed.

Recommendation 50: Cruise operators should have a thorough mobilization response plan in place prior to sailing to address the various scenarios that may require individuals with confirmed SARS-CoV-2 infection (guests or crew), and their close contacts, to debark from the ship.

Early in the pandemic, there were instances where full-scale debarkations were required, but unfortunately had not been planned for or practiced in advance. This led to significant delays and caused cruise operators and government officials to expend significant resources to manage the situation. While unlikely, a full-scale debarkation is a highly complex operation for which detailed emergency planning is warranted. The Panel therefore recommends planning, practicing, and revising operational plans to best prepare for this unlikely but resource-intensive scenario. Importantly, all protocols and preparations should ensure that the cruise operators are prepared to provide for a full-scale debarkation without burdening the resources of any federal, state, or local governments.

Specifically, full-scale debarkation plans should be sure to account for onshore care delivery (and transportation to the appropriate care facility) should the situation/individual medical condition warrant it. In a full-scale debarkation, all guests (including individuals with a SARS-CoV-2 infection and those who are healthy) will be removed from the ship and safely transported to the appropriate destination. Impacted crew should be debarked for self-isolation, treatment, or self-quarantine ashore until they can safely return to the vessel. Healthy crew may remain on board in order to conduct a full decontamination of the vessel. The designation of crew members as “impacted” or “healthy” is done through full ship testing and medical assessments, in addition to the contact tracing identification of close contacts.

Essential to this operational planning is the distinction between smaller- and larger-scale debarkation scenarios. An important part of planning will be to define in advance the low-, moderate-, and high-risk scenarios that may occur and what plans will be put into action at each level. While a specific number of cases may be too rigid to define in advance, the Panel recommends that cruise operators develop general parameters or ranges for each scenario.

Recommendation 51: Cruise operators should define the criteria for small-, moderate-, and large-scale debarkation scenarios in advance of cruising, including a clear decision-making process to guide thinking about when the threshold has been met for each risk level.

As a general matter, a low-risk situation would be one in which there are a low number of cases, no known onboard transmission, and a high degree of confidence of that assessment based on contact tracing and other onboard surveillance measures. The next level, moderate risk, is reached when there is an increased number of cases, limited onboard transmission is suspected or observed, there are potential gaps in contract tracing, and there is a risk of exceeding onboard resource availability. The highest risk scenario, which would necessitate a full ship debarkation and cancellation of the cruise, would be reached in the event of a high number of cases, extensive onboard transmission, contact tracing capacity being exceeded, and onboard resource capabilities being exceeded.

In all these cases, advance contracting with third-party providers will be needed to ensure that government resources (whether international, U.S. federal, or state/local) are not overburdened in addressing a cruise line-based COVID-19 outbreak (though collaborative decision-making with federal agencies such as CDC on the specifics of a debarkation may be appropriate).

The Panel also emphasizes the importance of timely and accurate contact tracing, testing, and other surveillance methods on the ship. If test results are not available rapidly or contact tracing takes a significant amount of time, precious time will be lost in identifying other persons who should be quarantined, and the scope of an outbreak may not be reliably determined.

Even with appropriate guidance in place, the decisions around debarking an entire ship are complex, and the inputs are many. While the Captain and medical team on board the ship will have the most timely, first-hand information about any cases on board, as a situation escalates the Panel recommends that use of a shoreside central command function would be prudent.

Recommendation 52: Cruise operators should establish offsite incident management with designated medical professionals' advice to respond rapidly and to aid in decision-making.

Coordinated emergency response planning by governments and the private sector routinely follows such a model that enables centralized leadership and decision-making and effective delegation of responsibilities. A well-executed central command function should enable a rapid and coordinated response, with high-level liaison functions to facilitate informed decision-making capability and guidance to vessels. In addition to ensuring that protocols are being followed and that information is being shared with all necessary parties, centralizing response would allow for learning and process improvement each time these situations arise.

As noted above, one of the most critical aspects of an effective evacuation plan is maintaining controls to reduce the spread of SARS-CoV-2. The Panel recommends that individuals who have tested positive for SARS-CoV-2, their close contacts, and anyone under investigation be separately debarked from the ship and transported using privately contracted transportation methods to a medical facility, home, or designated quarantine or isolation location to avoid exposing individuals off the ship to SARS-CoV-2.

Recommendation 53: In any debarkation scenario, individuals with confirmed SARS-CoV-2 infection, close contacts, and persons under investigation should be kept separate from any healthy individuals (*i.e.*, those not identified through contact tracing or those who have tested negative).

A safe path home or to medical treatment is the goal of any debarkation, whether small- or large-scale. In order to implement the recommendation of appropriately separating infectious and healthy individuals, it is very important that arrangements be made in advance for potential quarantine and treatment facilities, as well as privately contracted transportation that keeps infected individuals, close contacts, and suspected cases from using commercial means of transportation and potentially spreading infections during transport. The panel discussed and felt that in any scenario, including in a full-scale debarkation, it would be appropriate for healthy individuals not identified through contact tracing, or who have tested negative for SARS-CoV-2, to use commercial transportation.

The Panel recognizes that in a full-scale debarkation scenario, crew who are well may stay on board the ship and continue to work to keep the vessel operating or return it to a state that is safe for the resumption of cruising. Crew who are not being used for this purpose, however, should remain in their cabins until decontamination takes place and they are notified that wider movement is allowable.

