

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK**

CONEY ISLAND PREP; LESLIE-BERNARD
JOSEPH; HOUSING WORKS, INC.; CHARLES
KING; MARK LEVINE; and ALEXANDRA
GREENBERG,

Plaintiffs,

-against-

UNITED STATES DEPARTMENT OF HEALTH
AND HUMAN SERVICES; ALEX M. AZAR II, *in*
his official capacity as Secretary of Health and
Human Services; DR. ROBERT KADLEC, *in his*
official capacity as Assistant Secretary of Health and
Human Services; CENTERS FOR DISEASE
CONTROL AND PREVENTION; and DR. ROBERT
R. REDFIELD, *in his official capacity as Director for*
the Centers for Disease Control and Prevention,

Defendants.

No. 1:20-CV-9144

**MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' MOTION
FOR A PRELIMINARY INJUNCTION**

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Plaintiffs respectfully move this Court to enter a preliminary injunction ordering United States Department of Health and Human Services (“HHS”), Secretary Alex M. Azar II, Dr. Robert Kadlec, the Centers for Disease Control and Prevention (“CDC”), and Dr. Robert R. Redfield (collectively, “Defendants” or the “Administration”) to comply immediately with their obligations under federal law to respond to the 2019 novel coronavirus (“Covid-19”) pandemic and which they have ignored:

- To implement a Congressionally-mandated “biosurveillance network,” deadlines for which have passed, as required under Pub. L. No. 116-22 § 205, 133 Stat. 905, 924–25 (2019) (the “Pandemic Preparedness Act”) (to issue a Biological Threat Detection Report); 42 U.S.C. § 247d-4(c)(5)(B) (to convene a public meeting of stakeholders to discuss network’s design and implementation); *id.* § 247d-4(b)(2)–(3) (to issue “technical and reporting standards” to “coordinat[e]” the gathering of federal, state, and local public health data); 5 U.S.C. § 533 (notice and comment as to the proposed “technical and reporting standards”);
- To issue reports on public health and emergency preparedness, deadlines for which have passed, as required under 42 U.S.C. § 300hh-10(b)(7) (medical countermeasures budget), *id.* § 300hh-10(d) (medical countermeasures plan); *id.* §§ 247d-3a(i), (j), 247d-3b(i) (federal surge capacity funding to states); *id.* § 262a(k) (biological agents, toxins and related medical countermeasures); *id.* § 247d-6b(a)(2) (Threat-Based Review of the Strategic National Stockpile (“SNS”)); *id.* § 247d-6b(c)(2)(C), (3) (annual material threat determinations and related assessments of the SNS); *id.* § 242m(a)(1)-(2) (national health and health resources); *id.* § 242p (national disease prevention data profile); *id.* § 299a-1(a)(6) (from Agency for Healthcare Research and Quality); *id.* § 300u-6(f) (from the Office of Minority Health); Pandemic Preparedness Act § 606, 133 Stat. at 959 (vaccine development efforts); *id.* § 209, 133 Stat. at 929 (national blood supply);
- To enable public participation, deadlines for which have passed, as required under 42 U.S.C. § 300hh-10(d)(2)(H) (to solicit input from experts to aid the Administration’s medical countermeasures planning) and Pandemic Preparedness Act § 605, 133 Stat. at 958–59 (to convene a meeting on genomic engineering for health security and public health emergency countermeasures development); and
- To return the mandatory reporting by hospitals of Covid-19 case statistics to the CDC’s publicly available National Healthcare Safety Network (“NHSN”) system.

PRELIMINARY STATEMENT

Against the backdrop of a national crisis, this case rests on a simple but powerful proposition: the Administration must follow the law. In a series of statutes, including legislation enacted just last year, Congress imposed on certain federal agencies various discrete and clear obligations to prepare for and respond to an event like the Covid-19 pandemic.

Chief among these responsibilities is forging a “biosurveillance network,” with the Administration coordinating contributions from federal, state and local partners, to produce “near real-time” information “to enhance early detection of, rapid response to, and management of, potentially catastrophic infectious disease outbreaks, novel emerging threats, and other public health emergencies that originate domestically or abroad[.]” 42 U.S.C. § 247d-4(c)(1). Other obligations include publicizing information on federal emergency plans, public health threats, and vulnerabilities in our health systems; collecting data on disparities in access to healthcare; and engaging public stakeholders to participate in emergency preparations. To date, Defendants have failed to perform these duties.

In addition to ignoring Congressional mandates, the Administration has acted to make circumstances worse. Further complicating the nation’s pandemic response, Defendants shifted the reporting of daily Covid-19 hospitalization statistics from NHSN, a longstanding and publicly available CDC platform, to a closely held HHS database operated by private contractors. This change resulted in the availability of fewer and less useful data, untimely and out-of-date disclosures, and the withholding of crucial information about virus transmission.

Knowing where and how fast the disease has spread, the resources available to combat it, and the ways the public may be vulnerable to acute adverse outcomes is important for all Americans. It is especially so for individuals and organizations like Plaintiffs—Coney Island Prep (“CIP”) and Leslie-Bernard Joseph, a public charter school and its CEO; Housing Works, Inc.

(“Housing Works”) and Charles King, a non-profit health and housing organization and its CEO and founder; Mark Levine, a New York City Councilmember; and Alexandra Greenberg, a medical student and public health advocate. Plaintiffs are responsible for ensuring the health and safety of their communities, often communities of color, who bear a disproportionate burden from this pandemic. Plaintiffs have suffered and continue to suffer irreparable harm as a result of the Administration’s failure to abide by its statutory obligations, which has robbed Plaintiffs of critical information and resources for confronting the threats posed by Covid-19.

More than nine million people have been infected and more than 229,000 people have died in the U.S. from Covid-19. The Administration has been aware of the pandemic threat since fall of last year, yet they have continued to neglect their legal duties. As a result, Americans make up roughly one-fifth of Covid-19 cases and deaths world-over, millions of U.S. households grapple with historic economic damage, and a chasm of missing data and public records grows ever wider.

Relief is urgently needed. Plaintiffs’ injuries are irreparable and compound daily. The Court’s immediate intervention is necessary to compel Defendants’ compliance with their express statutory duties and jumpstart the Administration’s response to this public health emergency.

FACTUAL BACKGROUND

I. CONGRESS CREATED A ROBUST STATUTORY FRAMEWORK OF PANDEMIC-PREPAREDNESS OBLIGATIONS THAT DEFENDANTS HAVE IGNORED.

In 2019, with broad bipartisan support, Congress passed, and the President signed, the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019, Pub. L. No. 116-22, 133 Stat. 905 (2019) (the “Pandemic Preparedness Act” or “Act”). The Act mandated the creation of a “biosurveillance network” to provide “near real-time” information on the progress of public health emergencies like the Covid-19 pandemic, 42 U.S.C. § 247d-4(c), (j), and prescribed numerous additional pandemic response measures. These measures supplemented additional

existing obligations of Defendants to collect and report data on the nation’s public health infrastructure, communities suffering from inequitable access to healthcare, the federal government’s capacity for combatting an event like a pandemic, and other similar programs. The provisions at issue here are of three fundamental kinds.

First, attendant with the mandated creation of a “biosurveillance network” to better track and contain infectious disease outbreaks like the Covid-19 pandemic, *see* 42 U.S.C. § 247d-4, Defendants were required to, (1) by June 24, 2020, issue “technical and reporting standards” to “coordinat[e]” the gathering of federal, state, and local data seamlessly and effectively, 42 U.S.C. § 247d-4(b)(3)(A); (2) engage the public in the required notice-and-comment process regarding these standards under 5 U.S.C. § 533; (3) by December 21, 2019, convene a public meeting with experts and stakeholders to discuss in detail the goals, design and operation of the network, *id.* § 247d-4(c)(5)(B); and, (4) by December 21, 2019, issue a Biological Threat Detection Report on the nation’s current capabilities and shortfalls in “rapidly detect[ing] . . . the presence of biological threat[s],” Pandemic Preparedness Act § 205, 133 Stat. at 924–25 (collectively, “Withheld Biosurveillance Duties”).

Second, Congress imposed on Defendants numerous public health data-collection and reporting obligations to inform the Administration’s and the public’s emergency preparations and response. These duties, each with prescribed statutory deadlines, include publishing plans, budgets and reports with respect to the nation’s preparedness and response capacity for public health emergencies, the nation’s health and health resources, and public health disparities (collectively, “Withheld Reporting Duties”).¹

¹ *See* 42 U.S.C. § 300hh-10(b)(7) (medical countermeasures budget, due by March 15, 2020), *id.* § 300hh-10(d) (medical countermeasures plan, due by March 15, 2020); *id.* §§ 247d-3a(i), (j), 247d-3b(i) (federal health security and surge capacity funding to states); *id.* § 262a(k)

Third, Congress did not want the Administration to go it alone. The law is explicit that Defendants were to solicit the participation of the American people—particularly certain stakeholders and experts, like Plaintiffs—in their decision-making process to enhance the country’s public health capabilities and the “biosurveillance” measures Defendants were required to undertake. Specifically, governing statutes provide that Defendants must, (1) solicit the formal input of experts and stakeholders in public health emergency countermeasures planning, *see* 42 U.S.C. § 300hh-10(d)(2)(H); and, (2) by June 24, 2020, convene a meeting with “representatives from academic, private, and nonprofit entities . . . and other relevant stakeholders,” on genomic engineering technologies and their role in health security and medical countermeasures development, including those for infectious diseases, Pandemic Preparedness Act § 605, 133 Stat. at 958–59, after which Defendants must prepare a report (collectively, “Withheld Participation Duties”).

