UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

CONEY ISLAND PREP, *et al.*, Plaintiffs, - against - UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, Defendants.	**No. 20 Civ. 9144 (VM)**

DEFENDANTS' MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Statutes

Regulations

Other Authorities

PRELIMINARY STATEMENT

For nearly seven months the country has been battling against the novel coronavirus known as "COVID-19." Defendants, the U.S. Department of Health and Human Services ("HHS"), led by Secretary Alex M. Azar II (the "Secretary"), and Assistant Secretary for Preparedness and Reponse Dr. Robert Kadlec, HHS sub-agency the Centers for Disease Control and Prevention (the "CDC"), and the CDC's Director, Dr. Robert R. Redfield (together, the "Government"), have been at the forefront of the federal response to this virus. Their ongoing and evolving efforts include providing updates and information, including COVID-19 data, to the American people; funding and overseeing vaccine development efforts; and issuing guidance with respect to testing and safe reopening protocols.

Plaintiffs, a school and its CEO, a non-profit organization and its CEO/founder, a New York City council member, and a medical student/public health advocate have sued alleging that the Government has failed to meet a bevy of statutory obligations—mostly obligations to provide public health reports to Congress and to begin taking steps to create a biosurveillance network that is required to be completed by September 2023. Plaintiffs allege this alleged agency inaction violates Section 706(1) of the Administrative Procedure Act ("APA"). Separately, Plaintiffs allege that the Government's decision to switch to a new, more flexible database called HHS Protect to store and analyze COVID-19-related data collected from hospitals was arbitrary and capricious in violation of Section 706(2) of the APA. Plaintiffs also allege that, in addition to the APA, they are entitled to relief under the All Writs Act and the Mandamus Act.

The Court should deny Plaintiffs' motion for a preliminary injunction—an "extraordinary and drastic" remedy—because Plaintiffs are unlikely to prevail on any of their claims. To begin, Plaintiffs lack Article III standing because they have failed to demonstrate *any* injury—informational, procedural, or otherwise—caused by the Government's conduct. Most of the

reports/data and some of the participation opportunities that they claim the Government has failed to provide are not, by statute, required to be provided to them or to the public. Other reports/data and other allegedly withheld participation opportunities have, contrary to Plaintiffs' contentions, already been publicly provided, while yet others do not relate to COVID-19. In fact, the Biosurveillance Network—of which some of these reports and opportunities are building blocks—is, by statute, not required to be completed until *2023*, and therefore was not supposed to be completed by the time the pandemic began. Moreover, CDC has provided a multitude of information to the public that specifically addresses the COVID-19 pandemic—information that would be more useful to Plaintiffs and the public in responding to COVID-19 than many of the reports referenced in Plaintiffs' complaint.

Given this, Plaintiffs have failed to show how the allegedly withheld information or opportunities caused them to divert resources or otherwise impeded their operations. Accordingly, Plaintiffs fail to allege injuries that the Court can redress. Further, Plaintiffs lack statutory standing because their claims are not within the zone of interests protected by the relevant statutory provisions and rules. The Court should deny Plaintiffs' motion for a preliminary injunction on the basis of a lack of standing alone.

Nor are Plaintiffs likely to prevail on the merits of their claims. As an initial matter, contrary to Plaintiffs' allegations, the Government has in fact met many of the statutory duties raised in the Complaint (or is currently on schedule to meet a deadlines that have not passed). While the agency has missed certain other of its deadlines—in many cases because it redirected resources to the more exigent COVID-19 response—those deadlines are for reports due to Congress, and such obligations are not reviewable under the APA. Moreover, the Court should decline to exercise its equitable discretion to issue an injunction in light of HHS's pressing

COVID-19 responsibilities, particularly given that none of the outstanding reports have any direct impact on the Government's COVID-19 response.

Plaintiffs' claim that the Government's decision to collect COVID-19 data from hospitals through a system called HHS Teletracking for integration into the HHS Protect ecosystem was arbitrary and capricious will fail for three reasons. First, this decision, announced in a July 2020 guidance document posted on HHS's website, was not a final agency action. Second, whether and how to collect data from hospitals that participate in Medicare and Medicaid is a matter committed to the agency's discretion that cannot be reviewed under the APA. Third, the utilization of these new, more efficient systems was a reasonable decision made using the agency's expertise that is entitled to substantial deference.

Finally, Plaintiffs' All Writs Act and Mandamus Act claims fail because neither of those statutes can serve as the basis for an independent claim.

Because Plaintiffs have failed to show that without an injunction they will suffer harm or a substantial likelihood of success on the merits of any of their claims, and because both the public interest and the balance of the equities favor the Government, the Court should deny Plaintiffs' motion.

BACKGROUND

A. Statutory Background

1. PAHPAIA Directs the Development of an Advanced Biosurveillance Network

On June 24, 2019, the Pandemic and All-Hazards Preparedness and Advancing Innovation Act ("PAHPAIA"), Public Law No. 116-22 became law. PAHPAIA follows two previous statutes that addressed, among other things, HHS's preparedness and response activities—the Pandemic and All-Hazards Preparedness Act ("PAHPA"), Public Law No. 109-

417 (December 2006), and the Pandemic and All-Hazards Preparedness Reauthorization Act ("PAHPRA"), Public Law No. 113-5 (March 2013). PAHPAIA amends the Public Health Service Act (the "PHS Act") to build on HHS's work under the previous two preparedness statutes (as well as other laws) to advance national health security, including by enhancing the authorities of the Secretary, the Assistant Secretary for Preparedness and Response ("ASPR"), and the Director of the CDC to prepare for and respond to public health emergencies. *See* 133 Stat. 905.

Under section 319D of the PHS Act, 42 U.S.C. § 247d-4, as amended by PAHPAIA, the Secretary is required to complete by September 30, 2023, an integrated public health alert communications and surveillance network (the "Biosurveillance Network") between federal, state, and local public health officials, public and private health-related laboratories, hospitals, poison control centers, and other health care facilities, and other entities determined appropriate by the Secretary. 42 U.S.C. §§ 247d-4(b), (c), (g). In the context of the statute, "biosurveillance" means "the process of gathering near real-time biological data that relates to human and zoonotic disease activity and threats to human or animal health" for early warning and identification of health threats. *Id.* § 247d-4(j). The Biosurveillance Network will "allow for the timely sharing and discussion . . . of essential information concerning bioterrorism or other public health emergency, recommended methods for responding to such an attack or emergency, and coordination to maximize all-hazards medical and public health preparedness and response and minimize duplication of effort." *Id.* § 247d-4(b)(2). The statute provides that the Secretary may implement the network through the awarding of grants to States or consortia of States. *Id.* § 247d-4(d)(1).

Section 319D describes several of the interim steps the Secretary is to take to establish the Biosurveillance Network:

- "Not later than 180 days after June 24, 2019, the Secretary shall convene a public meeting for purposes of discussing and providing input on the potential goals, functions, and uses of the [Biosurveillance Network]," which "shall include representatives of relevant Federal agencies . . . State, local, Tribal, and territorial public health officials[,] stakeholders with expertise" in relevant areas, "and other representatives as the Secretary determines appropriate." *Id.* § 247d-4(c)(5)(B)(i), (ii).

- "Not later than 1 year after June 24, 2019, the Secretary . . . shall, as necessary, adopt technical and reporting standards, . . . for [the Biosurveillance Network] and update such standards as necessary. Such standards shall be made available on the internet website of [HHS], in a manner that does not compromise national security." *Id.* § 247d-4(b)(3)(A).

- "Not later than 18 months after June 24, 2019, the Secretary shall submit to the congressional committees of jurisdiction a coordinated strategy and an accompanying implementation plan" (the "Biosurveillance SIP") that is informed by the above-mentioned public meeting and identifies the steps the Secretary will take to carry out the plan. *Id.* § 247d-4(c)(6)(A).

The Government has partially met the requirement to adopt technical and reporting standards for the network through its Public Health Information Network resources and through coordination with HHS's Office of National Coordinator for Health Information Technology ("ONC"), which has promulgated the "Standards and Implementation Specifications for Health Information Technology," codified at 45 C.F.R. Part 170. Declaration of Ileana Arias ("Arias Decl.") ¶ 6. Additionally, although HHS has not convened the formal meeting specified in 42 U.S.C. § 247d-4(c)(5)(B)(i), (ii), it has taken multiple steps to engage with stakeholders, including state and local governments, with respect to ongoing, significant biosurveillance activities, including by convening a large meeting in July 2020. Arias Decl. ¶¶ 4-5. As the Biosurveillance Network as described in PAHPAIA is not expected to be fully operational for several years, there is no evidence that delays in these milestones affect the Government's COVID-19 response. Instead, a number of CDC's robust, long-standing biosurveillance systems that comprise the developing network have been leveraged to support the response to COVID-

19, including: (a) the National Syndromic Surveillance Program; (b) the U.S. Flu Vaccine Effectiveness Network; (c) the COVID-19, Associated Hospitalization Surveillance Network (which is built on the Emerging Infections Program and the Influenza Hospitalization Surveillance Project); (d) the New Vaccine Surveillance Network; and (e) the National Healthcare Safety Network. *Id.* ¶ 5.

2. Other Duties Under PAHPAIA

Several new HHS reporting requirements were added by PAHPAIA. First, a report "on the state of Federal biological threat detection efforts" (the "Biological Threat Detection Report") was due to Congress "not later than 180 days after the date of enactment of this Act," P.L. 116-22 § 205(c), 133 Stat. 905, 924-25. HHS has not yet prepared this report and will work to address that oversight by January 2021. Declaration of Nikki Bratcher-Bowman ("Bratcher-Bowman Decl.") ¶ 17.

Second, "a report containing recommendations related to maintaining an adequate national blood supply," is due to Congress "[n]ot later than 1 year after the date of the enactment of this Act," P.L. 116-22 § 209, 133 Stat. 905, 929. On March 23, 2020, OASH published a notice in the Federal Register, soliciting public comments on this report. *See* 85 Fed. Reg. 16,372 (Mar. 23, 2020). In April, OASH published a notice in the Federal Register announcing an extension of the period of public comment to June 21, 2020, in response to requests for more time from interested parties. *See* 85 Fed. Reg. 19,950 (Apr. 9, 2020); Declaration of Diane Foley, M.D. ("Foley Decl.") ¶ 4. HHS is currently working on the report, incorporating feedback from the public comments it received, and anticipates submitting the report to Congress in January 2021. *Id.*

Third, "a report describing efforts and activities to coordinate with other countries and international partners during recent public health emergencies," was due to Congress "[n]ot later than one year after the date of the enactment of this Act," P.L. 116-22 § 606, 133 Stat. 905, 959. The preparation and publication of this Vaccine Development Report has been slightly delayed as a result of the significant demand placed upon HHS's resources in responding to the COVID-19 pandemic. Bratcher-Bowman Decl. ¶ 14. At present, HHS has prepared a report covering the period of 2019 to early 2020 (April), and HHS expects that this report will be finalized and published by the end of 2020. *Id.* Based on the time period covered by the Vaccines Development Report, it will not address any issues related to vaccines for COVID-19. *Id.*

Fourth, "[n]ot later than 1 year after the date of enactment of this Act, the Secretary . . . shall convene a meeting to discuss the potential role advancements in genomic engineering technologies . . . may have in advancing national health security." P.L. 116-22 § 605, 133 Stat. 905, 958. HHS has taken steps to comply with this requirement, starting with an October 2019 meeting at the White House related to bioeconomy leadership. Bratcher-Bowman Decl. ¶ 16. HHS plans to engage subset of the meeting attendees for a more focused discussion on applying such advanced biotechnology to health security and medical countermeasures development, likely in 2021 when vaccines and therapeutics begin playing a greater role in COVID-19 mitigation. *Id.*

Fifth, "[n]ot later than 1 year after June 24, 2019, the Secretary shall report to the congressional committees of jurisdiction on the implementation of recommendations of the Federal Experts Security Advisory Panel [FESAP] concerning the select agent program" (related to dangerous biological agents and toxins and their countermeasures). *Id.* § 262a(k)(2). HHS has prepared this report, but has not yet submitted it to Congress as result of delays due to the

COVID-19 response. HHS expects to issue the report to Congress by the end of calendar year 2020. Bratcher Bowman Decl. ¶ 18.

