IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

STATE OF FLORIDA, Plaintiff, v. XAVIER BECERRA, Secretary of Health and Human Services, in his official capacity; HEALTH AND HUMAN SERVICES; ROCHELLE WALENSKY, Director of Centers for Disease Control and Prevention, in her official capacity; CENTERS FOR DISEASE CONTROL AND PREVENTION; UNITED STATES OF AMERICA, Defendants.	Case No.: 8:21-cv-00839-SDM-AAS

SUPPLEMENTAL *AMICUS CURIAE* BRIEF OF MARC S. YOUNG IN SUPPORT OF FLORIDA'S MOTION FOR PRELIMINARY AND PERMANENT INJUNCTION(S)

INTRODUCTION

Marc S. Young, PE a licensed chemical engineer in the State of Texas, Louisiana, Arizona and *Alaska* submits this supplemental *amicus curiae* brief in support of the State of Florida's motion for preliminary and permanent injunctions.[1] Mr. Young

[1] Dkt. 24. While Marc S. Young did not seek to intervene in this action as a plaintiff, Mr. Young may reserve the right refile his past litigation filed against the predecessors of these Defendants in the previous administration. *See 4*:20-cv-2299 In Federal District Court of South Texas, Houston Division.

was present on May 12 for Florida's and the DOJ's oral arguments. He submits this supplemental brief to provide the Court with better context related to his former *amicus curiae* brief and to suggest some answers to questions posed by the court more than once that did not seem to get satisfactory answers from either party. Mr. Young's interests are aligned with Florida's, Alaska's and Texas because a denial of Florida's motion may also inhibit Mr. Young from obtaining relief in time to save his July 2, 2021 fully paid cruise to Alaska and two other cruises prior to November 1, 2021.

STATEMENT OF FACTS: MARC YOUNG'S UNIQUE INTERESTS

A. Marc S. Young original statements

The statements of A. of the original *Amicus Curiae* Brief has changed. Effective 8:20 pm on May 21, Mr. Young has been notified that, even with the passage of the bills in Congress to allow for a direct cruise to Alaska from the U.S. Port in Seattle, bypassing the foreign stop requirements of the Passenger Vessel Services Act of 1886 (46 USC § 55103) until February 2022, his cruise to Alaska on July 2, 2021 has been cancelled. The remaining Statements in B. thru F. are the same and for the sake of brevity will not be repeated for the Court in this supplement.

QUESTIONS UNANSWERED

Questions posed by the Court in the preliminary injunction hearing on May 12, 2021, sometimes multiple times, seemed to remain unanswered. These were:

1. *"Does the CDC have the power or authority to make a NO SAIL ORDER or a CONDITIONAL SAIL ORDER?"*
2. *"Has the CDC ever quarantined a ship for six months, a year or longer and have they ever applied a Quarantine against an entire industry"*
3. "*If the Court were to vacate the Conditional Sail Order what regulations would take its place*?"
4. *"What 'Local' regulations would take the place of the CDC mandates*?"

and,

5. *Can the injury to the States, their economy and the obvious decimation of an entire cruise line industry be relieved by a court order vacating the CDC's order?*

INITIAL RESPONSES

It seemed clear that nobody had a good answer for any of these questions.

The Defendant's counsel argued, with respect to Question 1, that they had this power already via the NO SAIL provisions in the VSP (Vessel Sanitation Program) that the CDC already administers. Yet does the CDC have such authority under the VSP such that this is a satisfactory answer? The State of Florida's Counsel did not seem to be able to answer that question at all.

For the Second Question, a series of questions on quarantine, the Defendant's counsel only had an answer for the third part, trying to claim that somehow the

prohibition on importations of red ear turtles was somehow applicable to this case. The Court quickly saw through this response, replying that this might have been comparable if it had been the entire pet industry.

With respect to the Third Question, as to what regulations would take the CDC Order's place if the court vacated the CDC Order, multiple times the State of Florida seemed to imply things would return to self-regulation by the industry with an adoption by the Industry of the Healthy Sail Panel [HSP] protocols.

With respect to the fourth question, there was no answer as neither the counsel for the defendants, nor the counsel for the State of Florida was able to identify any "local" regulations that had been or would be in place. This was particularly pointed out in discussion on what was insufficient actions on the part of the states in preventing the spread of communicable disease thus allowing the Secretary to use 42 CFR §§70.2 to make their NO SAIL ORDER in the first place. More will be discussed later on the issue of the CDC claiming their rules preempt all local control.