Together, these discrete and concrete statutory obligations place Defendants at the forefront of the Federal government’s planning for and response to public health emergencies like the Covid-19 pandemic, and compel the amassing and dissemination of information critical to the public’s capacity to confront Covid-19.²

(biological agents, toxins and related medical countermeasures, due by June 24, 2020); *id.* § 247d-6b(a)(2) (Threat-Based Review of the SNS, due by March 15, 2020); *id.* § 247d-6b(c)(2)(C), (3) (annual material threat determinations and related assessments of the SNS); *id.* § 242m(a)(1)-(2) (national health and health resources, due by March 15, 2020); *id.* § 242p (triennial national disease prevention data profile, due by March 15, 2020); *id.* § 299a-1(a)(6) (annual health disparities report from the Agency for Healthcare Research and Quality (“AHRQ”)); and *id.* § 300u-6(f) (biennial report on the efforts of the Office of Minority Health (“OMH”)); Pandemic Preparedness Act § 606, 133 Stat. at 959 (international vaccine development efforts, due by June 24, 2020); *id.* § 209, 133 Stat. at 929 (national blood supply, due by June 24, 2020).

² Indeed, the Administration has shown it is aware of its data collection role: in July, 2020, HHS abruptly changed hospitals’ data reporting requirements about Covid-19 from the CDC’s NHSN system, which is publicly available and the longstanding repository of such

II. PLAINTIFFS ARE IRREPARABLY HARMED BY DEFENDANTS' FAILURES TO MEET THEIR EXPRESS OBLIGATIONS TO RESPOND TO THE COVID-19 PANDEMIC.

Defendants have shirked their legal obligations, prior to and throughout the Covid-19 pandemic, even as deaths have mounted into the hundreds of thousands. The result is that Plaintiffs and the public have been denied the information and resources they need to meaningfully respond to and mitigate the risks posed by Covid-19, exacerbating—if not causing outright—the calamitous effects of the pandemic.

Coney Island Prep, headed by Plaintiff Leslie-Bernard Joseph, teaches more than 1000 students from kindergarten through twelfth grade across three campuses in Brooklyn, New York. Decl. of Leslie-Bernard Joseph (“Joseph Decl.”) ¶ 3. The school is located in the Coney Island, Sheepshead Bay, and Gravesend neighborhoods, and it serves diverse communities that include high numbers of speakers of foreign languages, families in economic need, and students who require other special attention or care. *See id.* A significant majority of students identify as Black, Latinx, Asian, or Multi-Racial, and families include immigrants from four continents. *See id.* Despite CIP’s equity mission and achievements in closing education gaps prevalent in its community, *id.* ¶ 4, its students, families and staff have been severely impacted by the spread of Covid-19. Consequently, CIP continues to expend tremendous effort and divert substantial resources away from other priorities to provide lessons remotely, adapt facilities and programs to prevent Covid-19 transmission, build adequate health monitoring protocols, and support students and families facing Covid-related economic hardship with financial grants, regular meals,

information, to the significantly less transparent HHS Protect system. This has restricted the availability of important data, as discussed further *infra*.

counseling, and social support to ensure students continue to be educated in safe and stable environments. *See generally id.* ¶¶ 5–26.

Housing Works, of which Plaintiff Charles King is CEO and founder, is a non-profit whose organizational mission includes providing health care, housing, and other crucial services to New Yorkers in need, focusing particularly on individuals living with HIV/AIDS and other chronic conditions who are extremely vulnerable to adverse outcomes from contracting Covid-19. Decl. of Charles King (“King Decl.”) ¶¶ 1, 24, 33–34. Housing Works programs also offer primary medical care, supportive housing, mental health and wellness care, job training, and legal services, on behalf of their clients and their families. *Id.* ¶¶ 25–26, 33, 39–40. The organization has found itself on the frontlines of the pandemic, providing free public testing and housing to at-risk persons who need to isolate or quarantine due to Covid-19 exposure or infection. Such programs risk being overwhelmed by a resurgence of the virus in the fall and winter months. *See id.* ¶¶ 10, 13, 16, 18. Housing Works and Mr. King lead advocacy efforts against racial inequities in the health care system and the need for improved data for their remedy, efforts whose salience has increased during Covid-19. *Id.* ¶¶ 42–44. Approximately 92% of the people Housing Works serves are Black and/or Latinx and face disproportionate likelihood of exposure to and death from Covid-19. *Id.* ¶ 7.

Plaintiff Mark Levine represents the 7th District in northern Manhattan, a predominantly Non-White district, on the New York City Council where he serves as Chair of the City Council’s Health Committee. Decl. of Mark Levine (“Levine Decl.”) ¶¶ 1, 5, 8. He has been a leader in crafting legislation to guide the City’s response to the pandemic; even while the City Council shifted to conduct its operations remotely, he was forced to close his constituent offices, he himself fell ill with Covid-19, and the City lacked sufficient information about the virus spread. *Id.* ¶¶ 6–

10. Remedying such information deficits and responding to the rapid spread of the virus have forced Mr. Levine to divert attention from other worthy priorities and impeded constituent outreach programs that must now be provided remotely. *Id.* ¶¶ 10–12.

Plaintiff Alexandra Greenberg is a public health researcher and reform advocate; she is currently a medical student enrolled at State University of New York Downstate School of Medicine. Decl. of Alexandra Greenberg (“Greenberg Decl.”) ¶¶ 1–6. Recently, she and her colleagues formed Right to Health Action, an organization advocating to “alleviate the disparities in health and health care that are caused by racial injustice and economic inequality,” now “specifically addressing such disparate outcomes from Covid-19.” *Id.* ¶¶ 7–10. Her advocacy efforts, her education, and her school-supervised clinical care have been severely disrupted by the pandemic, disruptions which have been exacerbated by the lack of data, reporting standards, and resources to protect against the virus from the federal government. *See, e.g., id.* ¶¶ 12–16.

ARGUMENT

The extraordinary magnitude of Defendants’ neglect entitles Plaintiffs to extraordinary relief. Prompt action by the Court, in the form of a preliminary injunction, is warranted to cure the government’s noncompliance. Plaintiffs can demonstrate the elements required for obtaining this relief, namely: (1) that irreparable harm, causing potentially “extreme or very serious damage,” will result absent an injunction, (2) a “clear or substantial” likelihood of success on the merits; and (3) public interest weighing in favor of granting the injunction, and that the balance of equities tips in their favor. *Friends of the E. Hampton Airport, Inc. v. Town of E. Hampton*, 841 F.3d 133, 143 (2d Cir. 2016); *Tom Doherty Assocs. v. Saban Entm’t, Inc.*, 60 F.3d 27, 34 (2d Cir. 1995) (citations omitted); *see also Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008).

Each day Defendants flout their legal duties, the irreparable harms to Plaintiffs compound. Plaintiffs are substantially likely to prevail on their claims, authorized under the Administrative

Procedure Act (“APA”), because Defendants have unambiguously violated clear statutory mandates that were enacted to benefit Plaintiffs and others like them. And the public has everything to gain from the Court’s granting an injunction compelling Defendants’ long-overdue action, which would bolster national efforts to combat the pandemic.

These facts also satisfy Plaintiffs’ burden of establishing Article III standing to seek injunctive relief. Defendants’ unlawful acts and omissions have caused Plaintiffs concrete, particularized, ongoing injuries, which are fairly traceable to Defendants and will be (and can only be) redressed by a Court injunction. The Court should grant Plaintiffs’ motion.

I. PLAINTIFFS WILL SUFFER EXTREME, SERIOUS, AND IRREPARABLE HARM IN THE ABSENCE OF COURT ACTION.

Defendants’ maladministration and failure to fulfill their obligations to enhance the government’s “biosurveillance” capabilities, collect and publicize public health data, and solicit Plaintiffs’ engagement in these efforts have caused Plaintiffs harm that can only be remedied by, and will only grow worse absent, immediate equitable relief. Injunctions serve to secure against such “imminent and certain” harm where “adequate compensatory or other corrective relief will [not] be available at a later date, in the ordinary course of litigation.” *Jayaraj v. Scappini*, 66 F.3d 36, 39 (2d Cir. 1995). “To establish irreparable harm, a party seeking preliminary injunctive relief must show that there is a continuing harm which cannot be adequately redressed by final relief on the merits and for which ‘money damages cannot provide adequate compensation.’” *Kamerling v. Massanari*, 295 F.3d 206, 214 (2d Cir. 2002). The harm “must be shown to be actual and imminent, not remote or speculative.” *Id.*

The allegations in the Complaint, substantiated by the accompanying declarations, establish that Plaintiffs have suffered and continue to suffer harms caused by Defendants’ inaction.

None of these injuries can be remedied by delayed Court action or money damages—the need for injunctive relief now is pressing.

A. Defendants’ Failures to Collect and Report Data Have Caused Plaintiffs Irreparable Informational Injury.

Defendants’ failure to meet their data collection and reporting obligations harms Plaintiffs by depriving them of useful information that Defendants are required to disclose.³ These are well-established informational injuries. *McFarlane v. First Unum Life Ins. Co.*, 274 F. Supp. 3d 150, 161 (S.D.N.Y. 2017) (citing 15 James W. Moore *et al.*, Moore’s Federal Practice § 101.40 (3d ed. 2015)); *accord FEC v. Akins*, 524 U.S. 11, 21 (1998).

It is also well-established that Plaintiffs’ informational injuries constitute irreparable harm. “[W]here an obligation to disclose exists, plaintiffs may suffer irreparable harm if they are denied access to information that is highly relevant to an ongoing public debate.” *Lawyers’ Comm. for Civil Rights under Law v. Presidential Advisory Comm’n on Election Integrity*, 265 F. Supp. 3d 54, 70 (D.D.C. 2017) (citations omitted); *cf.*, *e.g.*, *N.Y. Civil Liberties Union v. N.Y.C. Transit Auth.*, 675 F. Supp. 2d 411, 427–28 (S.D.N.Y. 2009) (“The loss of First Amendment freedoms”—like the right of access to public meetings and information—“for even minimal periods of time, unquestionably constitutes irreparable injury.” (quoting *Elrod v. Burns*, 427 U.S. 347, 373 (1976))). “[G]iven that . . . informational injuries sustained by the plaintiffs defy calculation, there are no monetary damages or other legal remedies that would adequately compensate the plaintiffs.” *Ctr. for Biological Diversity v. Brennan*, 571 F. Supp. 2d 1105, 1134 (N.D. Cal. 2007).