Finally, communication remains critical in the event of a debarkation caused by COVID-19. The Expert Panel recommends that crew and guests on board are given timely and accurate information about SARS-CoV-2 infections on board the ship whether the cruise is ongoing or guests have already transported home. In many situations, it may be appropriate for cruise operators to standardize communications to ensure consistency of the information received.

Recommendation 54: Cruise operators should establish a communications plan, and assign a communications lead in advance, to share timely, relevant information with crew and guests on board the ship in the event of a SARS-CoV-2 infection during or after the cruise. Additionally, cruise operators should have systems in place to coordinate information about SARS-CoV-2 infections to relevant health authorities.

Transmission of accurate and timely information will be critical for all guests and crew in the event of a SARS-CoV-2 infection on board a ship. Cruise operators should be thoughtful about the best messages and distribution methods to ensure crew and guests can take the appropriate precautionary measures, understand when and how to seek medical evaluation if they suspect they may have been exposed or are feeling unwell, and modify their behavior and activities according to their risk level. Additionally, transmission of this information will be needed if a cruise operator needs to activate response protocols, including limitations on certain activities and—in the event of a high-risk situation— an order for guests and non-essential crew to stay in their cabins. Additionally, ongoing communication with guests is recommended following the conclusion of a cruise if the cruise operator learns of a post-disembarkation SARS-CoV-2 infection.

Timely, accurate, and regular communication with the relevant local health authorities is another important component of communications. Federal regulations already require ships destined for a U.S. port to report immediately a death or certain illnesses among ship guests or crew.⁵⁰ In addition to communicating with CDC, cruise operators should also notify the other relevant health authorities about cases on board or discovered after disembarkation.

⁵⁰ U.S. Dept. of Health and Human Services, Centers for Disease Control and Prevention, “Guidance for Cruise Ships: How to Report Onboard Death or Illness to CDC,” CDC website, last updated March 21, 2017, accessed September 18, 2020, <https://www.cdc.gov/quarantine/cruise/reporting-deaths-illness/guidance-how-report-onboard-death-illness.html>.

IV. Destination & Excursion Planning

Planning trip destinations is a particularly challenging task for cruise operators in the current environment, as decisions must be made well in advance of sailing and, ideally, in advance of ticketing. This requires cruise operators to leverage data projections and best estimates to predict the future conditions (as they relate to SARS-CoV-2 infections) in selected destinations to the greatest extent and with the most accuracy possible and to flexibly respond as this information changes. Furthermore, cruise operators must rely on imperfect inputs to these decisions (due to availability of disease-related data, data reporting, data accuracy, etc.) and also rely on partnerships across the globe to acquire as much up-to-date information as possible about a given locality, as well as establish arrangements for cruise line-sponsored excursions, etc.

The decision to visit a port has both risks and benefits for the cruise operator and the destination. The health and safety of the cruise guests and crew as well as the local communities they are visiting must be taken into consideration in selecting ports. Cruise travel has a strong economic benefit for many of the destinations frequented by cruise ships. At the same time, many of these locations have less developed health care and public health systems, and cruise operators should work diligently to prevent disease introduction to these locations and avoid burdening local health providers and health systems should any cruise guests or crew need medical care off the ship.

If cruise operators follow the Panel's recommendations regarding testing and other prevention measures, the chances of introducing SARS-CoV-2 onto a ship will be greatly reduced as will the risk to the local community. While visiting ports of call is an important element of the cruise experience, each time guests and crew debark from a ship at a port of call and mix with other individuals off the ship, the risk of introducing SARS-CoV-2 on the ship increases. Therefore, serious attention to ways to mitigate the risk is warranted.

Due to the rapidly changing landscape of COVID-19 and a variability among cruise operators with regard to potential routes, destinations, excursions, and partnerships, the recommendations in this section are provided as high-level guiding principles and baseline parameters for cruise operators to consider. While none of our recommendations should be considered hard and fast rules, the recommendations included in this section in particular should be integrated into much more robust, risk-based, and individualized strategies for cruise operators to appropriately plan safe and fun trips for guests.

i. Destinations and Itinerary Planning

When determining which ports are safe destinations for guests, cruise operators must consider the global status of the COVID-19 pandemic, the local status of COVID-19 in the country and locality of the destination port, public health measures being implemented in the destinations, and the cruise operator's relationships with local governments, tourism bodies, port authorities, tour providers, and other organizations with whom they will need to engage during the normal course of cruising, as well as in the event of an emergency.

With all these factors in mind, the Panel focused its recommendations on prioritizing the parameters to consider when determining which ports of call to visit, particularly taking into account the factor of COVID-19 incidence in destinations. In addition, the Panel identified two essential prerequisites, without which and independent of other factors, travel to a given port would not be advised.

Recommendation 55: There are two essential prerequisites that need to be satisfied in order for a ship to sail to a given port:

- 1) Approval from the local government to visit a port.**
- 2) Agreement to allow safe passage to SARS-CoV-2-infected individuals and their close contacts to debark and travel home.⁵¹**

It almost goes without saying that a local government must approve of cruise ships traveling to their port(s) of call and approve visitation by foreign nationals. For example, there are currently many countries around the world that do not permit visits by U.S. citizens. As such, any destination that places bans on entry of onboard guests would be struck from the list of potential cruise destinations. The cruise operator's longstanding relationships with these destinations will be important in ensuring that information is flowing both ways about the health status of the guests and crew on the ship, and in the destinations cruises are going to visit.