With respect to the Fifth Question the Court is facing a decision that can best be described as a Gordian Knot. CDC has noted that prior to the "No Sail Order" there were significant outbreaks onboard vessels prior to the issuance of the order. It is clear the public, the regulatory and the cruise communities all desire to NOT see a return to the examples the U.S. regulators have documented. Yet the question has to be asked: Was a true cause and effect determined? Was the failure

caused by the cruise industry or was the extensive outbreaks caused by a failure of the regulatory agencies? A failure of the regulatory health agency was clearly the answer to a study commissioned by the New South Wales authorities in Australia with respect to an outbreak on the Ruby Princess. [2]

ARGUMENTS

Q1: CDC AUTHORITY FOR NO SAIL ORDER/CONDITIONAL SAIL ORDER

Based on the documentation on the CDC website with respect to Ship Sanitation Certificate Information [Exhibit A] the CDC appear to derive their authority for the VSP as "Competent Authority" under the IHR (2005) for US Ports of Entry. It should be noted that the CDC does not require a Ship Sanitation Control Certificate/Ship Sanitation Control Exemption Certificate ("Ship Sanitation Certificates" or SSCC/SSCEC) as of the October 13, 2015, but they reserve the right to inspect vessels. If a cruise ship needs a SSCC or SSCEC they can request one during a VSP Inspection, but it is the CDC VSP inspectors' option if they have time to do the separate inspection. Because Cargo ships are not inspected under the VSP program, they cannot obtain such sanitation certificates.[3]

Further the CDC states, "The authority to issue, inspect, and require SSCCs/SSCECs within the United States or its territories resides solely with the

[2] [Report of the Special Commission of Inquiry into the Ruby Princess, 14 August 2020 ISBN: 978-0-646-82316-4 (online version)].

[3] This answers the Court's query to the Defendant's Counsel as to "Does the CDC treat all ships the same?" Cargo ships are not treated the same as Cruise Lines Ships.

Centers for Disease Control and Prevention's (CDC) Division of Global Migration and Quarantine (DGMQ), the 'Competent Authority' under the IHR (2005) for U.S. ports of entry. Any certificates issued by private companies in the United States are not valid." The CDC does have a statutory right per 42 CFR §§71.41 to inspect for sanitary reasons any ship and to determine if there is an outbreak onboard if they have reason to suspect an outbreak on a vessel.

Based on the declarations by Capt. Treffiletti, in Exhibit A of the Defendant's Memorandum[4], the Maritime Unit of the CDC found the HSP protocols "*inadequate to sufficiently mitigate the introduction, transmission, and amplification of COVID-19 on cruise ships and to U.S. communities*". Further she stated, "*Accordingly, more emphasis was needed on actions to mitigate potentially infected travelers* ***from boarding ships in the first instance*** *so that fewer government resources would be needed from local, state, and federal agencies—as well as onshore medical facilities—to manage cases and outbreaks*." (emphasis added)

Is the real reason that the NO SAIL ORDER was issued due to the exorbitant cost of manpower, cost for isolation and quarantine of ill and exposed passengers for the duration of an outbreak. Was it feared to be too great given the current budget of the CDC? If the WHO International Health Regulations are a guide, as noted in the original amicus curiae brief by Mr. Young, the CDC does appear to be

[4] DKT 31-1 Page 19, paragraph 44

trying to shift to the cruise lines the risk and the cost of any such outbreak. If 42 CFR §§70.6 (b) and 42 CFR §§71.33 are the guides, the Director of the CDC is still responsible for arranging "for adequate food and water, appropriate accommodation, appropriate medical treatments and means of necessary communication for individuals who are apprehended or held in quarantine or isolation" under Part 70 or Part 71.

