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,	:	No. 1:20-cv-9144(VM)
-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.	:	

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

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INTRODUCTION

Defendants' opposition papers concede their failure to perform their obligations under various federal public health statutes, each of which relate directly to our nation's ability to respond to the ongoing coronavirus pandemic. To excuse these failures, Defendants argue that Covid-19 has prevented them from meeting obligations due months or years before the disease surfaced in the United States, and paradoxically contend that the exigency of the pandemic should excuse—rather than *demand*—the completion of tasks directly related to this very event.

These duties are mandatory, and Defendants' failure to fulfill them has directly and irreparably harmed Plaintiffs, who stand on the frontlines of New York's Covid-19 pandemic response. Defendants, nonetheless, assert Plaintiffs would not "add value to, or likely benefit from" the creation of the biosurveillance network contemplated by the Pandemic Preparedness Act. Apart from ignoring the declarations of Plaintiffs and their experts, Defendants' argument contradicts the public position they have taken since the onset of the pandemic: local actors are responsible for their own solutions, and the federal government is meant to assist, but not lead, those efforts.

Plaintiffs do not ask this Court to implement their preferred policy outcomes or substitute Plaintiffs' preferences for the agencies' judgment. They only request that Defendants fulfill the duties demanded by Congress, whose public health laws depend on broad access to timely and accurate information. Given the urgent need for relief and Plaintiffs' factual showing, which is largely undisputed, the motion for a preliminary injunction should be granted.[1]

[1] Unless otherwise noted, in all references, emphasis is added, and citations, internal quotation marks, and alterations are omitted. Abbreviations used herein have the meaning assigned to them in Plaintiffs' Memorandum of Law, Dkt. [7] ("Mem."). "Opp." refers to Defendants' brief in opposition to this motion, Dkt. [33].

DEFENDANTS' ADMISSIONS

Defendants readily admit that they failed to perform nearly all of the duties at issue and promised to complete most of them within a matter of weeks, *see* Opp at 3-13:

1. Defendants failed to complete, but promise to soon deliver, **eleven reports or disclosures**: **five by December 31, 2020**, *see* Opp. at 7, 8. 11, 13 (regarding 42 U.S.C. § 247d-6b(c)(2) (SNS MTD Report); *id.* § 262a(k)(2)(A) (FESAP Report); *id.* § 299a-1(a)(6) (AHRQ Disparities Report), *id*. § 300hh-10(d) (Countermeasures SIP), P.L. 116-22 § 606, 133 Stat. 905, 959 (international vaccine report)); **one by December 31, 2020 or first quarter 2021**, *see* Opp. at 10 (regarding 42 U.S.C. § 247d-6b(a)(2) (SNS Threat Based Review)); **one by January 2021**, *see* Opp. at 6 (regarding P.L. 116-22 § 209, 133 Stat. 905, 929 (national blood supply report)); **one "early in 2021,"** *see* Opp. at 9 n.1 (regarding 42 U.S.C. §§ 247d-3a(i)(1)(E), (j), 247d-3b(i)(1)) (state/local emergency funding reports); and **three are "forthcoming," being "finalized," or "under development,"** *see* Opp. at 12-13 (regarding respectively 42 U.S.C. § 242m(a)(1)-(2) (four public health reports); *id.* § 242p(a) (disease prevention data profile); *id.* § 300u-6(f)(1) (OMH report)). As to **two other duties**, Defendants say one is delayed without a completion date, *see* Opp. at 8-9 (regarding *id*. § 300hh-10(b)(7) (Countermeasures SIP budget)), and claim no obligation to the other despite an explicit statutory provision for public disclosure, *see* Opp. at 11 (regarding 42 U.S.C. § 247d-6b(c)(3)(A)-(B) (SNS assessments)).

2. As to Defendants' **two duties involving public participation**, they promise to complete one in 2021, *see* Opp. at 7 (regarding P.L. 116-22 § 605, 133 Stat. 905, 958-59 (genomic countermeasures meeting)), and claim the other is completed, *see* Opp. at 8 (regarding 42 U.S.C. § 300hh-10(d)(2)(H) (Countermeasures SIP input)).