Additionally, should an outbreak occur on board, cruise operators must be able to debark guests to execute their evacuation plans. As such, cruise operators must preemptively secure agreement from any potential ports of call that a cruise ship with an active outbreak may debark and evacuate guests. As detailed above in our full recommendations on evacuation planning, it is important to note that it is not recommended that any individuals with confirmed SARS-CoV-2 infections use commercial transportation.

When considering the safety of various ports of call for cruise ship guests, cruise operators will need to assess the current burden of SARS-CoV-2 in destinations of interest. Critically, this evaluation must occur as the trip itinerary is planned, but must also occur in real-time so that ship Captains can avoid a pre-planned destination port should a situation that had been deemed safe for travel become a situation that is no longer considered safe. While there are a variety of potential metrics that may be used to evaluate a SARS-CoV-2 outbreak for severity, and several other potential metrics by which to evaluate local public health infrastructure and data accuracy, the Panel recommends that cruise operators prioritize evaluation of three key parameters.

Recommendation 56: Cruise operators should rely primarily on three key parameters when determining whether to travel to a given port:

- 1) Current burden of SARS CoV-2 as defined by testing rate, positivity rate, and death rate.**
- 2) Local testing capacity and utilization.**
- 3) Local/regional/national implementation of SARS-CoV-2 mitigation protocols.**

The Panel notes that while death rate is one of the common metrics cited to discuss the burden of SARS-CoV-2 in a given locality, death rate should only be factored in if considered along with testing rate and

⁵¹ Note: specific recommendations regarding travel are included in the "evacuation and onshore care" section of this report.

positivity rate given that death rates are lagging indicators and would likely be more helpful to “rule out” a hotspot rather than “rule in” a potential destination.

Critical to the evaluation of any of the three parameters above is the availability of accurate and reliable data. To increase the reliability and accuracy of the data being considered, the Panel recommends that cruise operators leverage partnerships and on-the-ground representatives/affiliates to ascertain the current COVID-19 situation in a destination. Cruise operators should leverage the local and regional health authorities to develop destination specific protocols. Additionally, the Panel believes that organizations like the Pan American Health Organization (PAHO) and the Caribbean Public Health Agency (CARPHA) could be helpful in creating additional links between cruise operators and localities that have ports of interest, particularly for ongoing surveillance during a cruise to Latin America or the Caribbean where some operators may choose to begin their initial return to service. However, in terms of data collection, these organizations are limited in their ability to acquire data because of their reliance on local governments to submit up-to-date information.

To further assist with ongoing surveillance, the Panel encourages cruise operators from different companies and for trade associations to regularly gather and share information on COVID-19 testing and surveillance at a destination of interest with each other.

The Panel discussed at length the challenge presented by the fact that available information may not provide enough specificity about the disease burden in a specific port location. If data are only available nationally, for example, it may not present an accurate picture of the disease situation in the particular part of the country a cruise ship is visiting. This further emphasizes the need for reliable partnerships and methods to collect on the ground information for good decision-making.

Given the difficulty of these decisions, the Panel recommends that cruise lines favor ports with low infection rates where risky contact points can be minimized. One way to do that would be to, on a temporary basis, sail primarily to the cruise operator’s privately owned and operated destinations, especially when first resuming passenger operations.

Recommendation 57: In the startup phase, cruise itineraries should be as simple as possible, utilizing private, cruise line-owned and operated destinations or ports where there can be tight control of the onshore experience.

While in the long term cruise operators will desire to return to a larger selection of available destinations, the Panel recommends that in the initial stage of return to service that they focus on cruises to their cruise-lined owned and operated destinations (private destinations) or tightly controlled ports if their own private destinations are not a reasonable option. In the case of sailing to a private destination, because the cruise operators have significantly more control over activities, social distancing, sanitation, use of PPE, staff wellness screenings, etc., they can greatly reduce the risk of exposure to SARS-CoV-2 at these destinations.

If cruise operators must expand travel beyond their own private destinations, the Panel supports sailing to strictly controlled ports and destinations where cruise operators can ensure health and safety protocols are in place (*e.g.*, social distancing, no crowding) and where they have confidence that those protocols are being followed. For many destinations, cruise operators may not have as much control

over social distancing, sanitation, use of PPE, etc., which is why the Panel would prefer that initial travel remain at private destinations if feasible.

The Panel recognizes that it is not sustainable in the long term to limit sailings to only private or strictly controlled destinations. But as a test case, in the initial phase of sailing, the Panel believes there is a significant advantage to starting in these locations. Not only will these destinations reduce overall risk during the first trips taking place when sailing resumes, but traveling to such controlled destinations will provide an opportunity for cruise operators to assess other health and safety protocols without the additional factors introduced by travel to various ports of call. Assuming that these initial, more controlled trips proceed with no incidents, it would be appropriate for cruise operators to expand their destination options for future trips.

Recommendation 58: Cruise operators should initially return to service with shorter length trips.

As mentioned above, during the initial return to service phase, simplicity and reduction of risk factors is advisable. Therefore, the Panel recommends trip lengths of no more than ten days at first. Cruises longer than that usually entail stops at several ports, and introducing this level of risk early in the return to service phase would be inadvisable.

ii. Guest Excursions

Prior to COVID-19, cruise operators allowed for both fully curated excursions and self-guided excursions and independent exploration at destinations of interest. However, the risk of exposure for the people in communities that are visited, and for cruise ship guests and crew, increase as more mixing between these groups occurs. Therefore, the Panel recommends that cruise operators initially prohibit self-guided tours and independent exploration and only allow certain curated indoor activities until further notice. This is a significant change to the cruise experience, so the Panel recommends this information be communicated clearly and early on to guests. Cruise operators should also leverage their existing agreements with vendors to further implement controls to reduce the likelihood of guests contracting SARS-CoV-2 while on shore.