³ Defendants’ actions that have caused Plaintiffs’ informational injuries include all of Defendants’ Withheld Reporting Duties as well as some of Defendants’ Withheld Biosurveillance Duties—i.e., the obligations to promulgate “technical and reporting standards,” 42 U.S.C. § 247d-4(b)(3)(A), and to issue a Biological Threat Detection Report, Pandemic Preparedness Act § 205, 133 Stat. at 924–25.

The lack of information—about, among other things, the development of “biosurveillance” capabilities to track the pandemic in “near real-time,” existing public health emergency capacities, Americans’ underlying health and health resources, and the need or ability to protect those most vulnerable to adverse outcomes—cripples Plaintiffs’ capacity to conduct themselves and their organizations safely and effectively during the pandemic.

CIP provides for the health and safety of its students, staff, and families, and the information it has been denied inhibits it from assessing Covid-19’s threat to its community members, implementing policies to mitigate Covid-19 transmission, providing in-person and remote programs to fulfill its educational mission, evaluating programs and interventions by other schools and in other jurisdictions, and advocating on behalf of itself and its community for improved public health interventions and educational policies. Joseph Decl. ¶¶ 34–39.

Housing Works is a primary healthcare provider and offers free services that detect and contain the spread of Covid-19. It depends on the information the Administration has denied to determine protocols for day-to-day operations to “direct isolation, treatment, and preventative care”—particularly with respect to the communities of color it serves—to “tailor services to address inequities,” and to develop “concrete plans to improve the health of communities of color.” King Decl. ¶¶ 24, 53–56.

One of the “primary challenges” for Plaintiff Levine and other City policymakers has been the lack of “sufficient information with which to make public health decisions” and “to tailor policy and guidance to rapidly evolving conditions.” Levine Decl. ¶¶ 7, 13–14, 20–21. Moreover, the lack of transparent national data restricts Levine from implementing better policies to prevent transmission from out-of-state travelers as well as evaluate municipal interventions in other jurisdictions. *Id.* ¶¶ 15–18, 20, 22–25.

The lack of detailed, reliable, and timely information about Covid-19 has hindered Plaintiff Greenberg’s efforts to advocate for health equity and better policy in response to Covid-19 and “for the best policies regarding remote instruction” from federal, state, and local policymakers, as well as her medical school. Greenberg Decl. ¶¶ 12, 18–20. On a personal level, it also constrains her ability to serve patients, participate in her medical education and protect at-risk relatives. *Id.* ¶¶ 16–17.

For all Plaintiffs, the Administration’s failure to collect data and timely report on health disparities with respect to race and ethnicity—both in terms of Covid-19 and generally—has robbed Plaintiffs of insights into these problems and their ability to advocate for or implement interventions that would materially safeguard their constituents. *See* Decl. of Dr. Mary T. Bassett (“Bassett Decl.”) ¶¶ 9–12 (age-related data on race and ethnicity reveals severe disparities in the impact of Covid-19 among Black and Latinx working-age adults); Decl. of Dr. Micaela Martinez (“Martinez Decl.”) ¶¶ 8, 14–15 (granular race and ethnicity data needed to determine how to deploy field hospitals, public information campaigns, and financial assistance).⁴

These harms “defy calculation” and can only be redressed by injunctive relief. They constitute irreparable informational injury.

⁴ According to a recent study in *Lancet*, Covid-19 case data with respect to race and ethnicity continues to be underreported to the CDC and others. *See* Williams Decl. Ex. A. Fifty percent of the cases on the CDC demographic tracker for Covid-19 are missing such data on race and ethnicity, but it offers no information on which states are creating the gaps. *The Atlantic’s* Covid-19 Racial Data Tracker, a project independent of the CDC but nonetheless linked to from its website, helps answer that question by providing state-by-state data, *see* Martinez Decl. ¶¶ 22–24: there, the median state is reporting racial data for only 21% of its cases, and we know which states contribute zero information; reporting on ethnicity is similarly poor. Williams Decl. Ex. A. The *Lancet* study indicates that recent HHS Covid-19 reporting requirements, *see id.*, have done little to improve gaps in data on race and ethnicity, despite the Administration’s promise to remedy those flaws promptly.

B. Defendants’ Failures to Convene Required Meetings and Initiate the Notice-and-Comment Process Have Caused Plaintiffs Irreparable Procedural Injuries.

Defendants’ failures to solicit public input, including their failure to abide by notice-and-comment requirements, have caused Plaintiffs irreparable procedural harm.⁵ Where a plaintiff is unlawfully denied participation in an agency decision-making process, irreparable injury is presumed. *See Nat. Res. Defense Council v. Lujan*, 768 F. Supp. 870, 890 n.36 (D.D.C. 1991) (“[T]he harm suffered by those who would otherwise participate in agency rulemaking under the APA is irreparable when the agency fails to afford them their rights to such participation.” (quotation omitted)); *see also Ctr. for Biological Diversity*, 571 F. Supp. 2d at 1134 (agency’s failure to solicit public comment on a report constituted a procedural injury which “def[ies] calculation” and requires injunctive relief). Here, the governing statutes require Defendants to seek public input in the development of a “biosurveillance network” and pandemic-preparedness capabilities, and specifically contemplate the inclusion of public-health stakeholders—like Plaintiffs—in that process. Defendants’ failure to do so irreparably injures Plaintiffs in three ways.

⁵ Defendants’ actions that have caused Plaintiffs’ procedural injuries include all of Defendants’ Withheld Participation Duties as well as some of Defendants’ Withheld Biosurveillance Duties—i.e., to engage the public in the notice-and-comment process regarding the “technical and reporting standards,” *see* 42 U.S.C. § 247d-4(b)(3)(A), and to convene a public meeting to discuss the network in detail, *id.* § 247d-4(c)(5)(B).

As a general matter, “because money damages are prohibited in APA actions, [injuries caused by APA violations] are irreparable.” *New York v. United States Dep’t of Homeland Sec.*, 969 F.3d 42, 86 (2d Cir. 2020) (citing 5 U.S.C. § 702; *Ward v. Brown*, 22 F.3d 516, 520 (2d Cir. 1994)). Moreover, “it is well established that the harm suffered by those who would otherwise participate in agency rulemaking under the APA is to be considered irreparable when the agency fails to afford them their rights to such participation.” *Nat’l Treasury Emps. Union v. Newman*, 768 F. Supp. 8, 10 (D.D.C. 1991) (citation omitted).

First, Plaintiffs are entitled to participate in the mandated public health emergency planning and each would bring valuable insight to the discussions. *See* Joseph Decl. ¶¶ 35, 40–41 (CIP’s pandemic mitigation strategies are a model for other schools and CIP is well-positioned to participate in regulatory fora and provide input); King Decl. ¶¶ 51, 59–61 (same, with respect to Housing Works, which routinely provides comment to federal rulemakings and collaborates with other health organizations in policy advocacy); Levine Decl. ¶¶ 19, 21 (same, with respect to local health policy); Greenberg Decl. ¶¶ 19, 20 (same, with respect to her work as a health advocate and her representation of fellow medical students). Experts agree that schools, community organizations, public health advocates, and other representatives of highly affected communities need to have a seat at the table in order for federal agencies to design effective policies that might soften the worst of Covid-19’s impact. *See* Decl. of Dr. Emily Oster (“Oster Decl.”) ¶¶ 6–8 (input of schools is important for understanding the data they can provide and need); Martinez Decl. ¶¶ 9–10 (local health organizations, such as those in the South Bronx, help shape leaders’ understanding of the issues and needs of vulnerable local communities); Decl. of Dr. Irwin Redlener (“Redlener Decl.”) ¶ 11 (non-profits and public health advocates are important for shaping and disseminating the latest data and best practices). The denial of these opportunities constitutes an irreparable harm unto itself. *See Nat. Res. Defense Council*, 768 F. Supp. at 890 n.36; *see also W. Watersheds Project v. Zinke*, 336 F. Supp. 3d 1204, 1239 (D. Idaho 2018) (agency’s limiting of the public participation process would cause plaintiff irreparable harm).

Second, Defendants’ failure to implement these processes irreparably injures Plaintiffs because they are prerequisites for Defendants’ further mandated “biosurveillance” and public health measures. *See, e.g., Ctr. for Biological Diversity*, 571 F. Supp. 2d at 1133 (plaintiffs harmed by preclusion from commenting on agency publication as well as the withheld agency action that

relied on that publication). By ignoring requirements to engage Plaintiffs and others in its pandemic-response decision-making, the Administration consequently has delayed making any decision, to Plaintiffs’ additional, irreparable detriment. *See, e.g.*, King Decl. ¶¶ 49–51 (lack of an informed “biosurveillance” program has hindered Housing Works’ ability to provide services related to Covid-19 that New York City also is under-resourced to handle); Greenberg Decl. ¶¶ 14–17 (hospital where she studies and her own medical program are impacted by poor data); Levine Decl. ¶¶ 22–25 (poor data diverts local government resources and hinders the policymaking process); Joseph Decl. ¶¶ 27, 31–32 (“near real-time” health surveillance and case tracking are important for keeping schools, families and their wider community healthy during the pandemic). *See also* Oster Decl. ¶ 6 (“biosurveillance” critical for developing best practices for schools); Martinez Decl. ¶¶ 14–15, 18 (comprehensive real-time data important for developing interventions on behalf of communities seeing disproportionate Covid-19 infections); Bassett Decl. ¶¶ 12–13 (contextual and socioeconomic data important in designing policy interventions); Redlener Decl. ¶ 12 (same).