Sixth, "[n]ot later than March 15, 2020, and biennially thereafter, the [ASPR] shall develop and submit to the appropriate committees of Congress a coordinated strategy and accompanying implementation plan for medical countermeasures to address chemical, biological, radiological, and nuclear threats . . . known as the 'Public Health Emergency Medical Countermeasures Enterprise Strategy and Implementation Plan'" (the "Countermeasures SIP"), which shall be made publicly available. 42 U.S.C. § 300hh-10(d)(1). While preparation and publication of the Countermeasures SIP has been slightly delayed as a result of the demand placed on HHS's resources by its need to respond to the COVID-19 pandemic, HHS has prepared a draft of this report and expects to finalize and transmit it to the Secretary for promulgation to Congress by the end of year 2020, at which time it will also be made publicly available. Bratcher-Bowman Decl. ¶ 6. As required by 42 U.S.C. § 300hh-10(d)(2)(H), HHS solicited the formal input of experts as part of the process of preparing this plan. *Id.* ¶ 15. Notably, the delay of this planning document has no implications for the Government's COVID-19 response as it is a future-looking plan, and by statute, pandemic threats are not required to be covered in it; the plan will mention COVID-19 only briefly. *Id.* ¶ 7. Prior Countermeasures SIPs are available online. *Id.*

ASPR also has responsibility for developing and updating not later than March 15 of each year, "a coordinated 5-year budget plan based on the medical countermeasure priorities described in" the Countermeasures SIP. 42 U.S.C. § 300hh-10(b)(7). While previous multi-year budget reports are available online at ASPR's website, this year's budget has been delayed by HHS's focus on the COVID-19 response. *See* Bratcher-Bowman Decl. ¶ 8. In particular, the key

personnel involved in providing data for the report are currently guiding the agency's financial management of the COVID-19 response. *Id.* Additionally, the multi-year budget's purpose is to forecast future resource needs for maintaining the country's preparedness capabilities, and the ongoing demands of the COVID-19 response have introduced a significant amount of uncertainty with regard to the financial resources agencies will need in future years. *Id.* Given that the multi-year budget describes plans for medical countermeasure development broadly, the Government is not required to include new or specific areas of focus such as COVID-19. *Id.*

3. Other At-Issue Obligations Under the PHS Act

A number of HHS's other statutory reporting duties are at issue in this case. The PHS Act empowers the Secretary to award cooperative agreements and grants to entities in order to meet certain of the preparedness goals of the National Health Security Strategy ("NHSS"). 42 U.S.C. §§ 247d-3a(a), (b), (d); *id.* §§ 247d-3b(a), (c); *id.* § 300hh-1(b) (describing NHSS preparedness goals). Entities awarded funds are required to submit annual reports on their activities to the Secretary, and the Secretary "shall compile the data submitted under this section and make such data available in a timely manner on an appropriate Internet website" available to the public. *Id.* § 247d-3a(i), (j); *id.* § 247d-3b(i)(1). This obligation has been satisfied as awardees of the Hospital Preparedness Program ("HPP") have submitted annual progress reports, annual performance measure reports, and grants management federal financial reports. Bratcher-Bowman Decl. ¶ 4. Fact sheets containing information about each HPP awardee through fiscal year 2018 are publicly available on ASPR's website.[1] *Id.* Additionally, awardees of CDC's

[1] In 2020, ASPR's work with each awardee to complete updated fact sheets for FY2019 was temporarily suspended because the awardees were forced to redirect resources to COVID-19 response activities. Bratcher-Bowman Decl. ¶ 5. Fact sheets for FY2019 would not have addressed COVID-19 response activities. *Id.* ASPR plans to develop fact sheets early in 2021 for FY2020 with updated funding data, health care coalition membership data, and recipient

Public Health Emergency Preparedness ("PHEP") cooperative agreements have been providing the annual reports to CDC as required under 42 U.S.C. § 247d-3a(i) pursuant to the notice of funding opportunity requirements. Arias Decl. ¶ 9. CDC has publicly posted the information concerning PHEP awardees' submissions through 2018 and current information on awardee funding on its website. *Id.*

The PHS Act, as amended by PAHPAIA, requires the Secretary, who has responsibilities related to the nation's stockpile of drugs, vaccines, and related supplies (the "Strategic National Stockpile"), to "conduct an annual threat-based review . . . of the contents of the stockpile" and submit it on March 15 of each year to the relevant committees of Congress. *Id.* § 247d-6b(a)(1)-(2). Publication of the annual Threat-Based Review of the SNS for 2020 has been slightly delayed as a result of significant demand placed upon the agency's resources in responding to the COVID-19 pandemic. Bratcher-Bowman Decl. ¶ 13. A draft of the report is awaiting reasonable deliberation and review by key personnel who are also responsible for guiding the agency's COVID-19 response. *Id.* HHS anticipates that the report will be submitted to Congress by the end of 2020 or the first quarter of 2021. *Id.* The Threat-Based Review of the SNS has no bearing on the Government's COVID-19 response, as the review is a routine, five-year projection of budgetary priorities for expenditures to maintain current or acquire future medical countermeasure for all threats. *Id.* This deliverable is "for official use only" and is not made

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highlights. *Id.* Also, in 2021, the National Healthcare Preparedness Programs branch of ASPR is planning to publish an annual report that will provide recent data and an overview of accomplishments from CY2020 across its health care readiness portfolio, including the Hospital Preparedness Program. *Id.* HPP awardees of COVID-19 emergency supplemental funding and administrative supplements to the existing HPP awards in 2020 will not report COVID-19 performance measures data until late 2021. *Id.*

publicly available (nor required to be made public) as it contains vulnerability and capability information that if exposed could jeopardize national planning and capabilities. *Id.*

Additionally, the Homeland Security Secretary, in consultation with the Secretary and others, must "assess current and emerging threats of chemical, biological, radiological, and nuclear agents; and determine which of such agents present a material threat against the United States population sufficient to affect national security" and "shall send to Congress, on an annual basis, all current material threat determinations and shall promptly notify the" relevant congressional committees when they have made a determination related to such a threat (the "Material Threat Determination Report" or "MTD Report"). 42 U.S.C. § 247d-6b(c)(2). HHS has prepared a draft of the 2020 MTD Report and expects that it will be provided to Congress by the end of 2020. Bratcher-Bowman Decl. ¶ 9. This report is considered extremely sensitive by HHS and the U.S. Department of Homeland Security ("DHS") and has been deemed "for official use only" and is not made publicly available. *Id.*

Relatedly, the Secretary is required by the Act to "institute a process for making publicly available the results of assessments" of material threats "while withholding such information as (i) would, in the judgment of the Secretary, tend to reveal public health vulnerabilities; or (ii) would otherwise be exempt from disclosure under section 552 of Title 5." *Id.* § 247d-6b(c)(3). Ongoing assessments have been made and continue to be made on an as-needed basis and are typically deemed "for official use only" or classified and are not publicly available (nor required to be made public).[2] Bratcher-Bowman Decl. ¶ 11; *see also id.* ¶ 10 (some information made public).

[2] In a footnote in Plaintiffs' brief (but not in their Complaint), they allege that the Secretary has "not given notice to Congress of his use of various emergency powers and funds to address the pandemic, *see id.* §§ 247d-4a, 247d-6b(c)(6), and 247d(e)(4)." PI Mem. 22 n.9.

In addition, under the PHS Act, the Secretary is required to submit various reports, including annual reports on health care costs, health resources, the utilization of health resources, and the health of the nation's people to the President and Congress. 42 U.S.C. § 242m(a)(1). The National Center for Healthcare Statistics ("NCHS") within CDC fulfills these statutory responsibilities through publication of *Health, United States*, a series of reports on the health status of the nation. Arias Decl. ¶ 10. The 42nd edition the Health, United States report was released on October 30, 2019, and is available online. *Id*. Preparation of the 43rd edition of the report is complete, and the report is in the final stages of review and publication is forthcoming. *Id*. While the report is produced and submitted annually, related health information is available throughout the year on the *Health, United States* website. *Id*. The Secretary is also required to submit a national disease prevention profile to Congress every three years. 42 U.S.C. § 242p. HHS addresses this directive holistically through its *Healthy People* initiatives. Arias Decl. ¶ 11. HHS provides online access to the *Healthy People 2020* databases, which integrate tracking data from many diverse data systems into an into an interactive data tool. *Id*. In addition, *Healthy People 2020 End of Decade Summary* is being finalized. *Id.*

The Secretary is also required to submit biennial reports to Congress "evaluating the extent to which activities carried out [by HHS's Office of Minority Health ("OMH")] have been effective in improving the health of racial and ethnic minority groups." *Id.* § 300u-6(f)(1). Some members of Congress have recently inquired about the status of the 2017 and 2019 HHS Reports

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CDC has activated the Infectious Diseases Rapid Response Reserve Fund and provided the required notifications to Congress as directed." Arias Decl. ¶ 12. No determination has been made regarding the sufficiency or selection of medical countermeasures specific to COVID-19 for expenditure of the Special Reserve Fund under§ 247d-6b(c)(3)-(5), and therefore there is no requirement to satisfy the statutory requirements of § 247d-6b(c)(6). With respect to § 247d(e)(4), HHS has not yet notified Congress of the reassignment requests and renewals made pursuant to this subsection but plans to address that. Bratcher-Bowman Decl. ¶ 12.

to Congress on Minority Health Activities, and HHS has informed them there is a delay in their submission. Declaration of Danny Nguyen ("Nguyen Decl.) ¶ 4. The HHS 2017 Report to Congress on Minority Health Activities (for fiscal years 2015-2016) is undergoing final revisions at OMH and is expected to be submitted to the Office of the Secretary for final clearance by December 31, 2020. *Id.* The 2019 HHS Report to Congress on Minority Health Activities (for fiscal years 2017-2018) is under development. *Id.* The development of the 2021 HHS Report to Congress on Minority Health Activities (for fiscal years 2019-2020) is expected to begin before the end of this calendar year. *Id.* In order to help prevent such delays in the future, HHS has awarded a contract to a company to assist in compiling information for these reports. *Id.* Prior reports are available online. *Id.* The 2017 and 2019 biennial reports would not have had any impact on the federal government's COVID-19 response as they concern pre-pandemic time periods. *Id.* ¶ 5.

Finally, under the PHS Act, the Director of HHS's Agency for Healthcare Research and Quality ("AHRQ") "shall . . . annually submit to the Congress a report regarding prevailing disparities in health care delivery as it relates to racial factors and socioeconomic factors in priority populations," known as the National Healthcare Quality and Disparities Report. 42 U.S.C. § 299a-1(a)(6). AHRQ is on track to publish this year's report by the end of the year. Declaration of Wendy Perry ("Perry Decl.") ¶ 4.