Recommendation 59: During the initial return to sailing, cruise operators should only allow guests debarking from a ship at a destination port to participate in cruise line-sponsored or verified excursions as a way of limiting potential exposures in the destinations they visit.

Given that cruise operators will not be able to fully control the SARS-CoV-2 mitigation efforts (*e.g.*, sanitation, social distancing) of every venue at the destinations of interest, the Panel recommends that in the startup phase, guests should only be permitted to disembark at ports if they are taking cruise line-sponsored excursions where such efforts would be subject to vendor management considerations described below. Cruise operators should consider employing strategies that would make these cruise line-sponsored excursions more appealing to guests (*e.g.*, potentially reconsidering the cost of curated experiences, offering a wider variety of excursions to private beach locations) than self-exploration or other externally sponsored excursions. As noted above, guests should be well informed about this new requirement at the time of booking and again prior to sailing.

An additional key component of maintaining the safety of guests is communicating with guests about the need to remain diligent in their efforts to maintain health and safety for the cruise ship population as they embark on their excursions.

Recommendation 60: Cruise operators should establish expectations of the vendors they work with at the destinations they visit to ensure that they are taking recommended steps to reduce the transmission of SARS-CoV-2.

Cruise operators have a thorough process by which they vet vendors for onshore excursions and activities and ensure that these vendors comply with the cruise operator's protocols and regulations. To adapt to the current environment with SARS-CoV-2, cruise operators will need to incorporate additional protocols and regulations into their vendor management processes. While the Panel recognizes that cruise operators should maintain their own individual approaches to vendor management given the wide variability of vendors, the Panel also recommends that cruise operators' additional protocols should, at a minimum, address physical distancing, crowding, PPE, sanitation, personnel screening, and training. Cruise operators may also benefit from working with local authorities to shape the oversight and credentialing of vendors.

Recommendation 61: Cruise operators should incorporate verification of compliance with SARS-CoV-2 protocols into their routine ongoing monitoring guidelines for excursion vendors.

To ensure that third-party vendors at destinations of interest are adhering to cruise operator's additional protocols (*e.g.*, social distancing, PPE, sanitation), cruise operators should incorporate additional compliance monitoring into their existing monitoring of vendors. The Panel supports the notion of having designated crew members act as "observers" and attend tours, excursions, etc., score the third-party vendors on their adherence to cruise operator protocols, and report back to the cruise operators. If it is found that third-party vendors are not adequately following cruise operator protocols, cruise operators may take corrective action as they see fit.

Recommendation 62: Cruise operators should ensure that guests are thoroughly informed about potential exposure risks and how to minimize their risk of contracting SARS-CoV-2 at the planned destination.

An important aspect of preventing the spread of SARS-CoV-2 or other infectious illnesses is ensuring that guests are informed about efforts they can take to minimize risk of exposure, such as hand hygiene and physical distancing. While the cruise operators have protocols in place to educate guests on these efforts at the time of booking, the Panel supports cruise operators' plans to continue these educational efforts on board and when guests arrive at destinations of interest. Furthermore, to the extent possible, cruise operators should ensure that proper signage and floor markings are placed around excursion venues to remind guests to physically distance and to indicate where hand hygiene stations are located.

Recommendation 63: Cruise operators should offer indoor excursions only if physical distancing, use of masks, and other recommended protective measures can be implemented.

CDC guidance states that outdoor activities and events should be prioritized over indoor activities to mitigate against the risk of SARS-CoV-2 transmission.⁵² Given that indoor excursions may lead to crowding, make it difficult for guests to properly physically distance, and significantly increase the risk of

⁵² U.S. Dept. of Health and Human Services, Centers for Disease Control and Prevention, "Coronavirus Disease 2019 (COVID-19): Your Health: Personal and Social Activities: Attending an Event or Gathering," CDC website, last updated September 11, 2020, accessed September 18, 2020, <https://www.cdc.gov/coronavirus/2019-ncov/daily-life-coping/personal-social-activities.html#event>.

airborne transmission of SARS-CoV-2, cruise operators should be very careful about which indoor excursions are permitted for guests. If cruise operators can ensure that onshore locations have comparable safety and public health measures to those being taken on board the ship, cruise operators can consider permitting indoor excursions. For example, if a cruise operator could secure exclusive use of facilities (*i.e.*, a tour for just cruise ship guests or a private event), that measure would provide some assurance of limited contact between cruise ship guests and other tourists who may not be following the same protocols. Indoor excursions that present a risk of uncontrolled crowding, poor ventilation, lack of mask usage, and improper physical distancing (*e.g.*, visits to a crowded indoor bar or restaurant, or indoor tourist destination without reduced capacity limits) may be infeasible in the initial return to sailing. The Panel recognizes and agrees that a wider selection of indoor excursions at destinations of interest may eventually be permitted if the risk of guests acquiring SARS-CoV-2 infection at these destinations is significantly reduced as compared to today.