Although Mr. Young still agrees with the Florida arguments that the CDC goes beyond its authority to micromanage the cruise ship industry, after listening to the oral arguments and reviewing the declarations by Captain Aimee Treffiletti, it is understandable that the CDC felt it was in their remit to be able to institute a "No Sail Order" in March 2020. The DOJ attorney for the CDC alluded to a fact, not in evidence, that the CDC could issue a No Sail Order under the Vessel Sanitation Program. This may have been a misunderstanding by the DOJ attorney. An important fact and distinction, as can be seen in the latest VSP Operations Manual[5] is that the VSP is a VOLUNTARY[6] program. While it states under the administrative section of the VSP Operations Manual entitled "Recommendations That the Vessel Not Sail", the CDC "can recommend or direct

[5] Vessel Sanitation Program 2018 Operations Manual (www.cdc.gov/nceh/vsp/docs/vsp_operations_manual_2018-508.pdf)

[6] 2018 VSP Operations Manual, 2.0 Authority, 2.1 Public Health Service Act, 2.1.1 Communicable Disease Prevention, 2.1.1.1 Communicable Disease Prevention: "***Although cooperation by vessels with VSP is voluntary***, the Public Health Service (PHS) is authorized by the Public Health Service Act (42 U.S.C. Section 264. QUARANTINE and Inspection - Regulations to control communicable diseases) to take measures necessary to prevent the introduction, TRANSMISSION, or spread of communicable diseases into the United States from a foreign country." (emphasis added)

the master of a vessel not to sail when an IMMINENT HEATH HAZARD or similar imminent threats to public health are found aboard a vessel" [7] The CDC clearly has Quarantine Authority when an Imminent Health Hazard is found. Yet, for sanitation purposes, if it is a voluntary program, why would a master of the vessel have the obligation to follow such a recommendation unless it was a Quarantine Order? Is there potential liability that could attach for not following such imminent health warnings if it were just a recommendation? The key in the case is it must be an IMMINENT HAZARD found on board. This is defined for infectious disease as an OUTBREAK which could subject newly arriving passengers to disease.[8] These facts clearly support the fact reported in Mr. Young's prior amicus brief that the CDC's Vessel Sanitation Program is a voluntary program not a mandate. Why is this an important distinction?

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[7] 2018 VSP Operations Manual, 12.0 Administrative Guidelines, Page 178; Subsection 12.9 Recommendations That the Vessel Not Sail: "12.9.2 Procedures: 12.9.2.2 ***No Sail: "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. Such a ***recommendation*** will be signed by the VSP Chief, with concurrence of the Director, National Center for Environmental Health/Agency for Toxic Substances and Disease Registry or the Director's designee. (emphasis added)

[8] 2018 VSP Operations Manual, Section 12.0 Administrative Guidelines, Page 178, 12.9 Recommendations That the Vessel Not Sail, 12.9.1 Imminent Health Hazard "An IMMINENT HEALTH HAZARD will be determined to be, but not limited to, one of the following situations:

- Free HALOGEN residual in the POTABLE WATER distribution system is less than 0.2 MG/L (ppm) and this deficiency is not corrected before the inspection ends.
- Inadequate facilities for maintaining safe temperatures for POTENTIALLY HAZARDOUS FOOD.
- Inadequate facilities for cleaning and sanitizing EQUIPMENT.
- Continuous problems with liquid and solid waste disposal, such as inoperative or overflowing toilets or shower stalls in passenger and crew member cabins.
- ***Infectious disease OUTBREAK among passengers or crew, and where it is suspected that continuing normal operations may subject newly arriving passengers to disease.***

The CDC is given the power to issue Quarantine, Isolation or Conditional Release ORDERS [See Exhibit F] and No Sail ***Recommendations***. Quarantine, Isolation or Conditional Release ORDERS also require, based on CFR §§70.15 Mandatory Reassessment of a Federal Order for Quarantine, Isolation, or Conditional release, a reassessment (in 72 hours), by an independent officer other than officer issuing the order, and consideration by the Director of whether there is a less restrictive alternative, and a separate order giving the results of the reassessment and the decision as to whether it should be continued, modified or rescinded. If it is to be continued or modified as a result of the reassessment, it must also explain the process for requesting an appeal that includes a medical review as outlined in CFR §§70.16. Clearly the series of NO SAIL ORDERs and the CONDITIONAL SAIL ORDER by the CDC do not comply with all these requirements. So, this would seem to imply that while a NO SAIL RECOMMENDATION can be made, a NO SAIL ORDER should not. It should be a Quarantine, Isolation or Conditional Release Order for a specific ship on a case-by-case basis not an entire industry.

The CONDITIONAL SAIL ORDER as noted below is more aligned with Bills of Health that are not required by current regulations. This raises clear Administrative Procedures Act concerns because to change or eliminate a standing regulation, e.g., 42 CFR §§71.11[9], should require proper notice and comment

[9] 42 C.F.R. §§71.11 Bills of Health - A carrier at any foreign port clearing or departing for any U.S. port

periods? **The answer to Question 1) above must therefore be NO.**

A1: The CDC Does Not Have the Authority to Issue A NO SAIL or CONDITIONAL SAIL ORDER, Just A RECOMMENDATION.