Third, the lack of public input places Plaintiffs at risk of being subject to or harmed by uninformed, let alone unlawful, government action. *Nat. Res. Defense Council*, 768 F. Supp. at 877 (plaintiffs harmed by “risk that serious environmental impacts [of proposed policy] will be overlooked” due to agency’s failure to obtain public input (quotation omitted)); *see, e.g.*, Joseph Decl. ¶¶ 33, 41–42 (unique perspective of educators would benefit federal decision-making); King Decl. ¶¶ 10–13 (same, with respect to Housing Works’ role in frontline pandemic testing, quarantine, and care, as well as their advocacy efforts on behalf of patients with chronic conditions and the homeless); Levine Decl. ¶ 19 (same, with respect to Levine’s “expertise and advocacy”); Greenberg Decl. ¶ 20 (same, with respect to her expertise in health policy and advocating on behalf

of fellow students for a “just and fair operation of our healthcare system”); *see also, e.g.*, Bassett Decl. ¶¶ 12–13 (absence of age specific data on race and ethnicity concealed the need for protections for working-age adults in communities of color); Martinez Decl. ¶ 13 (underreporting of data precludes important policies that might mitigate the harms to communities underserved by the health system); Oster Decl. ¶ 12 (underreported school transmission data conceals potential interventions and the opportunity to identify schools needing the most support).

These harms are real and imminent, and cannot be later addressed. Plaintiffs have suffered irreparable procedural injuries.

C. Plaintiffs Have Suffered Irreparable Harm because Defendants’ Violations Have Caused Plaintiffs to Divert Resources from Organizational Priorities.

Defendants have further injured Plaintiffs by causing them to divert resources from prior organizational goals to other efforts, such as to protect and inform their communities, provide care for sick or at-risk community members, or devise alternative procedures to confront the threat of Covid-19. *See Havens Realty Corp. v. Coleman*, 455 U.S. 363, 379 (1982). These efforts are made all the more challenging due to the dearth of information that Defendants have neglected to gather and disseminate.

Organizations “are deemed to suffer irreparable harm when governmental action forces them to divert resources away from their organizational missions.” *Islam v. Cuomo*, No. 20-cv-2328, 2020 WL 4336393, at *7 (E.D.N.Y. Jul. 28, 2020) (citing cases). Whether and to what degree this diversion results in economic injury to Plaintiffs does not change the propriety of injunctive relief. “[B]ecause money damages are prohibited in APA actions, [injuries caused by APA violations] are irreparable.” *New York v. United States Dep’t of Homeland Sec.*, 969 F.3d at 86; *see also, e.g., Open Communities Alliance v. Carson*, 286 F. Supp. 3d 148, 178 (D.D.C. 2017) (economic harm is irreparable where money damages are unavailable under the APA). Such

diversions include the provision of “new services,” and courts recognize irreparable injury where, as here, organizations must expend additional resources and energy to “educate” their clients as a result of wrongful government action. *Make the Rd. N.Y. v. Cuccinelli*, 419 F. Supp. 3d 647, 657, 665 (S.D.N.Y. 2019).

Plaintiffs CIP and Housing Works in particular have suffered such harm. As for CIP, which serves as a “health care provider” to its students in “normal times,” the pandemic has “charged this mandate with additional life-or-death significance.” Joseph Decl. ¶ 30; *accord* Oster Decl. ¶¶ 10–12 (schools are already performing important “biosurveillance”-like roles for their own purposes and governments should take advantage); Redlener Decl. ¶¶ 17–19 (schools have role in supporting the economic and physical health of families and communities); *see also New York v. United States Dep’t of Educ.*, 2020 WL 4581595, at *14 (S.D.N.Y. Aug. 9, 2020) (“It is apparent that the responsibilities of [schools] to respond appropriately to the Covid-19 pandemic are wide-ranging, numerous, and serious.”). CIP has struggled “to meet the conflicting demands of government officials” and respond to ever-shifting guidance from federal and state agencies. Joseph Decl. ¶ 31. Amid continuing uncertainty about the best way to mitigate the risks of the virus, CIP has had to: devise reopening plans that required investing in new health and safety equipment, reallocating resources to support remote learning and alternative in-person learning experiences, *id.* ¶¶ 14, 20, 25; provided laptops and tablets to its students and implement an off-site food program to provide for families who had relied on school meals, *id.* ¶¶ 15–17; and provide financial support and counseling for students whose families faced sudden financial hardship, *id.* ¶¶ 6–9, 18–22. These and other “extraordinary steps [were] necessary” for CIP “to continue to serve its education[al] mission” in the face of the pandemic. *Id.* ¶ 10; *see also id.* ¶¶ 2–4. These steps also prevented the school from carrying out the full range of education and supportive

programming to its students and families, such as its core in-person lessons, a range of career and college guidance, summer experience placements, and special education programs.

As for Housing Works, the Covid-19 outbreak has “forced significant changes on [its] programs” and significantly hobbled its mission-related activities. King Decl. ¶ 5. So long as the pandemic has not been contained, Housing Works will continue to divert resources to a series of Covid-19 specific programs and interventions necessary to safeguard their target population of homeless and at-risk persons. These programs include an isolation shelter for homeless individuals exposed to or infected with Covid-19, *id.* ¶ 10, support for recently released ex-offenders at greater risk of infection, *id.* ¶ 11, and free public testing and tracing programs in partnership with the City, *id.* ¶¶ 13–14. Absent better information with respect to the progress of the pandemic, Housing Works must continue to operate in an abundance of caution, forcing it to move remotely what programs it can, curtail some and close others altogether. By way of a handful of examples, Housing Works has: “truncate[d]” its daily health care services, thereby limiting the effectiveness of those services, *id.* ¶¶ 29–32, suspended group activities and visitors to shelters, *id.* ¶ 36, curtailed its advocacy efforts due to safety concerns and logistic burdens, *id.* ¶ 42, and closed its well-known thrift stores and retail outlets and canceled annual fundraising events, *id.* ¶¶ 46, 48.⁶ But for these diversions, Housing Works would have been able to provide services such as additional medical and mental health care, more robust job training services, wider advocacy outreach, and fundraising in the normal course.

⁶ Other Plaintiffs have similarly been concretely and particularly harmed. *See, e.g.*, Levine Decl. ¶¶ 10–12 (pandemic has impacted Levine’s constituent-outreach capabilities and diverted resources and attention away from legislative priorities); Greenberg Decl. ¶¶ 7–10 (Greenberg’s healthcare justice advocacy organization, Right-to-Health Action, focuses specifically on addressing the disparate and inequitable impact of Covid-19 on marginalized communities).

Thus, the facts presented clearly establish Plaintiffs have suffered and risk continued irreparable harm, meriting the Court's urgent action. Plaintiffs' motion should be granted.

II. PLAINTIFFS HAVE A CLEAR AND SUBSTANTIAL LIKELIHOOD OF SUCCESS ON THE MERITS.

The APA “sets forth the procedures by which federal agencies are accountable to the public and their actions subject to review by the courts.” *Dep’t of Homeland Sec. v. Regents of the Univ. of Cal.* (“*Regents*”), 140 S. Ct. 1891, 1905 (2020) (citation omitted). Courts adjudicating APA claims thus begin with “a strong presumption favoring judicial review of administrative action,” based on the recognition that unfortunately “legal lapses and violations occur,” and they will do so “especially” if they appear to have “no consequence” or repercussion. *See Weyerhaeuser Co. v. United States Fish & Wildlife Serv.*, 139 S. Ct. 361, 370 (2018) (citation omitted); *see also Sharkey v. Quarantillo*, 541 F.3d 75, 84 (2d Cir. 2008) (same).

Here, Plaintiffs are entitled to relief under two of APA's provisions: 5 U.S.C. § 706(1), which mandates court intervention to order agencies to take required actions “unlawfully withheld or unreasonably delayed,” and § 706(2), which provides courts the authority to enjoin agency actions that are “arbitrary and capricious” or otherwise unlawful. As described more fully in the sections that follow, Plaintiffs clearly are likely to succeed on the merits of their APA claims.

A. Defendants Have Unlawfully Withheld and Unreasonably Delayed Required Agency Action in Violation of APA Section 706(1).

The APA allows lawsuits from those who are “suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute.” *Norton v. S. Utah Wilderness All.*, 542 U.S. 55, 61 (2004) (quoting 5 U.S.C. § 702). An agency action is all or part of “an agency rule, order, license, sanction, relief, or the equivalent or denial thereof, *or failure to act.*” *Id.* at 62 (emphasis added) (quoting 5 U.S.C. § 551(13)). The law

authorizes courts to “compel agency action unlawfully withheld or unreasonably delayed.” 5 U.S.C. § 706(1).⁷

To have a viable claim under Section 706(1), a plaintiff must show “that an agency failed to take a discrete agency action that it is *required to take*.” *Id.* (emphasis in original); *Sharkey*, 541 F.3d at 89 n.13 (“[I]f an agency is under an unequivocal statutory duty to act, failure so to act constitutes, in effect, an affirmative act that triggers ‘final agency action’ review.”) (quoting *Sierra Club v. Thomas*, 828 F.2d 783, 793 (D.C. Cir. 1987)). Archetypical examples include “the failure to promulgate a rule or take some decision by a statutory deadline.” *Norton*, 542 U.S. at 62–63. Even should Defendants argue that “the manner of its action is left to the agency’s discretion,” the failure to act in and of itself is a violation, and the Court “can compel the agency to act” and adhere to its deadlines. *Id.* at 65.