B. The Government's Collection of COVID-19 Data from Hospitals

CDC's National Healthcare Safety Network ("NHSN") was created in 2005 to track and improve patient safety related to healthcare-associated infections, antibiotic resistant infections, and antibiotic use. Declaration of Perryn Ashmore ("Ashmore Decl.") ¶ 5. NHSN is a national surveillance system developed, maintained, and used by CDC, healthcare facilities, and state and local health departments for infection control activities, including healthcare-associated and

antibiotic resistant infection surveillance, health care and clinical quality measurement of those infections, and epidemiological and statistical analysis. *Id.* ¶ 6. Healthcare facilities provide their data through NHSN, and the data are analyzed and used by CDC in fulfilling its statutory responsibilities to prevent healthcare-associated infections. *Id.*

From March until July 15, 2020, NHSN collected data specifically related to COVID-19 cases from 3,500 of the approximately 6,200 hospitals in the United States on a voluntary basis. *Id.* ¶ 9. To do so, CDC created a COVID-19 Patient Impact and Hospital Capacity Module within NHSN and made it available for hospitals to use beginning on March 27, 2020. *Id.* On March 29, 2020, Vice President Pence notified hospital administrators across the country of the module and requested daily data reports on testing, supplies, capacity, utilization, and patient flows in order to facilitate the public health response to COVID-19. *Id.*

On April 10, 2020, Secretary Azar requested that hospital administrators submit hospital capacity data to the Government for the purposes of the emergency response to COVID-19. *Id.* ¶ 10. Secretary Azar described several methods through which hospitals could report these essential data: through HHS TeleTracking (a commercial product HHS now uses for data capture), NHSN, direct submission of data to HHS, or standardized publication on a state health department's website. *Id.* ¶¶ 10-11. Secretary Azar explained that the hospitals could choose any of these submission methods, and they only needed to submit data via one mechanism. *Id.* ¶ 10. The data from these various mechanisms are all aggregated in HHS's data management system, known as HHS Protect. *Id.* HHS Protect collects data from various sources, including TeleTracking, NHSN, and hundreds of other sources that provide daily uploads into it. *Id.* ¶ 12. For example, HHS Protect is currently used by the White House Coronavirus Task Force, the National Response Coordination Center, the Federal Emergency Management Agency, ASPR,

NORTHCOM, Army, the Department of Defense, and the Centers for Medicare & Medicaid Services ("CMS"). Each of these federal entities mentioned above, including CDC and ASPR, has access to the aggregated data in HHS Protect. *Id.*

In addition, beginning in late April 2020, NHSN began to collect COVID-19 resident, staffing, and supply data from nearly all of the approximately 15,400 CMS-certified nursing homes in the country. *Id.* ¶ 14. All nursing homes are required to report this information to NHSN pursuant to a CMS Interim Final Rule released on May 8, 2020, 85 Fed. Reg. 27,550 (May 8, 2020), and compliance is currently near 100 percent, Ashmore Decl. ¶ 14. CDC shares NHSN nursing home data with CMS for public, facility-level posting on CMS' webpage and for use by CMS for enforcement of reporting requirements. *Id.* ¶ 15.

On July 13, 2020, HHS issued updated guidance that stated that as of July 15, 2020, all hospitals that were choosing to submit COVID-19 data should do so through the HHS TeleTracking portal or via their state health department for submission directly to HHS Protect and provided specifications related to the data and its format (the "July 13 Guidance"). *Id.* ¶ 18. The July 13 Guidance also explained that as of July 15, 2020, hospitals should no longer submit COVID-19 capacity, staffing, and supply-related data to CDC's NHSN. *Id.* Hospitals that chose to report COVID-19 data to HHS TeleTracking still submit non-COVID-19 data to NHSN as part of their participation in various CMS payment and quality improvement programs. *Id.*

With TeleTracking as part of the HHS Protect ecosystem, HHS is able to create new data fields and collect data from 6,200 hospitals in the country in one to three days (much faster than NHSN). *Id.* ¶ 17. The ability to collect data in TeleTracking is expected to improve when automated submission capabilities are piloted with certain hospitals. *Id.* TeleTracking is also

designed to ease hospitals' data reporting burden by consolidating the reporting portals and easing reporting functionality. *Id.*

Though CDC will not collect COVID-19 hospital capacity and patient impact data directly, CDC staff have access to this information in HHS Protect. *Id.* ¶ 19. Further, CDC has access to the expanded data sets found within HHS Protect. *Id.* Finally, CDC manages access to CDC-provided data in HHS Protect. *Id.* While hospital capacity and patient impact data are no longer being collected directly by the CDC, the surveillance systems for cases, mortality, nursing homes, studies, and clinical data continue to be led by CDC. *Id.* ¶ 20. The joint analysis of all of this data will remain within the domain of the CDC and the other federal agencies in the COVID-19 response. *Id.* NHSN will continue to collect COVID-19 data from nursing homes and long-term care facilities, leveraging authority from CMS to require reporting from 100 percent of CMS-certified nursing homes across the country. *Id.* ¶ 24.

States, localities, and tribal partners also have access to the same information on their local situation as the federal government. *Id.* ¶ 21. HHS Protect creates a central repository for this data, allowing more collaboration, flexibility, and access for all federal, state, and local personnel responding to the pandemic. *Id.* HHS reports HHS Protect data publicly on HealthData.gov and the HHS Protect Data Hub online. *Id.* ¶ 22.

COVID-19 data reporting only became mandatory for hospitals with CMS's issuance of an Interim Final Rule on September 2, 2020 (the "September Rule"). *Id.* ¶ 23. That rule, among other things, requires hospitals "to report information in accordance with a frequency, and in a standardized format, as specified by the Secretary during the [public health emergency] for COVID-19." CMS, Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and

Regulatory Revisions in Response to the COVID-19 Public Health Emergency, 85 Fed. Reg. 54,820, 54,822 (Sept. 2, 2020); *see* 42 C.F.R. §§ 482.42(e), 485.640(d). The current version of the Secretary's guidance specifying the data, frequency, and format for hospital reporting (which supersedes the July 13 Guidance) was issued on October 6, 2020. Ashmore Decl. ¶ 23.

C. Plaintiffs' Lawsuit

Plaintiffs bring three claims. First, they allege that the Government has failed to satisfy a long list of statutory obligations, Compl. ¶¶ 121-28, and "as a result [has] withheld multiple iterations of various reports and disclosures," which they characterize as "agency action unlawfully withheld or unreasonably delayed" in violation of 5 U.S.C. § 706(1), Compl. ¶¶ 129, 134. As part of the same claim, Plaintiffs allege that the Government has also "failed to satisfy additional statutory duties to provide notice and/or opportunity for comment, information, and participation to the Congress and/or the public," in violation of 5 U.S.C. § 706(2)(D). Compl. ¶¶ 130, 132, 135.

Second, Plaintiffs allege that the decision to direct local hospitals to report COVID-19-related data to the HHS Protect database as of July 15, 2020, Compl. ¶¶ 58-65, was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" in violation of 5 U.S.C. § 706(2)(A), and "violates statutory obligations for public disclosure of federal health data" and thus violates 5 U.S.C. § 706(2)(C) (making unlawful agency action "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right"), Compl. ¶¶ 138-42. Plaintiffs also allege that the July 15, 2020 decision was a "rulemaking" for which the Government denied Plaintiffs notice and comment opportunities they are entitled to under 5 U.S.C. § 553. Compl. ¶ 143, and that the Government "failed to conduct any regulatory flexibility analysis" about how the July 15, 2020 decision would affect small entities in violation of the Regulatory Flexibility Act, 5 U.S.C. §§ 601 *et seq.*, Compl. ¶ 144.

Third, Plaintiffs allege that the violation of duties "enumerated in detail in the First and Second Claims" entitles them to relief under the All Writs Act, 28 U.S.C. § 1651(a) and the Mandamus Act, 28 U.S.C. § 1361. Compl. ¶¶ 149-58.

Plaintiffs request a declaration that the Government has failed to fulfill the enumerated duties and has violated the APA and an injunction compelling the Government to fulfill its duties. *Id.* at 51. In addition, Plaintiffs request "an injunction compelling Defendants to carry out sufficient public health surveillance to ensure they have the data necessary to meet their statutory mandates and future reporting obligations, including their duties to study and mitigate public health risks to racial and ethnic populations experiencing disparate health outcomes from Covid-19"; "an injunction compelling Defendants to reverse the migration of Covid-19 data reporting to HHS Protect, reinstate the NHSN Covid-19 data collection programs, and make all such information publicly available in near real-time"; and "court supervision or a receivership to ensure compliance with the Court's decree." *Id.* at 51-52.

ARGUMENT

I. Legal Standard

The Court should deny Plaintiffs' motion for a preliminary injunction. Preliminary injunctions are "extraordinary and drastic" remedies that should never be "awarded as of right." *Munaf v. Geren*, 553 U.S. 674, 689–90 (2008) (quotation omitted). To obtain the mandatory injunction they seek, Plaintiffs must demonstrate (1) "a strong showing of irreparable harm," (2) a "clear or substantial likelihood of success on the merits," (3) "public interest weighing in favor of granting the injunction," and (4) "that the balance of equities tips in [their] favor." *Yang v. Kosinki*, 960 F.3d 119, 127-28 (2d Cir. 2020) (internal citation omitted). Plaintiffs have not met their burden here.

Additionally, as a general matter, a request for emergency injunctive relief must have the

purpose of preserving the status quo. *See Univ. of Tex. v. Camenisch*, 451 U.S. 390, 395 (1981) ("The purpose of a preliminary injunction is merely to preserve the relative positions of the parties until a trial on the merits can be held"). Courts "proceed with extreme caution when the injunction would alter the status quo." *Paleteria La Michoacana, Inc. v. Productos Lacteos Tocumbo S.A. de C.V.*, 901 F. Supp. 2d 54, 56 n.1 (D.D.C. 2012); *see Tom Doherty Assocs., Inc. v. Saban Entm't, Inc.*, 60 F.3d 27, 34 (2d Cir. 1995). "'The burden is even higher on a party seeking a mandatory preliminary injunction that alters the status quo by commanding some positive act, as opposed to a prohibitory injunction seeking only to maintain the status quo.'" *Westchester Fire Ins. Co. v. DeNovo Constructors, Inc.*, 177 F. Supp. 3d 810, 812 (S.D.N.Y. 2016) (quoting *Cacchillo v. Insmed, Inc.*, 638 F.3d 401, 406 (2d Cir. 2011) (alterations omitted). Further, the APA authorizes courts to grant interim relief, *see* 5 U.S.C. § 705, but that authority "does not confer jurisdiction onto the Court to alter the status quo nor does it allow the Court in issuing interim relief to actually dictate specific terms or conditions to a governmental agency." *Salt Pond Assocs. v. Army Corp of Eng'rs*, 815 F. Supp. 766, 775-76 (D. Del. 1993); *see Comprehensive Cmty. Dev. Corp. v. Sebelius*, No. 12 CIV. 0776 PAE, 2012 WL 738185, at *8 (S.D.N.Y. Mar. 7, 2012) ("Like Federal Rule of Civil Procedure 65, § 705 empowers courts to act to maintain the status quo.").

II. Plaintiffs Are Unlikely to Succeed on Any of Their Claims

A. This Court Lacks Jurisdiction to Grant the Relief Sought Because Plaintiffs Do Not Have Standing for Any of Their Claims

The Court should deny Plaintiffs' motion for a preliminary injunction because Plaintiffs lack standing. Standing is necessary for plaintiffs to establish the existence of an Article III case or controversy, and thus, to invoke the jurisdiction of the federal courts. *See Clapper v. Amnesty*

Int'l USA, 568 U.S. 398, 408-09 (2013). "The law of Article III standing, which is built on separation-of-powers principles, serves to prevent the judicial process from being used to usurp the powers of the political branches." *Clapper*, 568 U.S. at 408. The doctrine of standing requires a plaintiff to establish three elements: (1) a concrete and particularized injury-in-fact, either actual or imminent; (2) a causal connection between the injury and defendants' challenged conduct, such that the injury is "fairly traceable to the challenged action of the defendant"; and (3) a likelihood that the injury suffered will be redressed by a favorable decision. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560-61 (1992). For an organizational plaintiff to establish standing, "the organization itself must meet the same standing test that applies to individuals." *N.Y. Civil Liberties Union v. N.Y.C. Transit Auth.*, 684 F.3d 286, 294 (2d Cir. 2012).