Q2: REASONABLE TIME FOR QUARANTINE OR ISOLATION

Based on the normal "Order for Quarantine" for COVID-19, the CDC would only impose quarantine or isolation under 42 USC §264 and 42 CFR §§70.6, 71.32(a) and 71.33, until a person is "no longer at risk of becoming ill and spreading the disease to others. This is commonly referred to as the incubation period for the disease. The incubation period for COVID-19 is currently believed to be up to 14 days." On this basis it should be logical to assume that a reasonable time for quarantine or isolation is 14 days or less. How can the CDC justify "quarantine or isolation" of the entire worldwide fleet of cruise line ships that want to sail to or from U.S. Ports, the largest market for cruising in the world, for more than a year? Is it not the Reasonable Time for Quarantine and Isolation of a Vessel the time it takes to allow any virus onboard and its host to be detected and either removed or isolated or quarantined based on the same 14 day incubation period? Why is a ship any different? Particularly since the latest evidence is it is not the fomite transfer

shall not be required to obtain or deliver a bill of health.

that causes the infection it is the direct person to person transfer.[10]

A2: A Maximum 14 Day Period Without Testing Should Be Reasonable. With Testing Even Less.

Q3: WHAT REASONABLE REGULATIONS WOULD TAKE THE PLACE OF THE CDC ORDERS?

Is there a major risk to the public and should the Court rely on non-health officials to help it in its determination? At issue is the needed expertise to make such a determination. The court clearly addressed this in its question to Florida on what public health authorities are they relying upon? They seem to have no response other than the "Healthy Sail Panel". It is becoming clear the issues has become political as well, with the public on both sides having major concerns on which public health officials in this country can be believed. So, if the public health officials, officials who are defendants in this case, are not to be believed, who does the court believe? WHO are the alternative experts in the area of public health? The answer may well the question itself. The WHO or World Health Organization.[11] Due to the United States Senate in a Joint Congressional

[10] Science Brief: SARS-CoV-2 and Surface (Fomite) Transmission for Indoor Community Environments Updated Apr. 5, 2021(https://www.cdc.gov/coronavirus/2019-ncov/more/science-and-research/surface-transmission.html)

[11] This is not a recommendation that Mr. Young makes lightly or even without much chagrin. It is just the logical conclusion. Mr. Young is a former candidate for Texas State Representative in 2012 and was considered to be one of the most conservative of the slate of five candidates in the primary race for his state house seat. Given the more recent direction the World Health Organization has gravitated particularly with so called self-professed public health emergencies such as the Climate Change, that

Resolution[12] having ratified the Constitution of the WHO in 1948[13] the United States has endorsed the World Health Organization as the lead public health experts with respect to international health. The primary purpose of the International Health Regulations are as outlined in their purpose and scope. "The purpose and scope of the IHR (2005) are "to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, ***and which avoid unnecessary interference with international traffic and trade***."

The Defendant, e.g., the CDC, acts as this countries '*National IHR Focal Point'* and '*Competent Authority*' responsible for the implementation and application of health measures under the International Health Regulations and Congress has given the Secretary of the HHS who has delegated that authority to the CDC pretty broad powers in the statutes. Thus, by doing so, Congress has in effect provided the required implementation of the legislative requirement, for the International Health Regulations to be considered as implemented by the CDC.

However, it should be noted that unlike the assertions made in the Mr. Young's original *amicus curiae* brief, the reservations contained in the 1948

many in the conservative groups think is not a genuine health consideration, the suggestion that the World Health Organization may be the best suited for dealing with global pandemic response may be seen to some as being nothing short of heresy. Yet the United States has been involved for almost a century with various forms of Sanitation Agreements which have culminated in the International Health Regulations of 2005.

[12] Joint Resolution 62 STAT. 441 (Chapter 469) [Exhibit D]

[13] Constitution of the World Health Organization, 62 STAT. 2679 TIAS 1808, 4 Bevans 119 [Exhibit E]

Congressional Joint Resolution do make it clear that the nothing in the constitution of the World Health Organization "commits the United States to enact any specific legislative program". Thus, the International Health Regulations may not be self-implementing (as formerly stated and implied by a New York Federal Court) and should require implementation by congressional legislation.