3. With respect to their **four duties to implement a national biosurveillance network**, one missing report is promised in January 2021. *See* Opp. at 6 (regarding P.L. 116-22 § 205(c), 133 Stat. 905, 924-25 (Biological Threat Detection Report)). The rest are only partly performed or not performed, and Defendants make no promises as to completion. *See* Opp. at 5-6 (regarding 42 U.S.C. § 247d-4(c)(5)(B) (public meeting); *id.* § 247d-4(b)(2)-(3) (standards and notice/comment)).[2]

By their own account, Defendants represent that they have fully met their statutory obligations in only one case—itself a prerequisite to an unfinished reporting duty. Opp. at 8; 42 U.S.C. § 300hh-10(d)(2)(H)). For some provisions, Defendants claim they *partially* performed some of their duties,

[2] For the Court's convenience, Plaintiffs append a chart of the statutory duties at issue, their deadlines, and Defendants' representations as to their proposed compliance as Attachment A to page 20 of this reply memorandum.

but these actions are at best stale, incomplete or unrelated, and thus do not satisfy the statute.[3]

ARGUMENT

In light of their admissions, Defendants are left to argue that Plaintiffs have not been injured—a contention repeated in the context of standing, likelihood of success on the merits, irreparable harm, and balance of equities. Fundamentally, Defendants argue that Plaintiffs are not the kinds of people and organizations who are entitled to or would benefit from the relief they seek. The argument strains credulity, given Plaintiffs' unique positions on the frontlines managing their communities' pandemic responses. Defendants' admitted violations must be remedied.

I. Plaintiffs' Claims are Substantially Likely to Succeed on the Merits, Because Defendants Already Acknowledged Violating Their Statutorily-Mandated Duties.

As set forth below, *each* of the Plaintiffs has suffered multiple types of injuries, and these injuries are concrete, particularized and actual. In light of these injuries and Defendants' admissions, Plaintiffs' claims have a clear and substantial likelihood to succeed.

A. Plaintiffs Have Standing Because They Have Been Directly Harmed.

Plaintiffs have been injured by Defendants' conduct in three, independent ways. First, they have suffered informational injury, because Defendants did not make statutorily-required public

[3] For example, as to Defendants' duties under 42 U.S.C. §§ 247d-3a(i)(1)(E), (j) and 247d-3b(i)(1), they point to two public websites, Opp. at 9-10, with concededly stale data: the latest from 2017 and 2018 respectively and last updated in October 2018. Defendants also refer to the performance of *other* statutory duties and claim it should partly satisfy here: e.g., they claim two biosurveillance duties—42 U.S.C. §§ 247d-4(c)(5)(B), 42 U.S.C. § 247d-4(b)(2)-(3)—were partially met by a "listening session" and by certain data standards, *see* Opp. at 5, but these acts were pursuant to *different* legislation—including the "21st Century Cures Act," P. L. 114-255, 130 Stat. 1033 (Dec. 13, 2016)—and relate to *different* purposes: data management and health privacy, not emergency preparations and biosurveillance. *See* Arias Decl. ¶ 5-6. Similarly, they point to a general meeting on "bioeconomy" to partly satisfy P.L. 116-22 § 605, 133 Stat. 905, 958-59, which by their own description did not discuss emergency or countermeasures preparations as required, nor did it include statutorily-required attendees. *See* Opp. at 7; Bratcher-Bowman Decl. ¶ 16. To satisfy P.L. 116-22 § 606, 133 Stat. 905, 959, they promise an admittedly incomplete report that would lack Covid-19 information and that would otherwise be required. Opp. at 7.

disclosures. Second, they have suffered procedural injury, because they have been denied the opportunity to participate in agency decision-making, also required by statute. Third, to step into the breach where Defendants failed, they have diverted organizational resources. All of these injuries are traceable to Defendants (who concede they are responsible for the failures) and redressable by an injunction (to compel them to take remedial action). Finally, Plaintiffs, who are directly involved in public health initiatives, services, and advocacy, are in the zone of interests covered by the public health statutes at issue. Plaintiffs therefore have standing.[4]

1. Plaintiffs Have Suffered Informational Injuries.

"The law is settled that a denial of access to information qualifies as an injury in fact where a statute (on the claimants' reading) requires that the information be publicly disclosed and there is no reason to doubt their claim that the information would help them." *EDF v. EPA*, 922 F.3d 446, 452 (D.C. Cir. 2019) (quotation omitted).[5]

Defendants repeatedly suggest that Plaintiffs injuries are "vague" and "conclusory." *See* Opp. at 20, 27, 29. Plaintiffs, however, have detailed their need for relief in the Complaint and

[4] Where "multiple parties seek the same relief, the presence of one party with standing is sufficient to satisfy Article Ill's case-or-controversy requirement." *Centro de la Comunidad Hispana de Locust Valley v. Town of Oyster Bay*, 868 F.3d 104, 109 (2d Cir. 2017).