V. Mitigating Risks for Crew Members

The majority of recommendations from the Panel apply to both guests and crew, and where the requirements are specific to one of those groups, they are marked as such (*e.g.*, preboard testing requirements differ for guests and crew). Nonetheless, the Panel believes a special focus on crew in our recommendations is warranted given that crew are on board ships for significantly longer than guests and have different living conditions and potential exposures based on their roles. In total, hundreds of thousands of individuals serve as crew on cruise ships worldwide and come from a wide variety of countries, so this is a significant population to address. During our work, the Panel spent time discussing the learning opportunities that have arisen from examining the role crew have played in cruise-related SARS-CoV-2 outbreaks and the experience of crew who remained on board ships during portions of the timeframe of the No Sail Order. This history informed the Panel's work and the Panel encourages cruise operators to review SARS-CoV-2 outbreaks that occurred during this time period to pinpoint any issues or breakdowns in protocols that can be improved upon in the future. A robust testing regimen for crew, precautions on board like physical distancing and PPE use, thorough training, attention to the living conditions for crew, and reinforcing a culture of self-reporting any health or safety concerns can create the conditions for a safer working and living environment for these valuable members of the cruise operator's team.

i. Prevention

Recommendation 64: Cruise operators should manage the population density of crew areas of the ship.

Just as cruise operators will manage population density in guest areas of the ship, the same principles should be applied in crew-only areas of the ship such as cabins, dining rooms, gyms, pools, and social areas. Crew on ships work hard and need to have time and space to relax and enjoy their off hours, so cruise operators will need to employ creative solutions to ensure that crew can still have enjoyable periods of down time without creating risky exposures.

Recommendation 65: Cruise operators should provide opportunities for crew to debark from the ship at destinations while maintaining reasonable limitations on their movement to reduce risk of exposure to SARS-CoV-2.

One of the major appeals of working on a cruise ship for many crew members is the opportunity to visit new places around the globe. This desire must be balanced against the imperative to reduce exposure to SARS-CoV-2 in the places the cruise ships visit, as further discussed in the destinations section of these recommendations. If local transmission rates are within acceptable limits, cruise operators may be able to balance these needs by, for example, providing transportation for crew to certain destinations (*e.g.*, a private beach or designated shopping area with appropriate controls in place) so that crew can take part in activities they enjoy during shore leave time, while limiting riskier exposures. In addition, cruise operators should consider reasons that crew debark from the ship (*e.g.*, to access the internet, make phone calls, shop for toiletries and supplies) and determine if there are ways to bring some of these services and amenities on board the ship or to provide them in safer ways off the ship.

Recommendation 66: Crew should be placed in single-occupancy crew cabins whenever possible to minimize extended periods of close contact with other crew members.

An important way to protect crew members from potential exposure to COVID-19 is to place crew in single-occupancy crew rooms whenever possible to minimize close contact time with other crew members. As ships begin sailing at reduced capacity, this should be easier for cruise operators to accomplish. As the number of guests on board increases, so too will the quantity of crew required, and double rooming may be necessary. While the Panel's understanding is that it is quite uncommon on modern cruise ships to have large crew bunk rooms (*i.e.*, four or more individuals), the Panel strongly recommends against such arrangements, since they would substantially increase the risk of exposing crew to SARS-CoV-2. Additionally, as noted in the air management recommendations, filtration and other HVAC strategies are important across all areas of the ship, including in crew-specific common areas and cabins.

Recommendation 67: Cruise operators should limit crew members' close personal contact with guests over extended periods of time wherever possible. When distancing isn't possible, crew should be provided with additional PPE appropriate to their job type.

Whenever feasible, crew's physical contact with guests should be limited for the protection of all parties involved. However, there are positions for which this is infeasible (*e.g.*, massage therapist, child care center worker, lifeguard). These personnel should be provided with additional PPE beyond masks (*e.g.*, gloves) whenever possible to limit their potential exposure to SARS-CoV-2.

Recommendation 68: Cruise operators should include crew in the surveillance, contact tracing, quarantine, isolation, and debarkation protocols that will be employed in the event that a SARS-CoV-2 infection is discovered on board.

The protocols covered in the response and contingency planning recommendations are applicable to crew as well as guests in nearly all cases. Whereas guests may be able to quarantine in their own cabins, crew (particularly if sharing a cabin) may need to be moved to designated quarantine or isolation rooms. If crew are assured that any necessary medical care will be provided to them at no charge should they contract a SARS-CoV-2 infection, it will help reinforce a culture of self-reporting any relevant symptoms.

ii. Training & Culture

Cruise operators should provide training on how to reduce the risk of SARS-CoV-2 transmission to all crew, ideally beginning before they even board the ship. The Panel defers to the cruise operator's

discretion about the exact contents and methods of training, but notes the importance this training will have in creating a culture of prevention and vigilance aboard the ship and recommends that the pre-contract phase when crew members are at home is the best time to begin communicating various aspects of the training program to ensure they are fully prepared for travel and the new environment on board (e.g., what will be expected upon arrival to the port, properly wearing PPE, safe travel tips).

Recommendation 69: Crew should be provided with regular training on protocols to reduce transmission of SARS-CoV-2 and empowered to take action to ensure these protocols are followed by guests and fellow crew members.

Crew should understand their own roles and responsibilities to prevent transmission of SARS-CoV-2 and protect health, as well as what will be expected of guests. For returning crew, some of these protocols will be new and more challenging to follow, so having a good basis of understanding about the public health rationale for these changes will make them easier to comprehend and abide by. Certain crew positions will involve risks that must be uniquely addressed, so training specific to these roles is also warranted. Drills that test response procedures are another important component of ensuring crew are prepared to respond when necessary, and these new drills will complement the many safety drills that already take place aboard ships.