This does not make them totally inapplicable. Apparently in many instances the CDC has assumed the authority they have in many particular areas of public health as being derived from the WHO and their International Health Regulations. Again, one area for this is with respect to Sanitation Certificates[14] [Exhibit A]. So, the answer to Question 3) and 4) above may be addressed in part by the CDC website with respect to Ship Sanitation Certificates in the United States? There it is stated:

> ***"Who is authorized to issue Ship Sanitation Certificates in the United States?"***
>
> ***"No port authorities, public agencies, or private organizations are authorized to issue SSCCs/SSCECs in the United States."*** *(emphasis added)*
>
> *"The authority to issue, inspect, and require SSCCs/SSCECs within the United States or its territories resides solely with the* ***Centers for Disease Control and Prevention's (CDC) Division of Global Migration and Quarantine (DGMQ), the "Competent Authority" under the IHR (200)}*** *for U.S. ports of entry. Any certificates issued by private companies in the United States are not valid." (emphasis added)*
>
> *"While* ***CDC DGMQ is the Competent Authority under the IHR (2005****), the authority to issue SSCCs/SSCECs for specific purposes has been delegated to certain*

[14] See Exhibit A which is copied from (https://www.cdc.gov/quarantine/maritime/shipsanitation.html)

U.S. government agencies/programs." (emphasis added)

- *"The U.S. Navy and U.S. Coast Guard may conduct inspections and issue SSCCs/SSCECs for certain types of ships, primarily vessels of their services and those of the National Oceanic and Atmospheric Administration."*
- *"The CDC Vessel Sanitation Program CVSP) may choose to issue SSCCs/SSCECs upon request during VSP inspections of cruise ships. Please contact VSP (vsp@cdc.gov} with questions about sanitation inspections on cruise ships."*

Further, the CDC website states:

> "Port authorities, public agencies, and private organizations are prohibited from requiring SSCECs/SSCCs for seafaring vessels at U.S. ports of entry. ***Such actions would contradict CDC's exercise of federal authority under the Supremacy Clause of the U.S. Constitution.***"

The answer to Question 3) based on the above is that if the court vacated the Conditional Sail Order, the regulations that would take its place are the ones that are now in place. i.e., the Quarantine, Isolation and Conditional Release Orders that are in the cited regulations for 42 CFR Part 70 and 42 CFR Part 71. Only they should be implemented on a case-by-case basis with the CDC required to use evidentiary basis for identification of cases of exposure or infection per 42 USC §264(d).

As stated earlier in Mr. Young's earlier brief in his similar action[15], and his original *amicus curiae* brief to this Court, the United States has been party to some sort of sanitation agreement for many decades [See Exhibit B.2], the latest is the International Health Regulations by the World Health Organization that was

[15] District Court of South Texas, Houston Division., Chief Judge Lee Rosenthal presiding (4:20-cv-2299)

ratified by the US in 2007.[16] However, the key reservations to this agreement[17] must be considered by the Court, along with Section 5[18] of the ratification of the WHO constitution, and it is for the Court to read and interpret these reservations,[19] both in the ratification of the WHO Constitution and the International Health Regulations for itself and determine how applicable they are to this case as an international treaty enforceable on the same basis as a federal statute.

There are some legal experts who argue that although a non-self-implementing congressional-executive agreement cannot on its own provide a basis or cause for a suit, the fact that the cause may be satisfied by other statutes,

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[16] WHO International Health Regulations, 3rd edition, [Exhibit C]

[17] WHO International Health Regulations, 3rd edition, [Exhibit C Appendix 2 Page 60-61] and [Exhibit C.1 the Diplomatic Note] A key reservation is:
"The Mission, by means of this note, and in accordance with Article 22 of the Constitution of the World Health Organization and Article 59(1) of the IHRs, submits the following reservation on behalf of the Government of the United States of America:"
"The Government of the United States of America reserves the right to assume obligations under these Regulations in a manner consistent with its fundamental principles of federalism. With respect to obligations concerning the development, strengthening, and maintenance of the core capacity requirements set forth in Annex 1, these Regulations shall be implemented by the Federal Government or the state governments, as appropriate and in accordance with our Constitution, to the extent that the implementation of these obligations comes under the legal jurisdiction of the Federal Government. To the extent that such obligations come under the legal jurisdiction of the state governments, the Federal Government shall bring such obligations with a favorable recommendation to the notice of the appropriate state authorities."