Here, Plaintiffs are seeking the Court’s intervention to require Defendants to take a number of discrete actions they failed to take by their statutory deadlines:

With respect to Defendants’ Withheld Biosurveillance Duties, they failed to:

- Convene, by December 21, 2019, a public meeting “for purposes of discussing and providing input on the potential goals, functions, and uses of” a “biosurveillance network” to provide near-real-time situational awareness of disease outbreaks and other public health threats, and to include at that meeting representatives from federal, state, local and tribal health agencies, public and private sector expertise, and other such stakeholders and representatives, as required by 42 U.S.C. § 247d-4(c)(5)(B);
- Prepare and publish, also by December 21, 2019, a “Biological Threat Detection Report . . . on the state of Federal biological threat detection efforts,” “the capabilities of

⁷ The actions Plaintiffs seek to compel by and large are all required by a “date certain . . . prescribed by Congress” and so have been “unlawfully withheld” and not “unreasonably delayed.” *Nat. Res. Defense Council v. Fox*, 93 F. Supp. 2d 531, 543 (S.D.N.Y. 2000) (citing *Forest Guardians v. Babbitt*, 164 F.3d 1261, 1272 (10th Cir. 1998)) (internal citation omitted). As to delay, while there is no *per se* rule as to how long is too long, “a reasonable time for agency action is typically counted in weeks or months, not years.” *Families for Freedom v. Napolitano*, 628 F. Supp. 2d 535, 540 (S.D.N.Y. 2009) (quoting *In re Am. Rivers & Idaho Rivers United*, 372 F.3d 413, 419 (D.C. Cir. 2004) (internal citation and quotations omitted)).

detection systems in use by Federal departments and agencies,” and the Defendants’ capacity to support and collaborate with State, local, Tribal and territorial public health systems, as required by Section 205(c) of the Pandemic Preparedness Act;

- By June 24, 2020, publish the “technical and reporting standards, including standards for interoperability” of federal, state, local, tribal, and private organizations for the data-sharing network, as required by 42 U.S.C. § 247d-4(b)(2)–(3); and
- Provide adequate notice of and public comment with respect to those technical and reporting standards, as required by 5 U.S.C. § 533.⁸

Absent fulfilling these mandatory pre-requisites, Defendants cannot fulfill their contingent duties under 42 U.S.C. § 247d-4(c)(1) to develop this “biosurveillance network” for “near real-time” reporting to the public on public health emergencies such as the ongoing Covid-19 pandemic.

With respect to Defendants’ Withheld Reporting Duties, they failed to:

- Compile and publish “in a timely manner” annual reports submitted to HHS from state and local entities receiving federal funding for health emergency preparedness, as required, 42 U.S.C. § 247d-3a(i), (j); 42 U.S.C. § 247d-3b(i);
- Prepare and publish, by March 15, 2020, a Strategy and Implementation Plan (“Countermeasures SIP”) from the Public Health Emergency Medical

⁸ An agency that fails to adhere to APA notice-and-comment requirements, *see* 5 U.S.C. § 533, also does not act in accordance with the law. *See Time Warner Cable Inc. v. FCC*, 729 F.3d 137, 168 (2d Cir. 2013). Notice-and-comment requirements apply to substantive agency rules, *see id.*, like the technical and reporting standards for the “biosurveillance network” that Defendants must promulgate under 42 U.S.C. § 247d-4(b)(3)(A). That is because the standards represent substantive requirements for participation in the network by state and local governments—such as the New York City government, of which Levine is an official—and private health care entities such as Housing Works or the hospital where Alexandra Greenberg works and studies.

The APA’s notice and comment provisions serve “to reintroduce public participation and fairness to affected parties after governmental authority has been delegated to unrepresentative agencies,” and “to assure that the agency is presented with all information and suggestions relevant to the problem at issue.” *White v. Shalala*, 7 F.3d 296, 303 (2d Cir. 1993) (internal marks and citations omitted); *see also Perez v. Mortg. Bankers Ass’n*, 575 U.S. 92, 109 (2015) (Scalia, J., concurring) (notice and comment operates “as a check upon administrators whose zeal might otherwise have carried them to excesses not contemplated in legislation creating their offices”) (citation omitted).

Countermeasures Enterprise (“PHEMCE”), 42 U.S.C. § 300hh-10(d); *see also* Pandemic Preparedness Act § 402, 133 Stat. at 943;

- Prepare and publish, by March 15, 2020, a five-year budget plan based on the medical countermeasure priorities identified in the Countermeasures SIP and to “include consideration of the entire medical countermeasures enterprise,” 42 U.S.C. § 300hh-10(b)(7);
- Prepare and publish, by March 15, 2020, annual reports 1) regarding national health care costs and financing, 2) regarding national health resources, 3) regarding utilization of health resources, and 4) regarding the health of the nation’s people, as required by 42 U.S.C. § 242m(a);
- Prepare and publish, on March 15, 2020, the national disease prevention data profile including mortality and morbidity data, as required by 42 U.S.C. § 242p;
- Prepare and publish annually “all current material threat determinations” as to and related assessments of the sufficiency of the SNS of public health emergency countermeasures, as required by 42 U.S.C. § 247d-6b(c)(2)(C), (3)(A)–(B);
- Prepare and publish on June 15, 2019 and on March 15, 2020, an annual Threat-Based Review of the SNS, as required by 42 U.S.C. § 247d-6b(a)(2);⁹
- Prepare and publish, by June 24, 2020, a report on international efforts to develop pandemic countermeasures including vaccines, as required by Section 606 of the Pandemic Preparedness Act, 133 Stat. 905, 959;
- Prepare and publish, by June 24, 2020, a report on biological agents and toxins and their public health countermeasures, as required by 42 U.S.C. § 262a(k);
- Prepare and publish, by June 24, 2020, a report on the adequacy of the national blood supply, as required by Section 209 of the Pandemic Preparedness Act, 133 Stat. 905, 929;
- Prepare and publish annually a report from AHRQ “regarding prevailing disparities in health care delivery as it relates to racial factors and socioeconomic factors in priority populations,” as required by 42 U.S.C. § 299a-1(a)(6); and

⁹ Based on information and belief, the Secretary has not provided Congress any ongoing material threat determinations with respect to the public health threat posed by Covid-19 and the sufficiency of the SNS countermeasures supply to combat it, 42 U.S.C. § 247d-6b(c)(2)(A); nor has he 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). Should that be true, the Secretary either has not exercised the fullest extent of his powers to address Covid-19 or has done so and violated further transparency obligations.

- Prepare and publish, in 2017 and 2019, a biennial report on the programs of OMH, as required by 42 U.S.C. § 300u-6(f), *see* Williams Decl. Ex. B.

With respect to Defendants’ Withheld Participation Duties, they failed to (1) solicit the formal input of experts and stakeholders in public health emergency countermeasures planning in the PHEMCE SIP process, as required by 42 U.S.C. § 300hh-10(d)(2)(H); and (2) convene 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, as required by Section 605 of the Pandemic Preparedness Act, 133 Stat. 905, 958–59.

As described more fully *supra* in Section I, Defendants’ failure to meet these explicit statutory deadlines has harmed Plaintiffs. Because the relevant statutes do not provide Defendants with any discretion to miss these mandatory deadlines, they cannot justify their failures to act, and the court must compel them to comply with the statutes. *See* 5 U.S.C. § 701 (reviewing court “*shall . . . compel agency action unlawfully withheld*”) (emphasis added); *see also, e.g., Rodriguez v. Nielsen*, 2018 WL 4783977, at *15 n.21 (E.D.N.Y. Sept. 30, 2018) (“[T]he Court need not make a reasonability determination in deciding whether agency action was ‘unlawfully withheld’”). Accordingly, this Court should enter an order declaring that Defendants have breached these statutory requirements and directing Defendants to comply with these mandates as soon as practicable, but in any event no later than 20 days after entry of the order granting this relief.

B. Defendants’ Decision to Reroute Covid-19 Data to the Restrictive HHS Protect System Was Arbitrary and Capricious in Violation of APA Section 706(2).

In addition to providing a remedy when an agency unlawfully fails to act, the APA also allows courts to review certain actions agencies have taken. Under 5 U.S.C. § 706(2), a court may “hold unlawful and set aside” agency actions that are “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” Only a “final agency action” is reviewable under the

APA. *Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 882 (1990) (quoting 5 U.S.C. § 704). The Supreme Court has set forth a two-pronged approach to determine whether a challenged agency action is final and thus reviewable:

First, the action must mark the consummation of the agency's decision-making process—it must not be of a merely tentative or interlocutory nature. And second, the action must be one by which rights or obligations have been determined, or from which legal consequences will flow.

United States Army Corps of Eng'rs v. Hawkes Co., 136 S. Ct. 1807, 1813 (2016) (citation omitted). The analysis “is, fundamentally, a ‘pragmatic’ one.” *NRDC, Inc. v. United States DOI*, 397 F. Supp. 3d 430, 446 (S.D.N.Y. 2019) (quoting *Hawkes*, 136 S. Ct. at 1815).

At its core, the APA “requires agencies to engage in ‘reasoned decision-making.’” *Regents*, 140 S. Ct. at 1905 (citation omitted). Courts evaluating whether an agency action should be set aside engage in a “narrow standard of review” under which “a court is not to substitute its judgment for that of the agency.” *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 513 (2009). Rather, the court must determine whether agency officials “examined ‘the relevant data’ and articulated ‘a satisfactory explanation’ for [their] decision, ‘including a rational connection between the facts found and the choice made.’” *Dep't of Commerce v. New York*, 139 S. Ct. 2551, 2569 (2019) (citation omitted). In defense of judicial review under the APA, the Supreme Court has held that federal courts are only prohibited from examining discretionary decisions in “those rare circumstances where the relevant statute is drawn so that a court would have no meaningful standard against which to judge the agency's exercise of discretion.” *Id.* at 2568 (citation omitted).

In sum, to survive Section 706(2) review of an agency action, the government must have considered the relevant facts, taken reliance interests into account, made a reasonable decision, and adequately stated the reasons for that decision. The APA does not put executive branch officials in a policy straitjacket, however. “Agencies are free to change their existing policies as

long as they provide a reasoned explanation for the change.” *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2125 (2016). Agencies must take into account whether a longstanding policy has created reliance interests before changing it because in that situation “a reasoned explanation is needed for disregarding facts and circumstances that underlay or were engendered by the prior policy.” *Fox Television Stations*, 556 U.S. at 515–16. The court’s review “is limited to ‘the grounds that the agency invoked when it took the action.’” *Regents*, 140 S. Ct. at 1907 (citation omitted).