Plaintiffs bear the burden of establishing the required elements of standing. *Lujan*, 504 U.S. at 561. "[A] plaintiff must demonstrate standing separately for each form of relief sought." *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 169, 185 (2000). "At the pleading stage, general factual allegations of injury resulting from the defendant's conduct may suffice," *Lujan*, 504 U.S. at 561, but "a plaintiff cannot rely solely on conclusory allegations of injury," *Baur v. Veneman*, 352 F.3d 625, 637 (2d Cir. 2003); *see also FW/PBS, Inc. v. Dallas*, 493 U.S. 215, 231 (1990). Here, none of the injuries Plaintiffs allege satisfy these requirements.

1. Plaintiffs Have Not Sustained An Injury-In-Fact

Plaintiffs lack standing because they have not sufficiently alleged a concrete and particularized injury. The standing requirement of "injury in fact" requires an allegation that the plaintiff "has sustained or is immediately in danger of sustaining a direct injury as a result of [the challenged] action." *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1552 (2016) (citation and internal quotation marks omitted). The injury or threat of injury must be "concrete and particularized"

and "actual or imminent, not 'conjectural' or 'hypothetical." *Lujan*, 504 U.S. at 560. Thus, an alleged future injury must be "'certainly impending,' *or* there is a 'substantial risk' that the harm will occur." *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 158 (2014) (quoting *Clapper*, 568 U.S. at 409 n.5). "Allegations of possible future injury' are not sufficient." *Clapper*, 568 U.S. at 409 (quoting *Whitmore v. Arkansas*, 495 U.S. 149, 158 (1990)).

a. Plaintiffs Have Not Sustained an Informational Injury

Plaintiffs' vaguely alleged informational injuries do not confer standing. Informational standing recognizes a narrow type of injury in fact—namely, the denial of access to "information which must be publicly disclosed pursuant to a statute." *Fed. Election Comm'n v. Akins*, 524 U.S. 11, 21 (1998); *see Tummino v. Hamburg*, 260 F.R.D. 27, 31 (E.D.N.Y. 2009) (noting that informational standing "has been limited to very specific statutory contexts where a statutory provision has explicitly created a right to information" (quotation marks omitted)). "To carry its burden of demonstrating a sufficiently concrete and particularized informational injury, the plaintiff must show that (1) it has been deprived of information that, on its interpretation, a statute requires the government or a third party to disclose to it, and (2) it suffers, by being denied access to that information, the type of harm Congress sought to prevent by requiring disclosure." *Elec. Privacy Info. Ctr. v. Presidential Advisory Comm'n on Election Integrity*, 878 F.3d 371, 378 (D.C. Cir. 2017) (citation and internal quotation marks omitted); *NRDC v. Dep't of the Interior*, 410 F. Supp. 3d 582, 597 (S.D.N.Y. 2019) (same). Plaintiffs have failed to meet this burden.

Plaintiffs—who describe themselves as a school and its CEO (CIP and Joseph), a non-profit housing organization that also provides healthcare services and its CEO/founder (Housing Works and King), a New York City council member (Levine), and a medical student/public health advocate (Greenberg)—allege injuries that are insufficient to confer standing. Compl.

¶¶ 10, 16-21, 79-116. Plaintiffs allege that they have been harmed by a perceived lack of information resulting from Defendants' allegedly withheld reporting obligations under the PAHPAIA and PHS Act and the reporting of COVID-19 data through the HHS Protect, rather than NHSN, system. Compl. ¶¶ 5-7, 39-48, 58-65, 68-71, 121-31, 139-141, 152; Memorandum of Law in Support of Plaintiffs' Motion for a Preliminary Injunction, Dkt. No. 7 ("PI Mem.") at 21-23, 25-30. They claim that they "would benefit from the information Defendants have withheld" and that the alleged lack of information has inhibited their operation and advocacy efforts and caused them to divert resources with respect to the COVID-19 pandemic. Compl. ¶¶ 86-88, 95-97, 102-05, 115, 133, 145, 153; PI Mem. 11-12, 28-29, 36-37.

i. Plaintiffs Have Not Been Deprived of Information to Which They Are Entitled

Fatal to the vast majority of Plaintiff's alleged informational injuries under PAHPAIA and the PHS Act is the fact that—as even Plaintiffs themselves allege—the relevant statutory provisions require the reports to be provided *to Congress*, rather than to be made publicly available. *See* P.L. 116-22 § 205(c), 133 Stat. 905, 924-25 (2019) (Biological Threat Detection Report); 42 U.S.C. § 247d-4(c)(6) (Biosurveillance SIP); 42 U.S.C. § 242m(a) & (c) (annual reports regarding national health care costs and financing, national health resources, utilization and health resources, and the health of the nation's people); 42 U.S.C. § 242p(a) (national disease prevention data profile); 42 U.S.C. § 247d-4a, 247d-6b(c)(6), and 247d(e)(4) (notice of use of various emergency powers and funds to address pandemic); 42 U.S.C. 247d-6b(c)(2)(C), (3)(A)-(B) (annual reporting of material threat determinations);[3] 42 U.S.C. § 247d-6b(a)(2)

[3] Although as Plaintiffs note, the statute states that "the Secretary shall institute a process for making publicly available the results" of the material threats determination, Compl. ¶¶ 45, 125; 42 U.S.C. § 247d-6b(c)(3)(B)), Plaintiffs neglected to mention that the statute also specifies that the Secretary can withhold information that "tend[s] to reveal public health vulnerabilities"

(annual threat-based review of the strategic national stockpile); P.L. 116-22 § 606, 133 Stat. 905, 959 (report on international cooperation to develop pandemic countermeasures, including vaccines); 42 U.S.C. § 262a(k)(2) (report on biological agents and toxins and their public health countermeasures); P.L. 116-22 § 209, 133 Stat. 905, 929 (report on adequacy of blood supply); 42 U.S.C. § 299a-1(a)(6) (report regarding prevailing disparities in health care delivery as it relates to racial factors and socioeconomic factors in priority populations); 42 U.S.C. § 300u-6(f)(1) (report regarding effectiveness of OMH activities); Compl. ¶¶ 39, 40-41, 45-47, 121-22, 125-27; PI Mem. 22 n.9; Bratcher-Bowman Decl. ¶¶ 9-14, 17-18; Arias Decl. ¶¶ 10-13; Foley Decl. ¶ 4; Perry Decl. ¶ 4; Nguyen Decl. ¶ 4.[4]

With respect to NHSN and HHS Protect, Plaintiffs fail to cite any statutory provision requiring that the data be made available to them (let alone in any specific database or format), and in any event, the data is in fact publicly available and regularly updated on government websites. *See* Ashmore Decl. ¶¶ 7-8, 22. Moreover, none of Plaintiffs is required to report any data through NHSN or HHS TeleTracking; nor have any of Plaintiffs requested or been denied access to either the NHSN, HHS Protect, or HHS's TeleTracking portal. *See* Ashmore Decl. ¶ 25. In fact, Plaintiffs fail to allege that they even use NHSN or HHS Protect data. The fact that some of Plaintiffs' experts or several public sources Plaintiffs cite allegedly prefer NHSN to

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or would otherwise be exempt from disclosure under 5 U.S.C. § 552. DHS and HHS consider all discussions about material threat determinations to be highly sensitive and do not make them public. *See* Bratcher-Bowman Decl. ¶¶ 9-11.

[4] Many of these reports that the relevant statutory provisions require only to be submitted to Congress have nonetheless been made publicly available, or contrary to Plaintiff's contentions, have already been provided to Congress or are not due yet—which is another reason that Plaintiffs have sustained no injury. *See, e.g.*, Arias Decl. ¶¶ 10 (annual reports regarding nation's health resources), 11 (national disease prevention data profile), 12 (notice of emergency powers and funds to address pandemic), 13 (report on biological agents and toxins); Perry Decl. ¶ 4 (prevailing disparities in health care delivery).

HHS Protect does not give rise to any injury to Plaintiffs themselves. *See, e.g.*, Compl. ¶ 62; Declaration of Dr. Micaela Martinez, Dkt. No. 16 ("Martinez Decl.) ¶¶ 18-29. As such, Plaintiffs have made no showing that the use of HHS Protect injures them.

Therefore, with respect to nearly all of the allegedly withheld information, Plaintiffs have failed show an essential element of informational standing—*i.e.*, that they have been deprived of information that a statute requires the government to disclose to them. *Akins*, 524 U.S. at 21; *see also, e.g., W. Virginia Highlands Conservancy v. Johnson*, 540 F. Supp. 2d 125, 143 n.12 (D.D.C. 2008) (no informational injury where statutorily required report was to Congress rather than to the public); *Elec. Privacy Info. Ctr.*, 878 F.3d at 378; *Am. Farm Bureau v. U.S. E.P.A.*, 121 F. Supp. 2d 84, 99 (D.D.C. 2000) (same).

Plaintiffs have also failed to demonstrate an injury-in-fact with respect to their few alleged informational injuries that do require reporting to the public. *See* 42 U.S.C. §§ 247d-3a(i) & (j), 3b(i) (reporting related to entities receiving federal funding for health emergency preparedness); 42 U.S.C. § 300hh-10(d) (Countermeasures SIP); 42 U.S.C. § 300hh-10(b)(7) (five-year budget plan based on Countermeasures SIP); 42 U.S.C. § 247d-4(b)(2)-(3) (adopt, "as necessary," technical and reporting standards for the Biosurveillance Network and make them available on HHS's internet website in a manner that does not compromise national security); Compl. ¶¶ 44, 124; Bratcher-Bowman Decl. ¶¶ 4-8; Arias Decl. ¶¶ 6-7, 9.

Plaintiffs have entirely failed to explain how any delay in the provision of each of these reports to the public led to a concrete, particularized, or imminent injury. *See Lujan*, 504 U.S. at 560. Nor have Plaintiffs shown how allegedly being denied access to each of these reports causes them to suffer the type of harm that Congress sought to prevent by requiring the disclosure. *See Elec. Privacy Info. Ctr.*, 878 F.3d at 378. As discussed above, contrary to Plaintiffs' contentions,

much of this information has been made publicly available, including the reporting related to entities receiving federal funding for health emergency preparedness and some of the technical and reporting standards. Arias Decl. ¶¶ 6-7, 9; Bratcher-Bowman Decl. ¶¶ 4-5. And none of the outstanding reports are directly related to COVID-19—the hook by which Plaintiffs seek to show injury in this case. Bratcher-Bowman Decl. ¶¶ 4-8; Arias Decl. ¶¶ 6-7, 9. For example, although the Government expects the Countermeasures SIP to be published soon, there is no statutory requirement that it address pandemic threats, and it will in fact not focus on COVID-19 response enhancing activities. Bratcher-Bowman Decl. ¶ 6; *see infra* Part II.B. Nor have Plaintiffs explained how any specific report, such as the Countermeasures SIP budget plan, which is also not required to address COVID-19, *see* Bratcher-Bowman Decl. ¶ 8, would be useful to them in their response to COVID-19. Simply put, because Plaintiffs allege injury with respect to their COVID-19 response from a lack of information and the reports that are outstanding do not relate to COVID-19, Plaintiffs have not suffered the type of injury Congress sought to prevent.

ii. Plaintiffs Have Not Diverted Resources or Suffered Any Other Impediment As A Result of An Alleged Lack of Information

Plaintiffs have also failed to show a diversion of resources or other impediment to carrying out their usual activities as a result of a lack of information. *See* Compl. ¶¶ 86-88, 95-97, 102-05, 115, 133, 145, 153. To establish standing based on diversion of resources or impairment of ability to carry out usual activities, a plaintiff show that the defendant's conduct or policy "has impeded, and will continue to impede, the organization's ability to carry out [its] responsibilit[ies]" or compels the organization "to act with a consequent drain on its resources." *See Centro de la Comunidad Hispana de Locust Valley v. Town of Oyster Bay*, 868 F.3d 104, 110 (2d Cir. 2017); *Havens Realty Corp. v. Coleman*, 455 U.S. 363, 379 (1982). An

organization's "mere interest in a problem, no matter how longstanding the interest and no matter how qualified the organization is in evaluating the problem, is not sufficient by itself to render the organization adversely affected" so as to confer standing. *Ctr. for Law & Educ. v. Dep't of Educ.*, 396 F.3d 1152, 1162 n.4 (D.C. Cir. 2005) (internal quotation marks omitted). The diversion-of-resources theory requires that a defendant's actions "divert" the entity's resources away from its "other current activities"—that is, the challenged conduct must make the plaintiff do something different with its resources than it had been doing beforehand, or lost some opportunity to engage in those activities. *Centro de la Comunidad Hispana de Locust Valley*, 868 F.3d at 110-11. There is no showing of "diverted resources that would otherwise have been available for other programming," when the organization was already devoting resources to the same goals. *New York v. DHS*, 969 F.3d 42, 61 (2d Cir. 2020).