[18] Joint Resolution 62 STAT. 441 (Chapter 469) [Exhibit D] Section #5

[19] Does an "understanding" in an executive agreement rise to the same level as a "reservation" in a U.S. Ratified Congressional-Executive Agreement with respect to this case. The understanding is referenced in footnote 9 above and is stated as: " The third understanding relates to the question of whether the IHRs create judicially enforceable private rights. Based on its delegation's participation in the negotiations of the IHRs, the Government of the United States of America does not believe that the IHRs were intended to create judicially enforceable private rights: The United States understands that the provisions of the Regulations do not create judicially enforceable private rights."

as in this case the APA, the agreement as a treaty is still the law of the land. Per the Supremacy Clause it is still fair to be considered by the Court in deciding situations such as is presented in this case, where a statute is ambiguous and needs further interpretation by the Court.[20]

Returning to Capt. Treffiletti comment. "Accordingly, *more emphasis was needed on actions to mitigate potentially infected travelers from boarding ships in the first instance*". A major flaw in the Conditional Sail Order is the requirements it seems to place on the cruise lines onboard activities. i.e., detection of the virus once onboard, mask wearing, social distancing, having labs onboard to detect it, having facilities to handle it once a large number of passengers are exposed, how to handle it once they arrive back at a U.S. Port (required agreements in place) and limitations on revenue paying passengers on test cruises and the length of cruises. Is there a scientific basis for limiting a cruise to seven days? This eliminates many of the longer and relatively lower cost on a per day repositioning cruises like the Transatlantic Cruise the Young's have scheduled in Late October.

This begs the question of how the Conditional Sail Order actions are any different from the requirements of a "Bill of Health" which based on the current regulations[21] appear not to be required of any carrier from a foreign port destined

[20] See Oona A. Hathaway, et al, International Law at Home: Enforcing Treaties in U.S. Courts, Yale Journal of International Law, [Vol 37: 1 2012] with respect to the third means of indirect enforcement or "interpretive enforcement". Pg. 88- 90.
[21] See Footnote 9

for a US Port. In the 1985 Final Rule Publication[22] of 42 CFR Part 70 and Part 71, Section 366(c) of the PHS Act (42 USC 269(c) was cited as conferring "the authority to prescribe regulations applicable to vessels in particular, 'for the purpose of preventing the introduction into the States or possessions of the United States of any communicable disease by securing the sanitary condition of such vessels, their cargos, passengers and crews. In this context the Department believes the provisions for carrier inspection, detention, and remedial action are clearly supported by the enabling legislation (PHS Act) and is within the statutory scope of authority."

What are the measures that could be employed in a proactive versus reactive manner? Are these not outlined in the Articles and Annexes of the International Health Regulations and in the WHO IHR Handbook for Management of Public Health Events on Board Ship? Why does the CDC insist on trying untried and unproven protocols? Have any of the requirements the CDC put forth by the Conditional Sail Orders been peer reviewed or even standardized as part of an International or National Health Panel or Group?

In the oral arguments the CDC's counsel said that they did not go so far as to mandate all passengers be vaccinated. It was only offered to the cruise lines as an option to avoid the more troublesome test cruise requirements. It was noted by the Court, that if they had invoked a vaccine mandate, the simple dilemma of the

[22] 50 FR 1519 Friday, January 11, 1985 / Rules and Regulations

State prohibitions against vaccination passports by businesses might have been preempted by the federal rule. But, by offering only an option to the cruise lines to avoid test cruises with non-revenue passengers by certification of a certain level of vaccination among the crew and the passengers, the cruise lines are not given a preemption of the state law.

The CDC seems to argue that they are the party responsible for making these requirements because the local community and state regulations are simply limited to their intrastate waters or local jurisdiction. How do these onboard rules being exerted against a foreign flagged ship have any jurisdiction beyond a U.S. Port or federal water, as the CDC seems to imply? Isn't this the jurisdiction of the flag state of a foreign flagged ship once in international waters? If the Flag state is a signatory party to World Health Organization and the other multinational treaties, is not it a violation of international law to force the ships' masters to comply with U.S. regulations or orders outside U.S. waters.