Recommendation 70: Cruise operators should reinforce a culture of honesty and collective responsibility among crew for following protocols and creating a safer environment.

In speaking with cruise operators, the Panel is confident in their ability to utilize training and other methods to instill in crew members the sense of collective responsibility and camaraderie that will foster repeated safe and healthy journeys. The Panel believes that it is incumbent upon cruise operators to foster a culture of honest reporting and collective acceptance and promotion of healthy behaviors among crew members not only by educating them about the updated health and safety protocols, and by making them aware of the potential repercussions should those protocols not be followed, but also by maintaining a culture of health promotion. Cruise operators should take care in their communication with crew members to foster a collective understanding of responsibility for the health of one's fellow crew members and the guests on board.

VI. Validation of Implementation

The Panel recognizes that just as important as writing health and safety protocols is ensuring that those protocols are implemented appropriately. As such, the Panel recommends that cruise operators have systems and processes in place to continuously evaluate implementation of and adherence to their revised protocols for health and safety on board.

Recommendation 71: Cruise operators should have measures and metrics in place to perform continual self-assessment of compliance with all updated health and safety protocols as well as methods for third-party verification of compliance.

Given that cruise operators will be implementing many new protocols as a result of the COVID-19 pandemic, it is imperative that appropriate measures to assess crew member and third-party vendor compliance are also implemented. Having such measures and metrics in place will not only protect the

safety and well-being of guests and crew members, but they will also remind crew members and third-party vendors of the new expectations that they must uphold on board and at destinations.

One way to do this is for cruise operators to perform a brief self-assessment and reflection during and/or after each cruise to verify that all health and safety protocols are being followed and to assess the success of these protocols in mitigating spread of SARS-CoV-2 on board. The Panel supports the notion that such self-assessments and reflections be performed even in scenarios where there were no SARS-CoV-2 infections on board, as there still may be gaps or areas to improve upon. These self-assessments will be particularly valuable in the startup phase when so many new procedures are being implemented, and will provide an opportunity for real-time course correction and modifications. While compliance is every crew member's responsibility, there could be an advantage to designating and empowering a specific crew member(s) to monitor and document compliance in the early phases of sailing. Just as important as assessing is having internal processes to implement remediation plans when they learn that protocols are not being followed.

In addition to self-assessment, third-party verification is a recommended step to provide another layer of assurance to cruise operators, guests, and regulators that recommended changes have been implemented. The Panel recognizes that third-party assessment entails significant time and expense. However, given that a successful return to service will require compliance, this expenditure of resources will be valuable.

Recommendation 72: Cruise operators should perform an “after-action review” following a cruise on which a SARS-CoV-2 infection was detected to assess gaps and make improvements prior to the next trip.

As the Panel has acknowledged, no prevention measure is perfect and it is likely that even with all the protocols that will be put into place, there will be SARS-CoV-2 infections on board cruise ships. Whenever this occurs, the Panel recommends that a thorough review be done following resolution of the individual case or outbreak to assess how the situation occurred, how it was managed, and what could be done to prevent it and/or improve the response to it in the future. The Panel has already detailed in a number of its recommendations where continued evaluation will be needed. For example, if a case is identified and contact tracing is completed, the cruise lines should evaluate after the fact how timely and accurate the contact tracing was and make any improvements needed. If the cruise operator learns that a case occurred because of a failure in a particular protocol or series of them, they should consider what can be done to change or better implement that protocol.

VII. The Path Forward

Cruise operators have demonstrated their commitment to adopting numerous new protocols to implement the recommendations made by the Panel. We have two final recommendations for cruise operators that we believe will bolster public confidence in their return to service: (1) iteratively testing these new risk mitigation measures, and (2) creating a cycle of continuous learning and improvement.

Recommendation 73: In their return to sailing, cruise operators should use a phased approach to demonstrate that protocols can be successfully implemented on board their ships before returning to full operations with guests on board.

As cruise operators return to service, they will be adjusting to many new processes in terminals, on board their ships, and at the destinations they visit. We see great benefit in testing these new procedures in a stepwise fashion, with a deliberate and careful expansion through a pre-determined series of phases. The Panel recommends cruise operators develop the specific details of their phased return to service as part of their return to sailing planning. Ideally working with regulators, cruise operators should agree in advance for a defined set of sailings in graduated phases, as described below, that would permit the cruise operator to move to the next step without seeking additional approvals.

A first step under this proposal would be a dockside simulation of a cruise using employees to role play guests. The pre-arrival and boarding protocols would be tested along with a limited number of onboard activities. Independent observers could watch the process and afterwards a full debrief with those observers would be done and corrective actions or modifications could be made.

Following this, a short overnight cruise with a limited load factor would be conducted. Again, employees would simulate the role of guests and a wider array of onboard activities would be conducted and additional protocols tested. Similarly, an assessment and debrief with designated observers would follow.

Next, a short cruise to a single destination would take place, preferably at a cruise operator's privately owned and operated destination. This would allow testing of embark and debark processes as well as the private destination protocols.

As cruise operators move to commercial sailings initial cruises should be as simple as possible with limited destinations, controlled excursions, and short trip lengths. Once these initial sailings are conducted and internally examined, it may be appropriate to carefully expand operations.

Overall, the Panel believes a controlled, phased approach to the return to sailing would build confidence among cruise operators and regulators alike that the new protocols can be implemented successfully or adapted as needed before full operations resume.