Plaintiffs have entirely failed to demonstrate how they meet this standard. As an initial matter, Plaintiffs cannot establish standing by expending resources to counteract a lack of information to which, as discussed above, they have no cognizable interest because "a self-inflicted budgetary choice [] cannot qualify as an injury in fact." *See Elec. Privacy Info. Ctr.*, 878 F.3d at 379 (citation omitted). Moreover, Plaintiffs have not explained what resources were diverted as a result of the Government's actions (and from where) or how their operations were impeded by not having the information in each of the reports or by the use of HHS Protect. Indeed, Plaintiffs admit that they were already devoting resources and actively involved in responding to COVID-19, but imply that they would somehow "divert fewer resources" to responding to COVID-19 or benefit in their response as a result of the additional information. PI Mem. 6-8, 17-18, 36; *see* Compl. ¶¶ 86-88, 95-97, 102-05, 115, 133, 145, 153; Declaration of Leslie-Bernard Joseph, Dkt. No. 9, ¶¶ 10-39; Declaration of Charles King, Dkt. No. 10, ¶¶ 8-57;

Declaration of Mark Levine, Dkt. No. 11, ¶¶ 5-27; Declaration of Alexandra Greenberg, Dkt. No. 12, ¶¶ 12-21. These vague and conclusory allegations present an insufficiently concrete basis on which to confer standing. *See, e.g.*, *Havens*, 455 U.S. at 379 (injury-in-fact would exist if defendants' actions "perceptibly impaired" the organization's activities by causing a "concrete and demonstrable injury to the organization's activities—with the consequent drain on the organization's resources," rather than "simply a setback to the organization's abstract social interests"); *N.A.A.C.P. v. City of Kyle, Tex.*, 626 F.3d 233, 238 (5th Cir. 2010) (finding no injury-in-fact where plaintiffs failed to identify specific projects that had to be put on hold or were curtailed as a result of defendants' actions). Further, to the extent that Plaintiffs argue that a lack of information has hindered their advocacy efforts, this clearly does not confer standing. *See, e.g.*, *Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26, 39-40 (1976) (holding certain organizations, "which described themselves as dedicated to promoting access of the poor to health services, could not establish their standing simply on the basis of that goal"); *Ctr. for Law & Educ.*, 396 F.3d at 1162 n.4 (standing based on mere "injury to [an advocacy group's] advocacy would eviscerate standing doctrine's actual injury requirement") (citing *Sierra Club v. Morton*, 405 U.S. 727, 739-40 (1972)). Therefore, Plaintiffs have failed to establish an injury-in-fact resulting from their alleged informational injuries.

b. Plaintiffs Have Not Sustained A Procedural Injury

Plaintiffs' alleged procedural injuries also do not confer standing. In order for a procedural violation to constitute an injury-in-fact, a plaintiff must show "some concrete interest that is affected by the deprivation." *Spokeo*, 136 S. Ct. at 1549 (plaintiff "could not . . . allege a bare procedural violation, divorced from any concrete harm, and satisfy the injury-in-fact requirement of Article III") (citation and internal quotation marks omitted); *see also Lee v. Bd. of Governors of the Fed. Reserve Sys.*, 118 F.3d 905, 911 (2d Cir. 1997) (the Supreme Court

"expressly has disavowed the argument that a procedural deficiency can satisfy the concrete-injury requirement 'without any showing that the procedural violation endangers a concrete interest of the plaintiff (apart from his interest in having the procedure observed).'") (quoting *Lujan*, 504 U.S. at 573 n.8); *Fla. Audubon Soc'y v. Bentsen*, 94 F.3d 658, 664 (D.C. Cir. 1996) (a "prospective plaintiff must demonstrate that the defendant caused the particularized injury, and not just the alleged procedural violation"). Plaintiffs have not made this showing.

Plaintiffs allege procedural injuries with respect to what they characterize as the Government's "withheld participation duties." Compl. ¶ 8; PI Mem. 13 & n.4. The participation duties that they allege the Government has not timely provided include the convening of a public meeting from federal, state, local and tribal health agencies, public and private sector expertise, and other such stakeholders and representatives, for purposes of discussing and providing input on the potential goals, functions, and uses of a biosurveillance network (42 U.S.C. § 247d-4(c)(5)(B)); the provision of adequate notice of and public comment with respect to technical and reporting standards of federal, state, local, tribal, and private organizations for the data sharing network (5 U.S.C. § 553); the solicitation of formal input of experts and stakeholders in public health emergency countermeasures planning in the Countermeasures SIP process (42 U.S.C. § 300hh-10(d)(2)(H)); and the convening of a meeting with representatives from academic, private, and nonprofit entities and "other stakeholders" on genomic engineering technologies and their role in health security and medical countermeasures development (133 Stat. 905, 958-59). *See* Compl. ¶¶ 39-40, 49, 121, 128, 153. Plaintiffs claim that as a result of these alleged procedural violations they have not been sufficiently represented in the COVID-19 response and that the Government would benefit from their input. Compl. ¶¶ 89, 98, 106, 115; PI Mem. 14-16, 38.

Plaintiffs have sustained no procedural injury. Contrary to their contentions, two of the alleged participation opportunities—the input of experts and stakeholders in public health emergency countermeasures planning in the Countermeasure SIP process and a meeting on genomic engineering technologies—have occurred. *See* Bratcher-Bowman Decl. ¶¶ 15-16. Although there likely will be future discussions regarding genomic engineering technologies, the participants in these discussions would include those who are actively involved in advanced biotechnology work (*see* Bratcher-Bowman Decl. ¶ 16)—an expertise that none of Plaintiffs purport to hold. Moreover, although the formal Biosurveillance Network meeting has not yet occurred, HHS and CDC have otherwise engaged with stakeholders regarding significant biosurveillance activities, have identified and provided public access to a wide range of surveillance data activities related to COVID-19, and have leveraged a number of biosurveillance systems to respond to COVID-19, *see* Arias Decl. ¶¶ 4-5—the lack of a formal meeting is therefore immaterial. Regarding the technical and reporting standards, there is no requirement that these standards be promulgated through a rulemaking process under the APA. *See* Arias Decl. ¶ 8. Therefore, Plaintiffs have failed to even assert a viable procedural violation.

Even if they had asserted a procedural violation, Plaintiffs also have not demonstrated the requisite "concrete interest that is affected" by the alleged procedural violations. *Spokeo*, 136 S. Ct. at 1549. Plaintiffs' vague and conclusory references to the mutual benefit of allowing them to participate in the process and the "risk" of "uninformed" and "detrimental" action that the Government will supposedly take without their participation, Compl. ¶¶ 89, 98, 106, 115; PI Mem. 14-16, 38, are simply not concrete or particularized enough to confer standing. To the extent that Plaintiffs claim these procedural violations caused them to divert resources, that

argument fails for the reasons discussed above. Therefore, Plaintiffs have failed to demonstrate an injury-in-fact from a procedural violation.[5]

2. Plaintiffs Have Not Satisfied the Traceability and Redressability Requirements of Standing

Article III standing also requires showings of traceability and redressability. *See Akins*, 524 U.S. at 25. For plaintiffs to establish standing "there must be causation—a fairly traceable connection between the plaintiff's injury and the complained-of conduct of the defendant." *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 03 (1998). Allegations must provide more than "'unadorned speculation" to "connect their injury to the challenged actions." *CREW v. Trump*, 953 F.3d 178, 191 (2d Cir. 2020) (quoting *Simon*, 426 U.S. at 44-45 (internal quotation marks omitted)). The allegations of fact must plausibly support a "substantial likelihood" that the plaintiff's injury was the consequence of the defendant's allegedly unlawful actions. *Id.* "The greater number of uncertain links in a causal chain, the less likely it is that the entire chain will hold true." *Am. Freedom Law Ctr. v. Obama*, 821 F.3d 44, 49 (D.C. Cir. 2016) (citation omitted).

Plaintiffs have not shown that the Government's actions caused them any injury. Although Plaintiffs vaguely allege that purportedly missing reports somehow impacted their operations or caused them to divert resources with respect to their COVID-19 response, *see supra* at 22, Plaintiffs have entirely failed to explain how any lack of information (or withheld participation opportunities) caused them to divert resources or otherwise impacted the operations. Plaintiffs fail to link the purported absence of any report (or participation

[5] Plaintiffs also do not sufficiently allege associational standing because they do not make "specific allegations that at least one identified member ha[s] suffered or [will] suffer harm." *See Summers v. Earth Island Inst.*, 555 U.S. 488, 498 (2009).

opportunity) to any specific injury. And it is difficult to see how the absence of these reports (including the many that the government has disclosed or to which Plaintiffs are not statutorily entitled) are related to or would harm Plaintiffs' COVID-19 response. *See, e.g.*, Arias Decl. ¶ 14; Bratcher-Bowman Decl. ¶¶ 4-8, 13-14; Nguyen Decl. ¶ 5; Foley Decl. ¶¶ 4-5. Further, the Biosurveillence Network itself is, by statute, not required to be completed until September 2023. *See* 42 U.S.C. §§ 247d-4(b), (c), (g). As such, the network was never supposed to be finished when the COVID-19 pandemic began. Thus, it defies logic that any delay in completion of these mere building blocks in completing the network could have caused any injury to Plaintiffs with respect their COVID-19 response. To the extent Plaintiffs desire access to government resources to help in their COVID-19-related efforts, there are publicly available resources, including data, reports, guidance, and educational materials, that are much more relevant to those efforts than those Plaintiffs claim are missing. *See* Arias Decl. ¶ 14. With respect to their allegations regarding HHS Protect data, Plaintiffs again make only flawed and vague allegations. Plaintiffs fail to even allege that they were users of NHSN, how they relied on NHSN, and how the switch to HHS Protect created data issues for them in a way that injured them by impacting their COVID-19 response. None of Plaintiffs has requested or been denied access to either NHSN, HHS Protect, or TeleTracking portal. *See* Ashmore Decl. ¶ 25.[6]

[6] Insofar as Plaintiffs complain about an alleged failure of the Government to provide reports or data that require information to be provided by states, localities, or other third parties, coupled with the notion that these reports or data will somehow make Plaintiffs respond better to COVID-19, this "highly attenuated chain of possibilities" does not confer standing. *See, e.g.*, Compl. ¶¶ 124, 140; 42 U.S.C. § 247d-3b(i); Bratcher-Bowman Decl. ¶¶ 4-5; Ashmore Decl. ¶¶ 7, 9, 18; *Lujan*, 504 U.S. at 561-62 (where causation "hinge[s] on the response of [a] regulated . . . third party to the government action," and "perhaps on the response of others as well," then standing is "substantially more difficult" to establish (quotation marks omitted)); *Lower E. Side People's Fed. Credit Union v. Trump*, 289 F. Supp. 3d 568, 580 (S.D.N.Y. 2018) ("speculation regarding the future actions of third parties is not sufficient to establish an imminent injury") (citing *Clapper*, 568 U.S. at 410).