None of those things happened with the decision to shift hospitals’ data reporting requirements about Covid-19 from the CDC’s NHSN system, which was mostly publicly available, to the HHS Protect data warehouse via TeleTracking and state reporting systems, which are nowhere near as transparent.

The shift to TeleTracking and HHS Protect is a final agency action reviewable by this Court under Section 706(2). It is not a tentative or interlocutory decision—as of July 15, 2020, HHS *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. *See, e.g.*, Williams Decl. Ex. C. This reporting is the *only* data used by the federal government to determine distribution of limited supplies and medications such as the antiviral drug remdesivir. *Id.* at 1. Hospitals’ obligations have been redrawn—as have the criteria for patients to have access to potentially lifesaving medication—and health officials’ and the public’s ability to access this information has been restricted.

The shift in data collection and reporting should be reversed pursuant to Section 706(2) as arbitrary and capricious and an abuse of discretion for several reasons.

First, the justifications HHS officials provided for the change do not align with its consequences. On July 15, 2020, the day the change went into effect, Defendant Redfield said in

a public statement that “[c]ollecting and disseminating [health] data as rapidly as possible” was “the reason for the policy change.” Williams Decl. Ex. D. He said the change “reduces the reporting burden—it reduces confusion and duplication of reporting. Streamlining reporting enables us to distribute scarce resources using the best possible data.” Defendant Redfield said that “(i)n order to meet this need for flexible data gathering, CDC agreed that we needed to remove NHSN from the collection process, in order to streamline reporting.” *Id.* He said that state and local health departments have access to the TeleTracking information through HHS Protect, the department’s data warehouse that takes in the TeleTracking data. *Id.* Also that day, then-HHS Chief Information Officer Jose Arrieta asserted that “[a]ll 50 states and 6 territories have access to [HHS] Protect data at this time.” *Id.* Arrieta said that HHS Protect is “a central way to make this data visible to first responders at federal, state and local levels.” *Id.* He said the HHS Protect platform “enables easy access for all of our public health experts and leaders across HHS, as well as our other partners beyond HHS, including states and tribal partners. We are working with Congress to give all elected officials access to the data as well.” *Id.*

The shift to TeleTracking and HHS Protect largely does the *opposite* of what HHS officials said it was intended to do, *i.e.*, streamline reporting. Instead, it burdens hospitals’ reporting efforts. Defendants were quickly put on notice of the challenges they had imposed on local hospitals and health providers:

- In a letter to Defendant Azar, 22 state attorneys general warned that “hospitals and state public health departments are incurring substantial costs and operational challenges in trying to respond to the new data requests and reporting system. This sudden disruption threatens to further undermine the nation’s already chaotic response to the pandemic.” Williams Decl. Ex. E.
- Dr. Lisa Maragakis, the head of infection control for the Johns Hopkins Health System, testified before a U.S. House subcommittee in September that the NHSN system was largely automated but the TeleTracking system was not, meaning that hospitals had to enter data manually that they had been able to provide through their existing computer

systems; as a result, hospitals had to scramble to create new processes and gather new data, which “caused immediate chaos and confusion, and diverted critical resources to accomplish the new reporting requirements.” *See* Williams Decl. Ex. F.

- A collection of former NHSN advisors issued a statement saying the change “will have serious consequences on data integrity” and risked abandoning years of CDC-NHSN experience in gathering and analyzing the data. *See* Williams Decl. Ex. G. Perhaps most significant, they noted that the shift would undermine “meaningful inter-state comparisons, and to understand which Covid-19 mitigation strategies were successful (or failed),” a key goal of the Pandemic Preparedness Act and recent public health policy. *Id.*

As experts predicted, the change did not provide more timely access to Covid-19-related data. Its complex requirements were announced without warning to or input from the hospitals required to comply, and so access by state and local officials, stakeholders, and the public has not increased—rather, the change means *less information* is available and updates are posted *less frequently*:

- In July 2020, a coalition of stakeholders from the Infectious Diseases Society of America and others identified immediate shortfalls from the change: “Widely accessed Covid-19 tracking sites have already lost access to ICU hospitalization data—a key indicator for monitoring the state of the pandemic.” Williams Decl. Ex. H.
- A month after the switch, data analysis experts at The Covid Tracking Project reported that the data reported on the new HHS Protect site was “spotty and difficult to interpret,” noting that in several states the HHS data varied widely from – and changed at different rates than – the same data reported by state health officials. Williams Decl. Ex. I.
- Concurring, former CDC Director Dr. Thomas Frieden noted, in August, that data reporting on the new system was lagging by as much as eleven days and the data was being updated only once a week, versus three times per week under NHSN. Williams Decl. Ex. J.
- Dr. Maragakis’s September testimony noted that the CDC is not able to validate the TeleTracking data HHS policymakers use it to make decisions, raising serious concerns about the data’s reliability. *See* Williams Decl. Ex. F.

Third, there is no evidence that the government considered reliance interests in the CDC’s longstanding NHSN reporting system, as required by law. *See Fox Television Stations*, 556 U.S. at 515–16. Here, the reliance interests implicated by removing the NHSN Covid-19 reporting were,

quite literally, matters of life and death. Public health officials, researchers, health systems and hospitals all relied on the NHSN data to make informed decisions about allocation of resources and other aspects of their response to the pandemic. As a coalition of public health experts and advocacy groups including the American Association for the Advancement of Science, the American Public Health Association, and the National Association of State Emergency Medical Services Officials wrote in a letter to Vice President Pence and other members of the White House Coronavirus Task Force:

Data transparency is particularly critical in the midst of an unprecedented national health crisis that is disproportionately impacting certain segments of the U.S. population, including Black/African American, Latinx and Native American communities. Widely accessed COVID-19 tracking sites have already lost access to ICU hospitalization data – a key indicator for monitoring the state of the pandemic.

Williams Decl. Ex. K. HHS Protect does not share case numbers or infection rates with the public, but instead shows the percentage of hospitals and other facilities reporting Covid-19 events, a very different measure of the pandemic’s progress, and blames this on the “multiple reporting pathways” the new system must integrate and the fact that hospitals are reporting data that “varies by collection date”—attributes that were either avoided or handled better by NHSN. *See* Martinez Decl. ¶ 29; Williams Decl. Ex. L. This contradicts the widely held belief of public health experts that responsible and effective emergency management requires the comprehensive *collection and dissemination together* and that even the absence of certain criteria in case information can rob Plaintiffs and the public of critical public health insights. *See* Redlener Decl. ¶ 16 (importance of public education in public health work); Bassett Decl. ¶¶ 12–13 (importance of contextual data such as age or socioeconomic demographics in informing public health policy); Martinez Decl. ¶¶ 19–23 (importance of race and ethnicity as criteria for data collection and the mitigation strategies

derived therefrom); Oster Decl. ¶¶ 14–15 (importance of national, cross-jurisdictional data for developing schools’ mitigation efforts).

Fourth, besides failing to support the policy change, HHS’s stated reasons for the shift appear to be pretextual. Evidence suggests 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 in which the White House and political appointees including Defendants had more control over the kinds of true information that could contradict the *mis*-information spread by the President, who has admitted he has tried to “play down” the danger and impact of the pandemic. *See* Williams Decl. Ex. M. Public directives confess the true motives for the change: the original explanation offered for the change was that it would “assist *the White House Coronavirus Task Force*,” but, after widespread criticism of the move by hospitals and public health experts, HHS revised the directive to state that it will “greatly assist *the federal Covid-19 response*,” a transparent attempt to elide the real reason for the change. *Compare* Williams Decl. Ex. C. (emphasis added) *and* Williams Decl. Ex. N (emphasis added). The true goal of moving the data out of the CDC and the public’s hands was to give the White House task force more control over what data is collected and made public.

National Public Radio recently obtained internal HHS emails that show detailed hospital data from the TeleTracking system is provided daily to only a few dozen officials at the CDC and other HHS agencies, including one member of the White House Coronavirus Task Force. *See* Williams Decl. Ex. O. A smaller subset of that data is made public—usually only once per week—hiding the daily analyses that show sharp increases in hospitalizations and strain on the nation’s health system, NPR reported. *Id.* Although HHS says some 800 state public health officials have access to the more detailed data, it is only available for their own state (unless other states agree to share), blinding state officials to regional trends. *Id.*

The decision to shift reporting of hospitals' Covid-19-related data from the CDC to TeleTracking should be reversed under the Administrative Procedure Act because it is a "clear error of judgment." *Weyerhaeuser*, 139 S. Ct. at 371 (citation omitted). This Court therefore should enter an order directing Defendants within 30 days to reverse the decision and resume hospitals' Covid-19 reporting via the NHSN system. In the alternative, the Court should enter an order directing Defendants to make the hospital reporting data publicly available to the same extent it had been under the NHSN system.

C. Plaintiffs' Injuries Fall within the Zone of Interests of the Pandemic Preparedness Act and Other Public Health Statutes They Seek to Enforce.