The CDC seems to lean heavily on 42 USC § 269 or the "Bills of Health" statute to provide them their authority, particularly with respect to the VSP program. Yet they do not argue that statute in their Orders or their filings in this case? Could it be because this is why the International Health Regulations, and the World Health Organization was empowered by 196 member nations to act as the coordinator of such international activity. It should be noted by the Court that

as far back as 1934,[23] in International Agreements that were eventually absorbed by the latest World Health Organization's International Health Regulations, the need for "Bills of Health" were eliminated. [See Exhibit B.1]. The Pan American Sanitation Agreement Treaty [Exhibit B.3] is cited by the State Department listing of Active Treaties [Exhibit B.2] as having the section related to Bills of Health [Article 16-26 of Exhibit B.3] replaced by the IHR in 1969 which was replaced by the IHR 2005. Even in 42 C.F.R §§71.11 "Bills of Health" it states that a carrier heading from a foreign port to a U.S. Port is not required to obtain or deliver one. Why is this regulation on the books when the federal statute 42 USC §269 Bills of Health is still in force?

Are the multitude of conditions being imposed on the cruise lines in the Conditional Sail Order considered all to be "sanitary conditions" that must be satisfied for a cruise ship to obtain a clean "Bill of Health"? Are these conditions prescribed by other health experts or best industry practices? Generally, those types of protocols that are contained in well vetted, peer reviewed and proven standards. The original VSP Operations Manual [Exhibit G], included the FDA 1976 Model Code for Food Service and the World Health Organization's Guide to Ship Sanitation and was published in 1989. Are the latest updates to the VSP Operations Manual based on the Conditional Sail Order really vetted or are they

[23] See International Agreements for Dispensing with Bills of Health and Consular Visas on Bills of Health in Article 58 of the International Health Regulations.

just the wishful musings of what some official thinks will work? What is the evidence of them successfully working in an actual cruise ship sailing environment? Why is it somehow more acceptable to "test the protocols" the government wants, and use them on a group of non-paying volunteers, versus a group of paying customers? Why are the cruise lines not allowed to restart from U.S. Ports with the set of protocols they have tested with reasonable results in Asia and Europe? Why can they not just give their passengers a fair assessment of the risks they are taking and ask them to sign a waiver? Given the higher vaccination rates, the number of persons who have been infected and recovered and may have acquired some immunity and the more knowledgeable public based on almost a year and a half of the world living with COVID-19, is the risk of a Diamond Princess reoccurrence really a possibly?

If the Healthy Sail Protocols which have been developed by a panel of health experts is not sufficient. What is? Maybe the full implementation of the requirements of the International Health Regulations, which puts the requirements of many of the items that Captain Treffiletti asked for in place. Does not the CDC providing more vetting of passengers prior to boarding using appropriate risk management measures and testing of high risk persons getting on board actually put more emphasis where it is needed. e.g. "*on actions to mitigate potentially infected travelers from boarding ships in the first instance*"

If the CDC would satisfy the IHR ANNEX 1 capabilities at key ports of entry

(and departure) to provide the requirements as outlined, many of their concerns would be addressed. Now if the cruise lines are willing to voluntarily provide these services, like they do with the VOLUNTARY VSP, then that is between them and the CDC. However, it should not be a mandatory ordered requirement to sail.

A3: The International Health Regulations, Annexes and Handbooks Should Be Used In Lieu Of CDC ORDERS.

Q4: WHAT LOCAL REGULATIONS COULD TAKE THE PLACE OF THE CDC ORDERS?

As noted above in C) the CDC insists that due to the Supremacy Clause of the U.S. Constitution, and the powers derived from the Commerce Clause they preempt Local and State rules. Because almost all cruise lines are foreign flagged ships and the due to compliance with the Passenger Vessel Service Act (PVSA) which mandates a stop in a foreign port, almost all cruise lines are in international or foreign commerce, this is clearly the case where the Commerce Clause does apply. With the current waiver of the PVSA by bills unanimously passed by Congress, if signed by the President or of any veto overridden, the sailings to Alaska are now taking on simpler Interstate Travel. The provisions of 42 U.S.C. §264(c) and 42 U.S.C. §264(d) come into play which only allow 42 U.S.C. §264 to apply to only individuals entering from foreign countries or possessions, and the quarantine of individuals that are in qualifying state. Not ships or Vessels.

Yet in the area of interstate travel after a cruise or on entering a State from a Port of Entry, it is clearly the states responsibility for Quarantine and Isolation outside the Port of Entry federal jurisdiction area.

A4: No Local or State Regulations of Foreign Flagged Ships Can Take the Place with Respect to The CDC'S NO SAIL or CONDITIONAL SAIL Rules, Just the International Health Regulations.