[5] Defendants argue that, to establish informational injury, Plaintiffs must show they suffered "the type of harm Congress sought to prevent by requiring disclosure." *NRDC v. Dep't of Interior*, 410 F. Supp. 3d 582, 597 (quoting *Electronic Privacy Info. Ctr. v. Pres. Advisory Comm'n on Elec. Integrity*, 878 F.3d 371, 378 (D.C. Cir. 2017), which predates the case law Plaintiffs cite). Plaintiffs' standard, however, traces to *FEC v. Akins*, the seminal Supreme Court decision on informational harm. *See* 524 U.S. 11, 21 (1998) (organization's injury was "concrete and particular" because there was "no reason to doubt [its] claim that the information [it was unable to obtain] would help [it]"). Plaintiffs satisfy Defendants' standard anyway for the same reasons their claims fall within the zone of interests protected by the statutes. *See infra* Part I.C. The statutes here contain countless calls to the values of participation, transparency, public education, and oversight. *See, e.g.*, 42 U.S.C. § 242m(c) (requiring information to be promptly disseminated to the public); *NRDC v. Dep't of Interior*, 410 F. Supp. 3d at 597.

their declarations.[6] While Defendants might not consider much of the information at issue here relevant to *their* pandemic response, *see* Opp. at 7-13, 30-31, 34-35; Bratcher-Bowman Decl. ¶¶ 7, 14, 16; Foley Decl. ¶ 5; Nguyen Decl. ¶ 5, public health experts widely agree that the information here is useful and relevant to Plaintiffs' local Covid-19 activities.[7]

Thus, the analysis turns on whether the Pandemic Preparedness Act and other relevant public health statutes require disclosure to Plaintiffs. To begin, several of the statutes explicitly require disclosures to the public, satisfying standing as to those reports.[8] These also include duties to improve the national "biosurveillance" network to detect and contain pandemic threats.[9]

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[6] *See e.g., See* Joseph Decl. ¶¶ 37-39 (informational injuries from Defendants' failure to report on disparities in health outcomes); King Decl. ¶¶ 53-54 (informational injuries from Defendants' failure to report on prevalence of disease and morbidities, which relate to Housing Works' mission); Levine Decl. ¶ 15-17, 20 (informational injuries from lack of national public health data and Defendants' failure to report on minority health disparities, which impacts legislator's constituency); Greenberg Decl. ¶ 20 (harm to ability to advocate for policies that could save lives because of lack of public meetings); *see also* Redlener Decl. ¶ 14 (noting importance of missing information to public health activities generally).

[7] Information on the government's preparations and capacity to respond to *all* public health emergencies—including the present pandemic—would aid Plaintiffs' advocacy efforts and avoid duplication at the community level. Redlener Decl. ¶¶ 10-12. Non-Covid-19 public health information provides much needed context to better understand the vulnerabilities of different communities to adverse Covid-19 outcomes. This includes information that would reveal the presence of comorbidities and underlying conditions that might interact with or exacerbate coronavirus infection; national and regional data that sheds light on why different jurisdictions and their intervention strategies fare better or worse; and how to mitigate the health disparities along race and ethnicity that arise in the communities Plaintiffs serve and that Covid-19 has exacerbated. Bassett Decl. ¶¶ 8, 12-13, 17-20, 22-23; Martinez Decl. ¶¶ 8-13, 18-26; Oster Decl. ¶¶ 5-8. 12-15; Redlener Decl. ¶¶ 10, 15. For example, Black and Latinx persons are three times as likely contract and twice as likely to die from Covid-19 as white persons. Bassett Decl. ¶ 18; Martinez Decl. ¶ 6.

[8] *See, e.g.*, 42 U.S.C. § 247d-3a(j) (state and local fact sheets); *id.* § 300hh-10(d) (Countermeasures SIP); *id*. § 300hh-10(b)(7) (countermeasures budget plan); *id.* § 242m(a), (c) (four annual public health reports); *id.* § 242p(a),(b) (national data prevention profile); *id.* § 247d-6b(c)(3)(A)-(B) (SNS MTD Report and assessments of countermeasures' availability and appropriateness). In their argument, Defendants ignore a number of statutes that explicitly require disclosures to the public. *See* Opp. at 24.