Plaintiffs additionally will satisfy the "zone of interests test" necessary to prevail on their APA claims because their interests in having Defendants fulfill their statutory duties in the face of the Covid-19 pandemic "fall within the zone of interests protected by the law[s] invoked." *Bank of Am. Corp. v. City of Miami*, 137 S. Ct. 1296, 1302 (2017).¹⁰ "Because Congress intended to make agency action presumptively reviewable under the APA, [the zone-of-interests] test is not especially demanding in the context of APA claims and may be satisfied even if there is no 'indication of congressional purpose to benefit the would-be plaintiff.'" *New York v. United States Dep't of Homeland Sec.*, 969 F.3d 42, 62 (2d Cir. 2020) (quoting *Clarke v. Sec. Indus. Ass'n*, 479 U.S. 388, 399–400 (1987)). Indeed, the test "forecloses suit only when a plaintiff's interests are so marginally related to or inconsistent with the purposes implicit in the statute that it cannot

¹⁰ Courts have previously classified this "zone-of-interests" test as an element of "prudential standing." *Fed. Defs. of N.Y., Inc. v. Fed. Bureau of Prisons*, 954 F.3d 118, 128 (2d Cir. 2020). However, interpreting the Supreme Court's 2014 *Lexmark* decision, the Second Circuit has clarified that "the zone-of-interests test actually determines whether a plaintiff has the right to sue under a particular substantive law, and is not of jurisdictional import." *Id.* (citing *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 126–27 (2014)). The "right to sue for violation of a statute," in other words, is "like any other element of a cause of action." *Lexmark*, 572 U.S. at 134 n.6 (quotations omitted).

reasonably be assumed that Congress intended to permit the suit.” *Fed. Defs. of N.Y., Inc. v. Fed. Bureau of Prisons*, 954 F.3d 118, 128 (2d Cir. 2020) (quoting *Match-E-Be-Nash-She-Wish Band of Pottawatomí Indians v. Patchak*, 567 U.S. 209, 225 (2012)). If the stated interest even “arguably” falls within the zone of interests protected by the statute, then this “lenient” test is satisfied. *Id.*

The substantive statutes at issue, rather than the APA, define the zone of interests for an APA claim. *Id.* (citing *Match-E-Be-Nash-She-Wish*, 567 U.S. at 224)). Plaintiffs’ interests easily fall within the zone of interests protected by the various statutes under which they bring suit because the harms wrought by Defendants’ misconduct are precisely those Congress sought to prevent when it voted them into law. Congress enacted the Pandemic Preparedness Act to enhance the government’s “capabilities for public health surveillance and reporting activities,” with the ultimate goal of developing a nationwide, “interoperable network of systems” to identify, track, and combat public health emergencies. 42 U.S.C. § 247d. Upon the passage of the Act, Defendant Kadlec understood the Act was intended to protect the country against “the adverse health effects of public health emergencies” such as “*a disease pandemic*” during which “*direct federal support is needed.*” Williams Decl. Ex. P. (emphasis added).

To these ends, the Act requires Defendants to amass and report public health data. *See supra* Section II.A. It similarly requires Defendants to make specific reports on the government’s health emergency infrastructure, the nation’s public health resources, public health risks facing the nation, and disparities in health care delivery among different racial and socioeconomic groups. *See id.* Overarching these obligations is Congress’s mandate to HHS to collect data on health-related issues and disseminate it in the form of “high quality, timely, and comprehensive” reports on “as wide a basis as possible.” 42 U.S.C. § 242b; *see New York*, 969 F.3d at 62 (analyzing the

challenged provision “within the broader context of the [law]” to obtain a “fuller picture of the interests implicated in the statute”). Indeed, this mission had been advanced by requiring hospitals to report Covid-19 data to the NHSN system prior to Defendants’ decision to channel information through the less transparent TeleTracking system.

Under each of these statutes, as discussed above, Plaintiffs have been irreparably harmed by Defendants’ failure to follow Congress’ command in collecting and reporting this data. Plaintiffs, individuals and organizations directly responding to the pandemic on behalf of their communities through direct care and advocacy, are among the parties in greatest need of the information and participation that Defendants have withheld. Far from being “marginally” or even merely “arguably” related to Congress’s purpose in enacting these statutes, Plaintiffs’ particular harms are exactly those that Congress sought to avert. Plaintiffs’ claims fall directly into the zone of interests protected by these statutes.

III. THE BALANCE OF EQUITIES AND PUBLIC INTEREST WEIGH IN FAVOR OF GRANTING THE INJUNCTION.

In assessing the balance of equities, “the court must ‘balance the competing claims of injury and must consider the effect on each party of the granting or withholding of the requested relief,’ as well as ‘the public consequences in employing the extraordinary remedy of injunction.’” *Make the Rd. New York*, 419 F. Supp. 3d at 665 (quoting *Winter*, 555 U.S. at 24). “These factors merge when the Government is the opposing party.” *Id.* (quoting *Nken v. Holder*, 556 U.S. 418, 435 (2009)).

Make the Road New York is an apt analogy. There, plaintiffs argued that DHS violated the APA (among other claims) when it promulgated a rule preventing noncitizens from gaining admission to the United States if they were found “likely at any time to become a public charge” due to their potential use of federal health programs and other government services. *Id.* at 653–54,

660–65. The court granted plaintiffs’ preliminary injunction, finding in part that remedying the “public health harms” threatened by non-citizens’ refusal to seek medical care in order to protect their immigration status provided “a significant public benefit.” *Id.* at 665–66. Defendants’ errant decision-making risked causing “worse health outcomes” such as “increased prevalence of communicable diseases,” “reduced productivity and educational attainment,” and “other unanticipated consequences and indirect costs.” *Id.* at 666. As for the government, there was “no public interest in allowing [defendants] to proceed with an unlawful, arbitrary, and capricious rule that exceeds their statutory authority,” and the court disregarded defendants’ arguments that it was an “impediment” to administer the immigration system without violating the APA. *Id.* at 666. The “inverse is also true: there is a substantial public interest in having governmental agencies abide by the federal laws that govern their existence and operations.” *Id.* (quoting *Planned Parenthood of NYC, Inc. v. United States Dep’t of Health & Human Servs.*, 337 F. Supp. 3d 308, 343 (S.D.N.Y. 2018) (alterations omitted)).

The analysis is the same here. There is substantial public interest in ensuring that the government fulfills its legal obligations. This is especially so where the legal obligations are attendant to keeping the public safe and informed in the midst of a nationwide public health emergency. *See, e.g., In re Sealed Case*, 121 F.3d 729, 749 (D.C. Cir. 1997) (“[O]penness in government [is] crucial to ensuring that the people remain in control of their government.”). Plaintiffs seek nothing from Defendants other than what is demanded of them by statute. “There is generally no public interest in the perpetuation of unlawful agency action.” *Planned Parenthood of NYC*, 337 F. Supp. 3d at 343 (quoting *League of Women Voters of U.S. v. Newby*, 838 F.3d 1, 12 (D.C. Cir. 2016)). Accordingly, the final factor favors granting preliminary injunctive relief.

IV. PLAINTIFFS HAVE STANDING TO SUE.

In addition to demonstrating that they are entitled to a preliminary injunction, the allegations and evidence here demonstrate that Plaintiffs possess standing, as required by Article III of the United States Constitution, to press their claims.

Standing is a prerequisite for invoking federal court jurisdiction, including when moving for a preliminary injunction. *See Cacchillo v. Insmed, Inc.*, 638 F.3d 401, 404 (2d Cir. 2011). A plaintiff has standing to sue so long as they “(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision.” *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016).¹¹ The plaintiff’s injury must be “concrete and particularized” and “actual or imminent, not conjectural or hypothetical.” *Id.* at 1548 (quotation omitted). This is not a demanding burden—according to the Second Circuit, there is a “low threshold” to establish an injury-in-fact. *John v. Whole Foods Mkt. Grp., Inc.*, 858 F.3d 732, 736 (2d Cir. 2017).

The traceability requirement is a question of causation. *See Rothstein v. UBS AG*, 708 F.3d 82, 91 (2d Cir. 2013). The harm need only be “fairly traceable” to the defendant’s conduct, *Melendez v. N.Y.C. Dep’t of Educ.*, 420 F. Supp. 3d 107, 118 (S.D.N.Y. 2019), which amounts to “something less than the concept of proximate cause,” *Connecticut v. Am. Elec. Power Co.*, 582 F.3d 309, 346 (2d Cir. 2009), *rev’d on other grounds*, 564 U.S. 410 (2011). The element is satisfied so long as “the injury was in some sense caused by the opponent’s action or omission.” *Cortlandt St. Recovery Corp. v. Hellas Telecomms., S.à.r.l.*, 790 F.3d 411, 417 (2d Cir. 2015).

¹¹ Although each of the Plaintiffs has standing with respect to all of the claims in the Complaint, the Court’s jurisdictional requirements are satisfied so long as it finds *one* Plaintiff who has standing to bring each claim. *Centro de la Comunidad Hispana de Locust Valley v. Town of Oyster Bay*, 868 F.3d 104, 109 (2d Cir. 2017) (making permanent the lower court’s preliminary injunction).

A plaintiff's injury is redressable if they "seek[] relief directly from [Defendants] that is within the court's authority to order." *Cacchillo*, 638 F.3d at 404. If court action is "reasonably designed" to provide even partial relief, this test is met. *Huntington Branch, NAACP v. Town of Huntington*, 689 F.2d 391, 394 (2d Cir. 1982); *Knight First Amendment Inst. at Columbia Univ. v. Trump*, 302 F. Supp. 3d 541, 561 (S.D.N.Y. 2018) (quotation omitted).

As discussed above, Plaintiffs have suffered numerous concrete and particularized harms caused by Defendants' inaction. *See supra* Section I. Moreover, each of these harms are likely to be at least partially redressed by a Court order that compels Defendants to adhere to the governing statutes. Plaintiffs meet this threshold requirement and have standing to sue.

A. Plaintiffs' Informational Injuries Constitute Injuries-in-Fact, Are Traceable to Defendants, and Will Be Redressed by Injunctive Relief.