Plaintiffs also have not shown that their injuries would be cured by a favorable ruling from this Court. The redressability requirement "lies at the core of the standing doctrine" because "[a]n abstract decision without remedial consequence seems merely advisory, an unnecessary expenditure of judicial resources that burdens the adversary and carries all the traditional risks of making bad law and trespassing on the provinces of the executive and legislature." *E.M. v. New York City Dep't of Educ.*, 758 F.3d 442, 450 (2d Cir. 2014) (citation and internal quotation marks omitted); *see also Hewitt v. Helms*, 482 U.S. 755, 761 (1987). Where a plaintiff requests prospective relief in the form of a declaratory judgment or injunction, the plaintiff must show that "prospective relief will remove the harm" and the plaintiff "personally would benefit in a tangible way from the court's intervention." *Warth v. Seldin*, 422 U.S. 490, 505, 508 (1975). "Relief that does not remedy the injury suffered cannot bootstrap a plaintiff into federal court; that is the very essence of the redressability requirement." *Steel Co.*, 523 U.S. at 107; *see also Simon*, 426 U.S. at 42-43 (finding remedy too speculative where plaintiff merely alleged that a government policy had "encouraged" private action and that a different regulatory requirement would "discourage" the same action).

Plaintiffs ask the Court declare the Government's actions unlawful, and to order an injunction requiring the fulfillment of the above-described reporting and participation duties and compelling Defendants to reverse the migration of COVID-19 data reporting to HHS Protect, reinstate NHSN data collection programs, make such information publicly available, and perform regulatory flexibility analyses with respect to all future rulemaking related to COVID-19 data collection. Compl. Prayer for Relief; Proposed Order to Show Cause for Prelim. Inj., Dkt. No. 6. Aside from the fact that Plaintiffs are not entitled to any relief, the relief Plaintiffs seek would not redress any of their alleged injuries. As an initial matter, much of the relief Plaintiffs

request is moot because the Government has already disclosed many of the reports and provided many of the participation opportunities that Plaintiffs allege were withheld. *See supra* at 24-25, 29. Other reports are, by statute, only required to be provided to Congress, not to the public. *See supra* at 22-23. Still other reports and participation opportunities would not aid in Plaintiffs' COVID-19 response. *See supra* at 25, 29-30. Further, Plaintiffs' request to revert back to NHSN from HHS Protect would not only not redress any injury, it could cause further injury given that HHS Protect provides a more efficient repository for the data. *See* Ashmore Decl. ¶¶ 12-13, 16-23. Finally, none of Plaintiffs' requested relief would redress their alleged injuries because they have not shown that the Government's actions caused them any concrete injuries. *See supra* at 25-27, 29-31. Therefore, because Plaintiffs have no injuries that could be redressed, they have failed to establish Article III standing.

3. Plaintiffs Are Not Within the Zone of Interests Protected by PAHPAIA, the PHS Act, or the September Rule

Plaintiffs' allegations are also not subject to judicial review because they lack statutory standing under the "zone of interests" test. Whether a plaintiff comes within the "zone of interests" is an issue that requires the Court "to determine, using traditional tools of statutory interpretation, whether a legislatively conferred cause of action encompasses a particular plaintiff's claim." *Lexmark Int'l, Inc. v. Static Control Components, Inc*., 572 U.S. 118, 127 (2014). In cases where the plaintiff is not a subject of contested regulatory action, the zone of interests test does not permit review if the plaintiff's interests are so marginally related to or inconsistent with purposes implicit in statute that it cannot reasonably be assumed that Congress intended to permit suit. *See Clarke v. Sec. Industry Ass'n*, 479 U.S. 388, 399-400 (1987). In APA cases, the zone-of-interests inquiry turns on "the particular provision of law upon which the plaintiff relies," rather than the "the overall purpose of the Act in question." *Bennett v. Spear*,

520 U.S. 154, 175-76 (1997). Congress's purposes in enacting the overall statutory scheme are relevant only insofar as they may help reveal its purpose in enacting the particular provision. *See Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1074-75 (D.C. Cir. 1998). When it comes to informational injuries, they "can surmount the zone of interests threshold only in very special statutory contexts." *Animal Legal Def. Fund, Inc. v. Espy*, 23 F.3d 496, 502 (D.C. Cir. 1994).

Plaintiffs' claims are not within the zone of interests established by PAHPAIA or the provisions of the PHS Act that they cite. The relevant portions of those statutes do not regulate actions on their part, and their interests are only marginally related to the purpose of the statute, which is to enhance the authorities of the Secretary, ASPR, and the Director of the CDC to prepare for and respond to public health emergencies. *See* 133 Stat. 905. Plaintiffs are also not federal, state, or local public health officials, laboratories, hospitals, poison control centers, or even primarily health-related facilities that would be part of the Biosurveillance Network. 42 U.S.C. §§ 247d-4(b), (c), (g). Nor would Plaintiffs—a school and its CEO, a housing organization and its CEO/founder, a NYC council member, and a medical student and self-described public health advocate—add value to, or likely benefit from in responding to the COVID-19 pandemic, the technical building blocks of the Biosurveillance Network under the PAHPAIA, a network which is not set to be completed until September 2023. *See supra* at 4, 31. Given that the network will not, by statute, be established for several years, Plaintiffs' alleged injury with respect to their COVID-19 response does not fall within the statute's zone of interests. Indeed, many of the reports about which they complain are only statutorily required to be submitted to Congress, rather than to the general public. Plaintiffs also have not shown how they have used the information that *is* available under this Act in their COVID-19 response.

With respect to Plaintiffs' complaints about HHS Protect, they are not within the zone of interests established by the September Rule, which requires *hospitals*—not Plaintiffs—to report COVID-19 data. *See* Ashmore Decl. ¶ 23. Plaintiffs do not even use the NHSN, HHS Protect, or the HHS Teletracking portal and have not shown how they rely on the publicly available data to respond to COVID-19. *See id*. ¶ 25.

In sum, for the reasons discussed in this section, Plaintiffs lack both Article III and statutory standing.

B. Plaintiffs Are Unlikely to Succeed on Their Claim that the Government Has Unlawfully Withheld or Unreasonably Delayed Action in Violation of Section 706(1) of the APA

Even if they did have standing, Plaintiffs are not likely to prevail on their claim alleging that the Government has failed to meet various statutory duties. As an initial matter, Section 706(1) of the APA "empowers a court only to compel an agency to perform a ministerial or non-discretionary act, or to take action upon a matter, without directing how it shall act." *Norton v. So. Utah Wilderness Alliance*, 542 U.S. 55, 64 (2004) ("*SUWA*") (internal quotation marks omitted). "[A] claim under § 706(1) can proceed only where a plaintiff asserts that an agency failed to take a *discrete* agency action that it is *required to take*." *Id.* at 63-64. ("[T]he only agency action that can be compelled under the APA is action legally required." (emphasis in original)). Thus, Plaintiffs' request, without reference to a specific legal authority, that the Court order the Government "to carry out sufficient public health surveillance to ensure they have the data necessary to meet their statutory mandates and future reporting obligations," Compl. at 51, should be dismissed as a "broad programmatic attack" that is not actionable under the APA. *See SUWA*, 542 U.S. at 64; *Del Monte Fresh Produce N.A., Inc. v. United States*, 706 F. Supp. 2d 116, 119 (D.D.C. 2010) ("broad review of agency operations is just the sort of 'entanglement' in

daily management of the agency's business that the Supreme Court has instructed is inappropriate.")

As to the discrete legal duties that Plaintiffs have identified, as discussed above, the Government has already complied with many of them. Specifically, the Government has:

- adopted and published some of the technical and reporting standards for the Biosurveillance Network as required by 42 U.S.C. § 247d-4(b)(3)(A); Arias Decl. ¶¶ 6-7;
- convened an initial meeting to discuss the potential role advancements in genomic engineering technologies may have in advancing national health security as required by 133 Stat. 905, 958-59; Bratcher-Bowman Decl. ¶ 16;
- compiled and published fact sheets containing information about each HPP awardee through fiscal year 2018 as required by 42 U.S.C. §§ 247d-3a(i), (j), 247d-3b(i)(1); Bratcher-Bowman Decl. ¶ 4;
- compiled and published information concerning PHEP awardees' submissions through 2018 and current information on PHEP awardee funding as required by 42 U.S.C. §§ 247d-3a(i), (j), 247d-3b(i)(1); Arias Decl. ¶ 9;
- made ongoing assessments of material threats as required by 42 U.S.C. § 247d-6b(c)(3); Bratcher-Bowman Decl. ¶ 11; and
- published the 42nd edition of the *Health, United States* report, and the 2020 *Healthy People* databases to comply with 42 U.S.C. §§ 242m(a)(1), 242p; Arias Decl. ¶¶ 10-11;

And the Government is currently on schedule to complete other of its obligations on time: the submission of the MTD Report required by 42 U.S.C. § 247d-6b(c)(2), Bratcher-Bowman Decl. ¶ 8, and the publication of this year's National Healthcare Quality and Disparities Report as required by 42 U.S.C. § 299a-1(a)(6), Perry Decl. ¶ 4. Plaintiffs' claims with respect to these obligations, which the Government has already met or for which the deadline has not passed are not viable.

As for the deadlines that the Government has missed, most are for reports HHS expects to submit to Congress within a few weeks or months. As discussed above, HHS expects to submit

this year's Countermeasures SIP to Congress by the end of 2020, Bratcher-Bowman Decl. ¶ 6; to submit the results of the annual threat-based review of the contents of the Strategic National Stockpile to Congress by the end of 2020 or the first quarter of 2021, *id.* ¶ 13; to submit the report related to the national blood supply to Congress in January 2021, Foley Decl. ¶ 4; to submit the Vaccine Development Report to Congress by the end of 2020, Bratcher-Bowman Decl. ¶ 14; and to submit the FESAP report by the end of 2020, Bratcher-Bowman Decl. ¶ 18.