Recommendation 74: Cruise operators should implement a formal process to review health and safety experiences related to COVID-19 on cruises to enhance best practices and shared learnings for continuous improvement.

Given the rapidly evolving nature of the science and best practices related to management of SARS-CoV-2, the Panel discussed throughout our work the need to continuously learn from real world experience once sailing resumes. As part of our process to develop these recommendations, we spent time studying and learning from the cruises that have already begun in the past few months. These conversations demonstrated the value of sharing learnings about what has worked and what has not worked across cruise operators.

This is not a new approach for cruise operators. They already have extensive processes for reviewing incidents in the context of a marine environment, often in conjunction with outside experts such as the U.S. Coast Guard and Classification Societies. We suggest developing similar procedures for reviewing COVID-19 incidents.

Conclusion

The challenge posed to the Healthy Sail Panel was complex. We were asked to identify protocols that would enable cruise operators to resume operations in ways that would minimize risk and would protect guests, crew, and destination communities. We endeavored to craft protocols that would offer a high assurance of safety for these important constituencies.

It is important to note that while the Panel was carefully assembled to draw upon experts in diverse and relevant areas of public health, infectious disease, biosecurity, hospitality and maritime operations, none of us were experts in all aspects of the cruise industry. However, the detailed planning already completed by cruise operators with whom we collaborated to advance these goals of safety was instrumental in providing us a framework from which to begin our discussions.

As part of our deliberations, we immersed ourselves in the challenges associated with reducing risk and increasing safety, and we applied careful consideration to every touchpoint of the cruise experience. We invested time in understanding the complexities of operating cruise ships and the challenges that might impact—and be impacted by—our recommendations, and we considered how best to apply public health principles to these complex endeavors. In pursuing these goals, we considered the latest scientific evidence surrounding SARS-CoV-2.

We also studied the experiences of cruise operators with past outbreaks early in the pandemic to inform best practices moving forward. It was apparent to us that these operators were attempting to address a crisis without the benefit of systematic planning rooted in science, and the associated procedures that would best ensure guest and crew safety. These early and tragic experiences informed our deliberations. Moreover, the application of evolving science, technology, and knowledge about addressing SARS-CoV-2 have also helped reduce the risks revealed by these early experiences.

Looking toward the future, we believe we have charted a path for a healthy and safe return to operations. Our comprehensive report represents a holistic plan to reopen the cruise industry in the safest ways possible. Safely returning more elements of our leisure sector is critical to helping Americans return to a life of normalcy. We believe that taken in totality, our recommendations are able to help provide these assurances.

To summarize, our recommendations are centered around four primary themes:

- 1) **Keep SARS-CoV-2 off ships:** Cruise operators must be rigorous in their efforts to prevent anyone with a SARS-CoV-2 infection from boarding a cruise ship, which is the most important step to reducing overall risk.
- 2) **Mitigate the risk of infection:** Cruise operators must employ vigilant practices to mitigate the risk of transmission onboard, including employing proper distancing, handwashing, and mask-wearing practices, as well as ensuring careful activity planning and venue management.
- 3) **Protect destinations:** When visiting a destination, cruise operators must be diligent in their planning to reduce the risk of guests and crew contracting the virus and to protect the communities that they visit and the people who live there.

- 4) **Detect and contain SARS-CoV-2:** In the event that there is a suspected or confirmed case on board, cruise operators must be prepared to execute a carefully planned response that cares for the affected individual and their party, while simultaneously protecting others from exposure.

We believe that if cruise operators address these four challenges with the detailed recommendations contained in this report, it will establish a careful approach for returning to operations. These protocols are based on a complete analysis of the cruise journey, as well as on today's understanding of the disease. That said, with new scientific and public health opportunities, including advances in testing, treatments, vaccines, emerging technologies, and other innovation, cruise operators' return to service plans will require ongoing, iterative adjustment and continuous improvement to further enhance the safety of passengers, crew, and destination communities. Just as cruise operators are planning continuous improvement protocols, we also will refine our recommendations as our scientific understanding of this disease evolves.

Overall, these recommendations are intended to work holistically as a set of complementary approaches that when woven together and implemented in totality, create a strong fabric of defense against the introduction and spread of SARS-CoV-2 infection on board cruise ships. We believe these protocols help provide a path for ships to return to operations safely and that this multi-layered approach can help protect passengers and crew against the risk of transmission.

In closing, we would like to acknowledge the contributions from all parties, including public health advisors to individual cruise lines, CLIA, other cruise operators, in addition to countless contributors from Norwegian Cruise Line Holdings Ltd. and Royal Caribbean Group. We also would like to acknowledge the Leavitt Partners team who managed the Expert Panel process, including the drafting and editing of this report. We greatly appreciate the time, dedication, and care everyone has devoted to improving health and safety. We are proud to have been a part of this important and collaborative effort.

APPENDIX A: HEALTHY SAIL PANEL



GOVERNOR MICHAEL LEAVITT, CO-CHAIR

Leavitt Partners, Founder

Former Governor of Utah

Former Secretary of Health and Human Services



DR. SCOTT GOTTLIEB, CO-CHAIR

Resident Fellow at American Enterprise Institute

Contributor at CNBC

Former Commissioner of the U.S. Food & Drug Administration

THE EXPERT PANELISTS



HELENE GAYLE, M.D., M.P.H.