Q5) CAN THE INJURY TO THE STATES, THEIR ECONOMY AND THE OBVIOUS DECIMATION OF AN ENTIRE CRUISE LINE INDUSTRY BE RELIEVED BY A COURT ORDER VACATING THE CDC'S ORDER?

The Conditional Sail Order and its overreaching protocols are currently the only thing preventing the cruise lines from sailing. This is evidenced by the plans for several of the cruise lines to start sailing again out of non-U.S. ports in the Caribbean starting in June, as well as out of Greece and Italy. The CLIA has embarked on a campaign called READY, SET, SAIL[24] to get the members of many of the cruise lines loyalty programs to "Take Action to Support the Return of Cruising in the United States" by contacting their representatives to demand legislative action if the CDC still refuses to drop their conditional sail order.

It must be noted that Congress in a rare display of bipartisan support has unanimously passed by both the House and the Senate a bill to allow the

[24] https://cruising.org/en/clia-action-center?vvsrc=%2fcampaigns%2f85099%2frespond%3fTrackingID%3dGSCSocial%26fbclid%3dIwAR0Ef8E5lzBp2WLud0cdnC8mYYxU5rlgtES4nzXqYvUaaw4gDwTJgnC7wQQ

suspension of the PVSA for cruise to Alaska. Thus allowing the closed ports of Canada to be bypassed.

Given the high level of continued participation in future cruise reservations, all that is needed for a rapid recovery is for a Court Order vacating the CDC Order. It may also require a mandamus order to demand that the CDC provide the required level of testing or proof of vaccination to protect the public from the virus. The other prophylaxis protocols being ordered by the CDC are more reactive and do not seem to comply with the declarations of their own expert Captain Aimee Treffiletti who has stated the need *to mitigate potentially infected travelers from boarding ships in the first instance***.**

A5: The Simple Requirement for Adequate Testing of Boarding Passengers or Proof of Vaccination is a Much Less Restrictive Alternative than the Conditional Sail Order Protocols Being Ordered.

FINAL ARGUMENT ON APPLICATION OF THE APA ON THIS CASE

Although not addressed above in the Questions that were asked but not fully answered, there were questions on the applicability of the Administrative Procedures Act and the questions related to standing that deserve some additional comment and discussion. In 2017 when the CDC was finalizing the FINAL RULE on 42 CFR Part 70 and Part 71 [CDC Docket No. CDC-2016-0068] RIN 0920-AA63

Control of Communicable Disease[25], in the response to comments the HHS/CDC states , "HHS/CDC received several comments on the Agency's accountability system, encouraging that a 'strong system of checks and balances' should be in place for this regulation to be implemented. HHS/CDC agrees that there should be accountability and oversight ***regarding the agency's activities***. We note that these regulations do not affect the ability of Congress to conduct its oversight activities *or affect the jurisdiction of federal courts to review federal agency actions under the Administrative Procedure Act (5 U.S.C. 704)*." and HHS/CDC received a comment that there is no court supervision of HHS/CDC activities. We disagree. *These regulations do not affect the jurisdiction of the Federal courts* or the statutory rights of individuals *to obtain judicial review of CDC's actions and decisions through appropriate mechanisms such as* the habeas corpus statute (28 U.S.C. 2241) or *the Administrative Procedure Act (5 U.S.C. 704)*."

THE CDC HAS STATED FOR THE RECORD THAT THE FEDERAL COURT HAS JURISDICTION FOR JUDICIAL REVIEW OF THE AGENCY'S ACTIVITIES.

CONCLUSION

If the Court were to vacate the CDC Order, what is necessary is a mandamus order by the court. The Mandamus Order would be a demand for the CDC to

[25] See 82 FR 6890 Thursday, January 19, 2017, Rules and Regulations [Exhibit H]

follow the International Health Regulations and their guidelines. The Order should also require nothing more than a high level of vaccination or testing by the CDC, or by the Cruise Lines, as long as the cruise lines are voluntarily doing it on behalf of the CDC. This must be done to limit the opportunity for the virus to get onboard. If the virus does get onboard, with a reduced number of susceptible recipients, it should not be able to effectively replicate, thus avoiding the Diamond Princess outbreak scenario. The cruise lines should be allowed to adopt the protocols they believe are most effective for their situation, in keeping with their obligations to keep their vessel free from such infectious agents under the International Health Regulations and not as "Sanitation Requirements"

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