Although the Government has missed some of its targets, the Court should not issue an injunction in this case for two reasons. First, unless Congress has indicated otherwise—which, in this case, it has not—congressional reporting requirements are not susceptible to judicial review. *NRDC v. Hodel*, 865 F.2d 288, 317-19 & n.31 (D.C. Cir. 1988); *see also Greenpeace USA v. Stone*, 748 F. Supp. 749, 765 (D. Haw. 1990) ("There is no legal precedent which would allow plaintiffs a private right of action to enforce a reporting provision of a Congressional appropriations bill."). That is because "[t]he function of judicial review of agency action—to check agency exercise of delegated power—has no place where a report is simply a management tool employed by Congress for its own purposes." *NRDC v. Lujan*, 768 F. Supp. 870, 882 (D.D.C. 1991) (internal quotation marks omitted). Plaintiffs fail to show that any of the outstanding reports were "intended as anything more than a vehicle to inform Congress," and thus "[i]t is for Congress, not the courts, to determine [whether the] statutory requirements it enacted" were met. *Id.*

Second, the Court should exercise its discretion and decline to order such extraordinary relief. A statutory violation does not always lead to the automatic issuance of an injunction and in "exercising their sound discretion, courts of equity should pay particular regard for the public consequences in employing the extraordinary remedy of injunction." *Weinberger v. Romero-*

Barcelo, 456 U.S. 305, 313 (1982)); *see also In re Barr Labs., Inc.* 930 F.2d 72, 76 (D.C. Cir. 1991) ("The agency is in a unique—and authoritative—position to view its projects as a whole, estimate the prospects for each, and allocate its resources in the optimal way."). The public consequences of an injunction counsel against issuing an injunction in this case. HHS has a leading role in the federal response to the COVID-19 crisis and needs the flexibility to exercise discretion over the management of its resources during this pandemic. While Plaintiffs have attempted to connect the outstanding reporting obligations to the COVID-19 crisis, based on their timing and/or their subject matter, they fail to show how any of them has a direct bearing on the Government's COVID-19 response. Notably, for several of the reports, the deadlines at issue were missed in large part because HHS diverted resources away from those non-COVID-19-related tasks to more pressing COVID-19 response work. *See* Bratcher-Bowman Decl. ¶ 6 (Countermeasures SIP); *id.* ¶ 13 (SNS threat-based review); *id.* ¶ 14 (Vaccine Development Report); *id.* ¶ 18 (FESAP report). Issuing an injunction would have the perverse effect of requiring HHS to reallocate resources to expediting these reports, potentially at the expense of the agency's more urgent COVID-19 work. Given these undesirable "public consequences," the Court should decline to issue an injunction. *See Weinberger*, 456 U.S. at 313 (1982).

C. Plaintiffs Are Unlikely to Succeed on Their Claim That the Government's Use of HHS Protect Violates Section 706(2) of the APA

Plaintiffs will also not prevail on their claim that the July 13 Guidance's direction to hospitals to report data to the HHS Protect system instead of NHSN violates Section 706(2) of the APA. Compl. ¶¶ 138-42; PI Mem. 23-30. Plaintiffs argue that this decision was arbitrary and capricious because the stated purpose of the system change does not match the consequences and also allege that the July 13 Guidance violates unspecified "statutory obligations for public disclosure of federal health data." Compl. ¶ 142.

Plaintiffs will not succeed on this claim for several reasons. First, the July 13 Guidance is a set of interim guidelines with no legal effect, not a final agency action reviewable under the APA. Second, the Government's decisions to request that hospitals report COVID-19 data to a specific portal (and later to make that reporting mandatory with the September Rule) are matters committed to agency discretion that cannot be reviewed under the APA. Third, the agency's decision to direct hospitals to provide COVID-19-related data to HHS Protect instead of NHSN was neither arbitrary nor capricious, but instead was a reasonable decision entitled to substantial deference.

1. The July 13 Guidance Is Not a Final Agency Action

Under APA section 704, judicial review is limited to "final agency action[s]." 5 U.S.C. § 704. In *Bennett v. Spear*, the Supreme Court established a two-part test for determining finality. 520 U.S. 154 (1997). It held that in order to be "final," the action (1) "must mark the 'consummation' of the agency's decisionmaking process" and not be "merely tentative or interlocutory," and (2) "must be one by which 'rights or obligations have been determined,' or from which 'legal consequences will flow.'" *Id.* at 178 (citations omitted). Both prongs "must be satisfied independently for agency action to be final," and "deficiency in either is sufficient to deprive [plaintiff] of a cause of action under the APA." *Soundboard Ass'n v. FTC*, 888 F.3d 1261, 1267 (D.C. Cir. 2018), *cert. denied sub nom. Soundboard Ass'n v. FTC*, 139 S. Ct. 1544 (2019). Plaintiffs bear the burden of identifying with specificity the discrete final agency action that they challenge. *See Elk Run Coal Co. v. U.S. Dep't of Labor*, 804 F. Supp. 2d 8, 31 (D.D.C. 2011) (dismissing APA claims because plaintiff failed to "identify any discrete, final agency actions that this Court can review"); *see also Colo. Farm Bureau Fed'n v. U.S. Forest Serv.*, 220

F.3d 1171, 1173 (10th Cir. 2000) ("Plaintiffs have the burden of identifying specific federal conduct and explaining how it is 'final agency action' within the meaning of section 551(13).").

The only agency action Plaintiffs challenge is HHS's publication of the July 13 Guidance. Compl. ¶¶ 58-65; PI Mem. 25 (citing Declaration of Kahlil Williams ("Williams Decl.") Ex. C). But the July 13 Guidance is not final agency action and is not reviewable under the APA because it fails both prongs of the *Bennett v. Spear* test.

First, the July 13 Guidance does not mark the consummation of any federal agency's decision-making process. Rather, as the guidance explains on the first page, it is intended to guide and assist hospitals and other entities in their ongoing, and evolving, efforts to report COVID-19 data to the federal government: "This document details the Federal Government's data needs, explains the division of reporting responsibility between hospitals and states, and provides clear, flexible options for the timely delivery of this critical information." Williams Decl. Ex. C at 1. Additionally, this guidance has since been revised, *see* Ashmore Decl. ¶ 23, as Plaintiffs discuss in their papers. *See* PI Mem. 29 & Williams Decl. Ex. N. Thus, the July 13 Guidance was "tentative or interlocutory."

Second, the July 13 Guidance does not determine the rights or obligations of any party and it has no legal consequences. Plaintiffs argue that "[t]he shift to [HHS] TeleTracking and HHS Protect is a final agency action" because it "*requires* hospitals and state health agencies report Covid-19 data to the TeleTracking and HHS Protect systems and *prohibits* hospitals' use of the NHSN system for Covid-19 data." PI Mem. 25 (emphasis original). Plaintiffs are wrong. The July 13 Guidance merely provided the guidelines applicable at the time for hospitals choosing to voluntarily report COVID-19 data to the Government; it created no obligation that they do so. *See* Ashmore Decl. ¶¶ 9, 23. As COVID-19 data reporting was not required of

hospitals, only approximately 3,500 of the more than 6,000 hospitals in the U.S. reported their data to NHSN. *Id.* ¶ 9. To reach universal COVID-19 reporting by hospitals, the Secretary made it a mandatory condition of participating in Medicare and Medicaid through the September Rule.[7] 85 Fed. Reg. 54,820, 54,822, 54,872-73 (Sept. 2, 2020) (adding 42 C.F.R. §§ 482.42(e), 485.640(d)). It is that rule, not the July 13 Guidance, that established hospitals' rights and obligations. *See Golden & Zimmerman, LLC v. Domenech*, 599 F.3d 426, 432-33 (4th Cir. 2010) (agency reference guide FAQs whose "publication did not itself alter the legal landscape" and are "simply informational" as "legal consequences do not emanate from [the FAQs] but from the Gun Control Act and its implementing regulations.").

As the July 13 Guidance satisfied neither prong of the *Bennett v. Spear* test, it is not a final agency action that can be reviewed under the APA and Plaintiffs' Section 706(2) claim will not prevail for that reason alone.

2. Requiring Hospitals to Report COVID-19 Data Is a Matter Committed to Agency Discretion That Is Not Reviewable

The Government's decision to direct hospitals to report COVID-19 data to HHS Protect is not reviewable for a second reason—it is a matter committed to agency discretion. While the APA establishes a waiver of sovereign immunity and a cause of action for injunctive relief for parties adversely affected by either agency action or agency failure to act, 5 U.S.C. §§ 702, 706(1)-(2), the waiver of sovereign immunity is limited. It does not apply in circumstances

[7] Plaintiffs allege that the July 13 Guidance's direction that hospitals provide data for use in HHS Protect was a "rulemaking" for which the Government denied Plaintiffs notice and comment opportunities to which they are entitled under 5 U.S.C. § 553. Compl. ¶ 143, and that the Government "failed to conduct any regulatory flexibility analysis" about this decision in violation of the Regulatory Flexibility Act, Compl. ¶ 144. As discussed above, the July 13 Guidance merely provides guidelines that carry no legal force and thus is not a legislative rule within the meaning of the APA. *See* 5 U.S.C. § 553. Additionally, HHS followed the proper

where "statutes preclude judicial review," 5 U.S.C. § 701(a)(1), or "agency action is committed to agency discretion by law," *id.* § 701(a)(2).

In *Heckler v. Chaney*, the Supreme Court articulated the fundamental inquiry for the application of section 701(a)(2):

> [E]ven where Congress has not affirmatively precluded review, review is not to be had if *the statute is drawn so that a court would have no meaningful standard against which to judge the agency's exercise of discretion*. In such a case, the statute ("law") can be taken to have "committed" the decisionmaking to the agency's judgment absolutely.

470 U.S. 821, 830 (1985) (emphasis added); *see also Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 410 (1971) (section 701(a)(2) applies "where 'statutes are drawn in such broad terms that in a given case there is no law to apply'") (quoting S. Rep. No. 79-752, at 26 (1945)), *abrogated on other grounds by Califano v. Sanders*, 430 U.S. 99 (1977). Under *Heckler*, the starting point of any analysis under section 701(a)(2) is whether there is a "meaningful standard" provided in the governing statute. *Lunney v. United States*, 319 F.3d 550, 558 (2d Cir. 2003); *see also Webster v. Doe*, 486 U.S. 592, 600 (1988) (application of section 701(a)(2) "requires careful examination of the statute on which the claim of agency illegality is based").

Where the statute does not provide any judicially manageable standard, "regulations promulgated by an administrative agency in carrying out its statutory mandate can provide standards for judicial review." *Ctr. for Auto Safety v. Dole*, 846 F.2d 1532, 1534 (D.C. Cir. 1988) (per curiam). However, "general statements of policy," 5 U.S.C. § 553(b)(3)(A), which are prospective and do not grant rights or impose obligations, are not treated as binding norms for purposes of identifying "law to apply" in the section 701(a)(2) context. *Padula v. Webster*, 822 F.2d 97, 100 (D.C. Cir. 1987) (citation omitted).

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notice and comment procedures and conducted a regulatory flexibility analysis with respect to

No review is possible where the relevant statute is so vague and broadly drawn that it does not provide a reviewing court any criteria for evaluating the agency's exercise of its discretion. *See Heckler*, 470 U.S. at 830; *see also, e.g.*, *Webster*, 486 U.S. at 600 (no criteria provided to evaluate exercise of authority to remove employees whenever the "Director shall *deem* such termination necessary or advisable in the interests of the United States") (citation omitted); *Steenholdt v. FAA*, 314 F.3d 633, 638 (D.C. Cir. 2003) (power to rescind examiner's license "at any time for any reason the Administrator considers appropriate" is not reviewable) (citation omitted); *Claybrook v. Slater*, 111 F.3d 904 (D.C. Cir. 1997) (agency official's power to adjourn an advisory committee meeting for a reason "in the public interest" is not reviewable).

Additionally, review is not permitted where the agency decision "requires complicated balancing of a number of factors which are peculiarly within its expertise," including what "best fits the agency's overall policies." *Lincoln v. Vigil*, 508 U.S. 182, 191, 193 (1993) (quoting *Heckler*, 470 U.S. at 831); *see, e.g.*, *Interstate Commerce Comm'n v. Bhd. of Locomotive Eng'rs*, 482 U.S. 270, 282 (1987) (agency's refusal to reconsider a prior decision based on an alleged "material error" unreviewable due to the "impossibility of devising an adequate standard of review for such agency action"); *Nat'l Fed'n of Fed. Emps. v. United States*, 905 F.2d 400, 405-06 (D.C. Cir. 1990) (no review where statute "sets forth nine specific criteria to be considered in making base closing decisions").