[9] Defendants have had duties related to biosurveillance since 2013, when legislation called for the

As to other requirements, Defendants argue that because statutes "require the reports to be provided to Congress, rather than to be made publicly available," Opp. at 22, Plaintiffs are not entitled to the information and do not have standing. They cite *NRDC v. Hodel*, 865 F.2d 288 (D.C. Cir. 1988) for the proposition that "congressional reporting requirements are not susceptible to judicial review," Opp. at 37. But just last year, this Court explained that *Hodel* only applies to the situation where a Plaintiff claims "that the statutorily mandated report [was] somehow 'inadequate.'" *New York v. United States DOC*, 351 F. Supp. 3d 502, 645 (S.D.N.Y. 2019) *aff'd in relevant part by Dep't of Commerce v. New York*, 139 S. Ct. 2551 (2019) (quoting *Hodel*, 865 F.2d at 318-19). But where the claim, as here, is that "the relevant Executive Branch official . . . *failed entirely* to report back to Congress," private plaintiffs can challenge the failure. *New York*, 351 F. Supp. 3d at 645. *New York* squarely governs, and *Hodel* does not apply.[10] *See also Ctr. for Biological Diversity v. Brennan*, 571 F. Supp. 2d 1105, 1125 (N.D. Cal. 2007) (a challenge to "the adequacy or sufficiency of required reports" to Congress is not actionable, but plaintiff may

creation of such a network by 2015. *See* P.L. 113-5 § 204, 127 Stat. 161, 177-78 (Mar. 13, 2013) (amending 42 U.S.C. § 247d-4(c), (g). The provisions of the Pandemic Preparedness Act improve upon that foundation, and their purpose, in large measure, was to engage public input. *See, e.g.*, 42 U.S.C. § 247d-4(c)(5)(B) (public meeting) and *id.* § 247d-4(b)(2)-(3) (reporting standards and notice/comment). Defendants' argument that *these* duties can be left unfulfilled because the statute requires final completion of *others* in 2023, *see* Opp. at 3-6, 31, 34, fails for multiple reasons. First, the already unmet provisions are substantive in their own right and advance the nation's biosurveillance capabilities, public awareness and public participation. Second, these are not "building blocks" with no utility until there is a "finished" network, Opp. at 31, but a renovation of the existing biosurveillance infrastructure per prior legislation and to which piecemeal improvements can result in immediate benefits. Finally, Defendants will set their own implementation timeline in the Biosurveillance SIP to which the public meeting is a prerequisite, per 42 U.S.C. § 247d-4(c)(6), and they or the next administration can choose to expedite measures as needs arise.

[10] Notably, although Defendants cite *Hodel* for the broad proposition that Congressional reporting requirements are not reviewable, the *Hodel* Court itself said it was *not* "pass[ing] on the broad, theoretical question whether an interbranch reporting requirement can ever be reviewable in the absence of an express provision for judicial review." 865 F.2d at 318 n.33.

challenge "the complete failure to produce the [report] at all."). Where the plaintiff is harmed by the government's failure to collect and disclose information, it is irrelevant that the chosen medium for that information is a Congressional report.

Additionally, and independently, courts recognize plaintiffs' standing where they are entitled to receive information or provide input to Congressional disclosures, or where the missing disclosures are predicates to other agency action that could benefit the litigant. *See, e.g.*, *NRDC v. United States EPA*, 961 F.3d 160, 168-69 (2d Cir. 2020). These circumstances exist here, where the statutes explicitly rest on a foundation of public education, transparency and oversight.

Plaintiffs have suffered injury-in-fact due to the missing Congressional disclosures for multiple other reasons. First, they stand to benefit from the agency action that will be informed by this missing data, but in the absence of the reports, they cannot so benefit. Second, if the reports had been provided, Plaintiffs could obtain them via a Freedom of Information request (or because the agency historically made the information public) to assist their own efforts to mitigate the effects of the pandemic. *Cf. Phillips v. Immigration & Customs Enf't*, 385 F. Supp. 2d 296, 310 (S.D.N.Y. 2005) ("information . . . having been made to Congress in a final report, ought to be made available to the plaintiff" through FOIA). But Plaintiffs cannot do so when the reports have not been filed at all. In short, Plaintiffs have been directly harmed by Defendants' failures, even where relevant reports were to be submitted to Congress. *See New York*, 351 F. Supp. 3d. at 645.[11]

[11] Defendants raise national security concerns as to certain disclosures, Opp. at 11, 22-23 n.3, claiming these are "for official use only," *see, e.g.*, Op. at 11, 22 n.3; Bratcher-Bowman Decl. ¶ 9. But the statutes make clear that national security, while important, is not a bar against disclosure, either because the duties relate to already public information or because public disclosure is required. *See, e.g.*, 42 U.S.C. § 247d-6b(a)(2), (c)(2), (c)(3); P.L. 116-22 § 606, 133 Stat. 905, 959. For example, the Government cites FOIA to claim it can withhold "sensitive" documents, *see* Opp. at 11, 22 n.3, but that requires production of all "reasonably segregable" non-exempt information, for example, by redacting the sensitive information. 5 U.S.C. § 552(b). Defendants cannot cite national security as an excuse for nonperformance.