Dr. Gayle is CEO of the Chicago Community Trust. Dr. Gayle spent 20 years with the Centers for Disease Control. She worked at the Bill & Melinda Gates Foundation, directing programs pertaining to global health issues. Dr. Gayle serves on multiple boards including The Coca-Cola Company, Colgate-Palmolive Company, Brookings Institution, the Center for Strategic and International Studies, the Federal Reserve Bank of Chicago, and the Economic Club of Chicago. She is a member of the Council on Foreign Relations, the American Public Health Association, the National Academy of Medicine, the National Medical Association, and the American Academy of Pediatrics.



JULIE GERBERDING, M.D., M.P.H.

Dr. Gerberding is EVP/Chief Patient Officer for Merck and a world-renowned public health expert. Prior to joining Merck, she served as the Director of the CDC from 2002-2009. While at the agency, she led more than 40 emergency responses against crises such as anthrax, SARS, bird flu, food-borne outbreaks, and natural disasters. Previously, Dr. Gerberding was a tenured faculty member in Infectious Diseases at the University of California at San Francisco (UCSF). She continues as an Adjunct Associate Clinical Professor of Medicine at UCSF.



STEVEN HINRICHS, M.D.

Dr. Steven Hinrichs is Professor and Chair of the Department of Pathology and Microbiology at the University of Nebraska Medical Center in Omaha, former Director of the University of Nebraska Center for Biosecurity, and former Director of the Nebraska Public Health Laboratory (NPHL). He is the principal investigator of multiple national awards from the Association of Public Health Laboratories, CDC, and the U.S. Department of Defense for the development of an outreach program to extend training and expertise in the early recognition of biological warfare agents. He has published more than 180 papers in basic science and medical journals.



MICHAEL OSTERHOLM, M.D., PH.D.

Dr. Osterholm is one of the foremost experts in public health, infectious disease, and biosecurity. As director of the Center for Infectious Disease Research at the University of Minnesota, he is an international leader on pandemics preparedness. He is a consultant to the WHO, NIH, FDA, DoD, and CDC. From 2001 to 2005, he served as advisor to the Secretary of U.S. Health and Human Services on issues related to bioterrorism and public health preparedness. From 2018 to 2019, he served as a Science Envoy for Health Security on behalf of the U.S. State Department. He has also been appointed to the National Science Advisory Board on Biosecurity and the World Economic Forum's working group on pandemics.



STEPHEN OSTROFF, M.D.

Dr. Ostroff was Acting Commissioner of the FDA from 2015 to 2016, and prior to that role he served as the FDA's chief scientist. He joined FDA in 2013 as chief medical officer in the Center for Food Safety and Applied Nutrition and senior public health advisor to FDA's Office of Foods and Veterinary Medicine. Before his time at the FDA, Dr. Ostroff served as deputy director of the National Center for Infectious Diseases at the CDC. He retired from the Commissioned Corps of the U.S. Public Health Service at the rank of Rear Admiral (Asst. Surgeon General). Dr. Ostroff also served as director of the Bureau of Epidemiology and acting physician general of Pennsylvania.



WILLIAM RUTALA, PH.D., M.S., M.P.H.

Dr. Rutala is the Director and co-founder of the NC Statewide Program for Infection Control and Epidemiology and a Professor in the Division of Infectious Diseases at the University of North Carolina's School of Medicine. He was the Director of Hospital Epidemiology, Occupational Health and Safety Program at the University of North Carolina Hospitals for 38 years. He is a retired Colonel with the U.S. Army Reserve. He has been an advisor to the CDC, FDA, EPA, and FTC. His research interests are the epidemiology and prevention of healthcare-associated infections (including new and emerging pathogens) with a focus on disinfection and sterilization, outbreak investigations, as well as the contribution of the environment to disease transmission.



KATE WALSH, PH.D.

Dr. Walsh is Dean and E.M. Statler Professor at the School of Hotel Administration at Cornell University, and is recognized as a leader in education for the global hospitality industry. A professor of management, Dr. Walsh's primary research is in organizational service design, leadership, and strategic investments in human capital. She has over 20 years of academic experience. In addition, Dr. Walsh has held a number of executive positions in hospitality human resources and is a former New York State certified public accountant. Dr. Walsh serves on the board of the American Hotel and Lodging Association.



PATRIK DAHLGREN

Captain Dahlgren is the SVP of Global Marine Operations and Fleet Optimization for RCL. Patrik's seagoing experiences began as a bridge officer with tugboats, yachts, and an array of cargo vessels and ferries. He rose through the ranks during over 15 years on board Royal Caribbean International's cruise ships, with his last seagoing command as Master of Oasis of the Seas and Quantum of the Seas. He was the lead contributor to the Quantum of the Seas development, which received the esteemed RINA (Royal Institute of Naval Architects) award for its innovation and largest contribution to maritime safety.



ROBIN LINDSAY

Mr. Lindsay is the EVP of Vessel Operations for NCL. He was appointed to this position in January 2015. In this role, Mr. Lindsay is responsible for Marine & Technical Operations, Hotel Operations, Entertainment, Product Development, Port & Destination Services, Fleet Personnel, Out Islands, and New Build & Ship Refurbishment. Mr. Lindsay served in a similar capacity as EVP of Vessel Operations at Prestige Cruise Holdings, the parent company of Oceania Cruises and Regent Seven Seas Cruises. Mr. Lindsay's history with the company goes back to the inception of Oceania Cruises in 2003, when he joined as SVP, Hotel Operations and Vessel Operations. Lindsay earned his B.S. degree from Louisiana Tech University.