Plaintiffs have failed to identify a judicially manageable standard—or even an applicable statute—to guide the review of HHS's decision. *See* PI Mem. 23-30. And indeed, there is no "meaningful standard" that applies here. The recently issued regulations that made hospitals' COVID-19 data reporting mandatory were promulgated pursuant to the Secretary's broad

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the September Rule. *See* 85 Fed. Reg. 54,853-54, 54,858, 54,863.

authority under the Social Security Act. That statute authorizes the Secretary to prescribe such regulations "as may be necessary to carry out the administration of the insurance programs under this subchapter," 42 U.S.C. § 1395hh(a)(1), and "as may be necessary to the efficient administration of the functions with which [the Secretary] is charged under this chapter," 42 U.S.C. § 1302(a). *See* 42 C.F.R. §§ 482.42(e), 485.640(d); *see also Trustees of Masonic Hall & Asylum Fund v. Leavitt*, No. 5:84-CV-991 (HGM), 2006 WL 1686405, at *9 (N.D.N.Y. June 7, 2006) ("The phrase 'as may be necessary' [in 42 U.S.C. § 1302(a)] strongly suggests that Congress intended to commit such matters to the Secretary's discretion . . . .").

This is the paradigmatic example of a situation in which the applicable "statutes are drawn in such broad terms that in a given case there is no law to apply." *See Citizens to Pres. Overton Park*, 401 U.S. at 410. The administration of Medicare and Medicaid—including by requiring data reporting as a condition of participation in those programs—is left to the Secretary's discretion. Therefore, the Secretary's decisions as to what data to collect for use by CDC and other federal decision-makers and how to collect it are not judicially reviewable. Nor should such decisions be reviewable as they "involve[] a complicated balancing of a number of factors which are peculiarly within [the agency's] expertise," including what "best fits the agency's overall policies." *Lincoln*, 508 U.S. at 191, 193; *see* Ashmore Decl. ¶¶ 13, 16-17.

3. The Decision to Use HHS Protect Was Not Arbitrary nor Capricious

Even if the Court finds that July 13 Guidance is reviewable, Plaintiffs will not prevail on their Section 706(2) claim because the Government acted reasonably in directing hospitals to submit COVID-19 data to HHS TeleTracking and HHS Protect rather than to NHSN and in making the submission of such data mandatory.

As relevant here, a court should uphold an agency decision unless it is, among other things, "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law[.]"

5 U.S.C. § 706(2)(A). Under the arbitrary and capricious standard, the agency's decision is presumed valid, and a court reviews only whether that decision "was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Citizens to Preserve Overton Park*, 401 U.S. at 416. An agency's decision may be deemed arbitrary and capricious only in circumstances where the agency "has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency," or its decision "is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). Under this highly deferential standard, the court may not "substitute its judgment for that of the agency." *Id.*

Plaintiffs' unfounded allegations do not demonstrate that HHS has acted unreasonably.[8] Plaintiffs argue that the decision to change data systems was arbitrary and capricious because the stated purposes of that change do not match its consequences. Specifically, Plaintiffs (none of whom are hospitals) allege that while the change was designed to streamline reporting, it actually "burdens hospitals' reporting efforts." PI Mem. 25-26. Plaintiffs also allege that as a result of the system change "less information is available and updates are posted less frequently." *Id.* at 27. Plaintiffs further allege that "there is no evidence that the government considered reliance interests in the CDC's longstanding NHSN reporting system." *Id.* Finally, Plaintiffs speculate

[8] When evaluating claims brought pursuant to the APA, a court reviews an agency decision based on the administrative record. *Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 744 (1985) (citing *Citizens to Preserve Overton Park*, 401 U.S. at 420). The Government has submitted the Ashmore Declaration in order to provide the Court with information that may be useful for deciding Plaintiffs' request for preliminary relief. However, this declaration is not part of the administrative record, which has not yet been compiled.

that the "real reason for the shift was to take data reporting from the public health experts at the CDC and place it in a system" over which "the White House and political appointees had more control." *Id.* at 29.

The Preamble to the September Rule explains the agency's rationale for requiring hospital reporting of COVID-19 data and requiring it in a standardized format. The Secretary determined that universal reporting by hospitals (as opposed to partial reporting on a voluntary basis) "will be an important tool for supporting surveillance of COVID-19 and for future planning to prevent the spread of the virus." 85 Fed Reg. 54,825. Further, the Secretary sought to balance the need for timely and continued reporting and "the crucial need for data reporting options that will help eliminate the duplicative and sometimes competing reporting requests that continue to place a significant burden on hospitals." *Id.* Thus, "the new reporting requirements that will be specified by the Secretary, . . . include reporting channel options to make submission of data as user-friendly as possible to reduce the strain and burden hospitals [] are currently experiencing as they face data requests from a multitude of federal, state, local, and private entities" including by requiring reporting "in a standardized format specified by the Secretary," referring to the July 13 Guidance and subsequent superseding versions of it. *Id.*

The Government's decision to use TeleTracking and HHS Protect was a reasonable one based on the need for a modern system that could adapt quickly to the Government's needs. As has been explained publicly, *see* Williams Decl. Ex. D, and as HHS's Acting Chief Information Officer explains here, the use of the legacy NHSN system for the collection of COVID-19 data presented challenges because that system was less able to allow the Government to make rapid changes or additions to the system's data elements. Ashmore Decl. ¶¶ 16-17. Further, by incorporating COVID-19 data in the HHS Protect ecosystem, HHS was able create a single

portal with over 3.5 billion data elements across 200 different data sets in real time, and to use all of that information to drive HHS's response to the COVID-19 pandemic. *Id.* ¶ 13.

Additionally, stakeholders continue to have access to COVID-19-related data. Ashmore Decl. ¶¶ 21-22. While Plaintiffs may prefer NHSN, the agency's decision to prioritize the flexibility of its data collecting and aggregating system during a pandemic over that system's accessibility is not arbitrary or capricious. And as for "reliance interests in the CDC's longstanding NHSN reporting system," PI Mem. 27, there is no such reliance interest with respect to COVID-19 data, which hospitals only reported voluntarily for the first few months of the pandemic, *see* Ashmore Decl. ¶¶ 9, 23. In addition, NHSN continues to be used to for its longstanding non-COVID-19 reporting purposes, *id.* ¶¶ 5-6, as well as to collect COVID-19 data from nursing homes and long-term care facilities, *id.* ¶ 24.

Finally, Plaintiffs cannot salvage this claim by resorting to speculation that HHS's use of HHS Protect is designed to give "the White House and political appointees" more control by taking "data reporting from the public health experts at the CDC." PI Mem. 29. CDC staff have access to all of the COVID-19 data reported by hospitals in HHS, as well as the expanded data sets available in that system. Ashmore Decl. ¶ 19. CDC continues to lead the surveillance systems for cases, mortality, nursing homes, studies, and clinical data, including population-based surveillance data on hospitalization through as system called "COVID-NET." *Id.* ¶ 21. No control has been wrested from CDC—the joint analysis of all of this data will remain within the domain of CDC and the other federal agencies that are part of the COVID-19 response. *Id.*

D. Plaintiffs Are Not Likely to Succeed on Their All Writs Act or Mandamus Act Claims

Plaintiffs allege that the same conduct addressed in their first two claims also entitles them to relief under the All Writs Act, 28 U.S.C. § 1651(a) and the Mandamus Act, 28 U.S.C. § 1361. Compl. ¶¶ 149-58. It does not.

"The All Writs Act grants federal courts authority to 'issue all writs necessary or appropriate in aid of their respective jurisdictions and agreeable to the usages and principles of law.'" *United States v. Schurkman*, 728 F.3d 129, 135 (2d Cir. 2013) (quoting 28 U.S.C. § 1651(a)). "[T]he remedies permitted under the Act are extraordinary and should not be used simply to avoid the inconvenience of following statutory procedures that govern the particular circumstances." *Citigroup, Inc. v. Abu Dhabi Inv. Auth.*, 776 F.3d 126, 130 (2d Cir. 2015) (internal quotation marks omitted). "Where a statute specifically addresses the particular issue at hand, it is that authority, and not the All Writs Act, that is controlling." *Penn. Bureau of Correction v. U.S. Marshals Serv.*, 474 U.S. 34, 43 (1985); *see Edelson PC v. Bandas Law Firm PC*, No. 16-cv-11057, 2018 WL 723287, at *13 (N.D. Ill. Feb. 6, 2018) (All Writs Act "does not provide an independent basis for jurisdiction and does not create a private cause of action."). In this case, Plainitffs cannot use the All Writs Act to circumvent the fact that their claims are governed by the APA.

Plaintiffs' Mandamus Act claim also fails. "The common-law writ of mandamus, as codified in 28 U.S.C. § 1361, is intended to provide a remedy for a plaintiff only if he has exhausted all other avenues of relief and only if the defendant owes him a clear nondiscretionary duty." *Heckler v. Ringer*, 466 U.S. 602, 616 (1984). "The party seeking the writ must show that 'its right to issuance of the writ is clear and undisputable.'" *Range v. 480-486 Broadway, LLC*, 810 F.3d 108, 113 (2d Cir. 2015) (quoting *Gulfstream Aerospace Corp. v. Mayacamas Corp.*,

485 U.S. 271, 289 (1988)). Plaintiffs do not and cannot allege that Defendants owe them any such clear and nondiscretionary duty. As discussed above, Plaintiffs do not have standing to bring their claims and they are not owed any duty by the Government. Nor have all other avenues of relief been exhausted as Plaintiffs are also pleading APA claims related to the same conduct.

Because neither the All Writs Act nor the Mandamus Act can serve as the basis for an independent claim, Plaintiffs will not prevail on this claim.

III. Plaintiffs Have Not Shown Irreparable Harm

Plaintiffs also have failed to meet their burden to show that they will suffer irreparable harm in the absence of a preliminary injunction. *See Freedom Holdings, Inc. v. Spitzer*, 408 F.3d 112, 114 (2d Cir. 2005) (movant must show "that absent a preliminary injunction they will suffer an injury that is neither remote nor speculative, but actual and imminent." (quotations omitted)). As discussed above in the context of standing, Plaintiffs have not shown that they have sustained, or are likely to sustain, any injuries unless the Court grants them preliminary relief. Plaintiffs have not suffered informational or procedural injuries, as the reports and participation opportunities at issue were either not required to be provided to them, have been provided, or are not required to address the COVID-19 pandemic. *See supra* at Part II.A.1. Moreover, Plaintiffs have made no showing that their alleged informational and procedural injuries will cause them to divert resources, impede their operations, or otherwise harm their COVID-19 response. *See supra* at Part II.A.1. Therefore, Plaintiffs have not met their burden of showing irreparable harm.

IV. The Balance of Equities and the Public Interest Are in the Government's Favor

A preliminary injunction is also not appropriate because the balance of the equities and the public interest weigh in the Government's favor. As explained *supra*, HHS is in the best position to evaluate how best to use its limited resources to most effectively respond to the

COVID-19 pandemic. These considerations demonstrate that the equities weigh against a mandatory injunction deeming judicial micromanagement of HHS's operations to be statutorily required. Such an injunction would require this Court to function as a "superagency" at a critical time for HHS and the country, a task that neither the present record nor the Court's institutional role and nature would allow this Court to properly perform. *See Ethyl Corp. v. EPA*, 541 F.2d 1, 36 (D.C. Cir. 1976). Nor have Plaintiffs even explained how the particular actions they are asking this Court to order will improve HHS's COVID-19 response or justify overriding HHS's expertise and internal management. There is a real risk that entering the requested injunction could counterproductively divert HHS resources and attention to Plaintiffs' preferred activities rather than allowing the agency to effectively discharge its duties on behalf of the entire public in the exercise of its informed discretion.

CONCLUSION

The Court should deny Plaintiffs' motion for a preliminary injunction.

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Respectfully submitted,

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