A plaintiff suffers a concrete and particularized injury-in-fact where an agency unlawfully fails to collect and report information that could provide some benefit to the plaintiff. "The law is settled that a denial of access to information qualifies as an injury in fact where a statute (on the [plaintiffs]' reading) requires that the information be publicly disclosed and there is no reason to doubt [the plaintiffs'] claim that the information would help [them]." *NRDC, Inc. v. United States EPA*, 961 F.3d 160, 168–69 (2d Cir. 2020) (quotation omitted); *see also, e.g., NRDC*, 961 F.3d at 168–69 (EPA's decision exempting some manufacturers from mercury reporting requirements concretely harmed the NRDC's environmental advocacy efforts and the state plaintiff's law enforcement efforts). Such an injury may occur even where the law does not require disclosure to the plaintiff personally, even where the impact is only to the plaintiff's ability to advocate or evaluate public policy, and even from a mere degradation in data quality. *See, e.g., Akins*, 524 U.S. at 21 (group of voters suffered an injury-in-fact when they were unable to obtain information that would help them "evaluate candidates for public office"); *Public Citizen v. Dep't of Justice*, 491

U.S. 440, 449 (1989) (finding informational injury where withheld information regarding the selection of federal judges impeded effective participation in the judicial selection process); *New York v. United States DOC*, 351 F. Supp. 3d 502, 610–15 (S.D.N.Y. 2019), *aff'd in relevant part sub nom. Dep't of Commerce v. New York*, 139 S. Ct. 2551 (2019); *ASPCA v. Feld Ent., Inc.*, 659 F.3d 13, 26–27 (D.C. Cir. 2011) (injury-in-fact exists where agency activity is at “loggerheads with the organization’s mission” and impacts its advocacy efforts); *United to Protect Democracy v. Presidential Advisory Comm’n on Election Integrity*, 288 F. Supp. 3d 99, 110 (D.D.C. 2017) (informational injury predicated in part on the harm caused to plaintiff’s ability to engage in “advocacy efforts” during notice-and-comment process); *Nat. Res. Def. Council v. Lujan*, 768 F. Supp. 870, 872–75, 877 (D.D.C. 1991) (individual and organizational plaintiffs harmed where they were “frustrated in their ability to participate in the . . . debate”).

Accordingly, the harms Plaintiffs have suffered are cognizable injuries-in-fact. The Pandemic Preparedness Act and related statutes impose clear-cut requirements on Defendants, including the Withheld Biosurveillance Duties and Withheld Reporting Duties, to collect and promptly report, in public fora, certain public health information. *See supra* Section II.A. By neglecting these requirements, Defendants have deprived Plaintiffs of information to which they are entitled. *See, e.g., NRDC*, 961 F.3d at 168–69. A similar deprivation arises from Defendants’ arbitrary and capricious decision to divert hospital data from public CDC databases to restricted locations. *See supra* Section II.B.

This missing data unquestionably would be helpful to Plaintiffs, providing “near real-time” information regarding viral prevalence and positioning Plaintiffs to develop and advocate for better policy, improve their efforts to contain the virus within their communities, and divert fewer resources to their own health surveillance and mitigation efforts. *See Greenberg Decl.* ¶¶ 16–20;

Joseph Decl. ¶¶ 27–39; King Decl. 49–57; Levine Decl. ¶¶ 17–20, 22–27; *see also* Oster Decl. ¶¶ 6–8 (aggregating Covid-19 data across schools can reveal effective mitigation strategies and best practices). They also would be alleviated of the burden of having “to find the same information elsewhere.” *Council of Parent Attorneys & Advocates, Inc. v. DeVos*, 365 F. Supp. 3d 28, 40–41 (D.D.C. 2019). These satisfy the injury-in-fact requirement.

The remaining elements of standing are satisfied as well. Plaintiffs’ “injuries are . . . fairly traceable to the [Defendants’] omissions of information, in the sense that they would not suffer from the asserted informational deficit absent the challenged reductions in reporting and disclosure,” *NRDC*, 961 F.3d at 169, and Defendants’ omissions here caused Plaintiffs’ harms. Granting the relief Plaintiffs seek would “redress those injuries by requiring that [Defendants] report” the information they are unlawfully withholding. *Id.*; *see also, e.g., EDF v. EPA*, 922 F.3d 446, 453 (D.C. Cir. 2019) (plaintiff has standing where there was “no reason to doubt that access to additional information . . . will promote [plaintiff]’s environmental interests, research, and educational activities” (quotations omitted)). With this information finally disclosed, Plaintiffs will be better able to mitigate the risks and harms posed to them and their constituents by Covid-19—and, beyond, Plaintiffs stand to benefit from the nation’s enhanced “biosurveillance” capabilities. Plaintiffs have suffered informational injuries that are traceable to Defendants and redressable by the Court. They each, therefore, have standing to bring their claims.

B. Plaintiffs’ Procedural Injuries Constitute Injuries-in-Fact, Are Traceable to Defendants, and Will Be Redressed by Injunctive Relief.

The procedural harms Plaintiffs have suffered at the hands of the Administration’s inaction also confer standing to sue. “When a litigant is vested with a procedural right, that litigant has standing if there is some possibility that the requested relief will prompt the injury-causing party to reconsider the decision that allegedly harmed the litigant.” *Massachusetts v. EPA*, 549 U.S. 497,

518 (2007). A plaintiff, therefore, has standing when they are deprived of an opportunity, required by statute, to participate in an agency's decision-making, including the notice-and-comment process. *See Lafleur v. Whitman*, 300 F.3d 256, 259, 271 (2d Cir. 2002) (neighbor of proposed chemical plant had standing to challenge EPA's decision exempting the plant from heightened permitting requirements, which deprived plaintiff of "the benefit of additional procedures" such as "additional environmental impact studies and further public commentary"); *Town of Babylon v. Fed. Hous. Fin. Agency*, 699 F.3d 221, 228–29 (2d Cir. 2012).

Because the harm suffered is *procedural*, and not grounded on the *substance* of the challenged action, the burden for establishing standing is somewhat relaxed, and Plaintiffs readily satisfy Article III's requirements. Aside from the concrete harm caused by Plaintiffs' exclusion from the decision-making process in and of itself, Defendants' failure to solicit public input constitutes an injury-in-fact because it prevents the Administration from taking further mandated action to combat the Covid-19 pandemic and subjects Plaintiffs to the risk that any action the Administration does take will be uninformed and detrimental. *See, e.g., Ctr. for Biological Diversity*, 571 F. Supp. 2d at 1112–13, 1116 (standing to challenge failure to provide an environmental report—even though there was no direct provision requiring public involvement in the report—because, "reading the statute as a whole," public participation was required in information gathering that underlay the report); *Nat. Res. Def. Council*, 768 F. Supp. at 877 (plaintiffs harmed by "risk that serious environmental impacts [of the proposed policy] will be overlooked" due to agency's failure to obtain public input (quotation omitted)).

The existence of procedural harms also "relaxes a plaintiff's burden on the traceability and redressability prongs of the Article III standing test." *Ctr. for Biological Diversity*, 571 F. Supp. 2d at 1122 (citing *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 572 n.7 (1992)). Here, each Plaintiff

would have benefitted from the opportunity to participate in Defendants' decision-making and, with that opportunity, could have advocated for measures to improve agency action, increase the government's situational awareness of issues arising from the pandemic, and decrease Plaintiffs' and their communities' risk from Covid-19 and future health threats. Plaintiffs have standing to bring their claims.

C. The Diversion of Resources Constitutes an Injury-in-Fact, Is Traceable to Defendants, and Will Be Redressed by Injunctive Relief.

Finally, courts have long recognized that organizations have standing to challenge conduct that causes "concrete and demonstrable injury to [the organization's] activities—with the consequent drain on [the organization's] resources." *Havens Realty*, 455 U.S. at 379; *see also Make the Rd.*, 419 F. Supp. 3d at 657 ("[A]n organization has standing where the defendant's conduct interferes with or burdens the organization's ability to carry out its usual activities, or where the organization is forced to expend resources to prevent some adverse consequence on a well-defined and particularized class of individuals." (citation omitted)). Injury-in-fact requires "only a 'perceptible impairment' of an organization's activities," *Nnebe v. Daus*, 644 F.3d 147, 157 (2d Cir. 2011) (quotation omitted), where defendants' actions in any way impede the organization's ability to carry out its responsibilities. *See Town of Oyster Bay*, 868 F.3d at 110.

This element is met here. As detailed *supra* in Section I.C., Plaintiffs CIP and Housing Works have been forced, due to the lack of information, guidance, or resources for addressing the risks presented by the pandemic, to divert resources from their usual organizational priorities in order to protect their communities against an uncertain threat. And these injuries are traceable to Defendants and redressable by the Court. The relief Plaintiffs seek will compel the Administration to perform its Withheld Reporting Duties and Withheld Biosurveillance Duties, and the information produced, though belated, will help CIP and Housing Works better tailor their

programs to the risks their respective communities confront. Moreover, the opportunity to participate in rule-making comment and public discussions will ensure that the needs and experience of organizations like CIP and Housing Works will be considered in the design and implementation of the “biosurveillance network” and, going forward, produce the “near real-time” information they need to operate during the pandemic. This, in turn, will alleviate the burden they bear in carrying out duplicative health monitoring and alternative programs, allowing Plaintiffs to return their resources to fulfilling their organizational missions. A clear causal chain links Defendants’ infractions and Plaintiffs’ harms, which is all that Plaintiffs need to show. *See, e.g., New York*, 351 F. Supp. 3d at 622–23 (traceability is established “where record evidence, statistical analysis, or just plain common-sense support a [causal] finding” (citing *Davis v. FEC*, 554 U.S. 724, 734–35 (2008))). Thus, Plaintiffs have standing to sue.

CONCLUSION

Congress directed Defendants to complete discrete, express tasks to aid the government and the public’s preparation for and response to emergencies like the Covid-19 pandemic. Defendants continue to ignore these obligations, causing significant, particular, ongoing and irreparable harm to Plaintiffs, and exacerbating the crisis facing the American people at large. The Court should compel Defendants immediately to fulfill their statutory duties. For all of the foregoing reasons, Plaintiffs respectfully request that the Court grant their Motion for a Preliminary Injunction.

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