Next, as to Plaintiffs' Section 706(2) claim, Defendants try to impose a heightened evidentiary burden on informational injury, noting that "Plaintiffs fail to even allege . . . how the switch to HHS Protect created data issues for them in a way that injured them *by impacting their COVID-19 response*." Opp. at 31. Though Plaintiffs' activities are impacted by Covid-19, their informational harms are injury enough: they need not manufacture secondary harm (e.g., to operations or financial interests). Moreover, Plaintiffs have explained repeatedly how the kind of "biosurveillance" information at issue in the shift from NHSN to HHS Protect is necessary to their pandemic response, and Plaintiffs' expert highlights deficiencies in the new system.[12] This meets the test for informational injury.[13]

2. Plaintiffs Have Suffered Procedural Injuries.

Plaintiffs have also suffered procedural injuries, having been denied the opportunity to participate in public meetings that Defendants failed to convene.[14] *See, e.g.*, Redlener Decl. ¶ 13 (noting denial of opportunity to contribute experience on emergency and infectious disease management); Oster Decl. ¶ 18 (stressing the need for schools and administrators have input on a biosurveillance network). These are not an abstract interest in "having [a] procedure observed," Opp. at 27-28, but rather, a specific participatory interest that was a critical component of the statutory scheme. For example, Defendants' "biosurveillance" duties are laced with obligations to involve the public, they were obligated to seek input prior to and after promulgating technical and

[12] *See, e.g.*, Joseph Decl. ¶¶ 37-39; King Decl. ¶¶ 53-54; Levine Decl. ¶¶ 13-16; Greenberg Decl. ¶ 18; Martinez Decl. ¶¶ 27-31.

[13] Defendants claim Plaintiffs lack standing because they did not request access to the HHS Protect database. As a factual matter, it is unclear how Plaintiffs were to have requested access when the site requires login credentials and does not explain how to obtain them. As a legal matter, *NRDC* rejected a nearly-identical argument from the government that plaintiffs lacked standing because they "did not formally request to attend the meetings in question." 410 F.3d at 597.

[14] *See, e.g.*, Joseph Decl. ¶ 41; King Decl. ¶ 60; Levine Decl. ¶ 20; Greenberg Decl. ¶¶ 19-20; Redlener Decl. ¶ 19; Oster Decl. ¶¶ 12-15.

reporting standards, and the public meeting was a material precondition of the final SIP to be submitted to Congress. *See* 42 U.S.C. §§ 247d-4(c)(5), (c)(6)(i).

Notably, Defendants cite no case (other than a general reference to *Spokeo*, which does not relate to participation rights) for the proposition that Plaintiffs cannot have been injured by the denial of *these* participatory obligations because Defendants have undertaken *other* public engagement strategies. *See, e.g.*, Opp. at 29 ("HHS and CDC have otherwise engaged with stakeholders."). Even if Defendants' "otherwise engag[ing]" with the public were relevant, none of the substitutes they propose satisfy essential aspects of their statutory duties, *see supra* p. 2.[15]

3. Plaintiffs CIP and Housing Works Have Diverted Resources

Finally, the plaintiff organizations have standing because they had to divert resources to make up for Defendants' failings. For example, absent improvements to federal biosurveillance sufficient to coordinate a government-led response, Housing Works partnered with local officials to track and trace the virus, performed free public Covid-19 testing and provided isolation and quarantine shelters, as well as primary care for high-risk patients. King Decl. ¶¶ 13-18. Similarly, without better federal information, Coney Island Prep has invested in its own research to determine

[15] Defendants incorrectly suggest Plaintiffs lack standing because they would not personally be invited to participate in various public meetings. In *Lafleur v. Whitman*, 300 F.3d 256, 271 (2d Cir. 2002), analogous here, the court held that a petitioner had standing to challenge an agency's decision not to undertake various reporting and public participation obligations. Because "petitioner [would] not have the benefit of these additional procedures," he had standing. It was not necessary that the petitioner be specifically invited to participate. *Cf. Babylon v. Fed. Hous. Fin. Agency*, 699 F.3d 221, 228–29 (2d Cir. 2012). Although it does not matter whether Plaintiffs may not be selected to participate in a particular meeting, Opp. at 28, 34, Defendants' representations that they would only invite advanced biomedical experts is contrary to the statute's instructions which require the attendance of representatives from "academic, private, and nonprofit entities" who with experience "medicine" generally and "other relevant stakeholders." P.L. 116-22, 133 Stat. 905, 958-59. Charles King, with over 30 years working to treat infectious disease outbreaks, King Decl. ¶¶ 1-4; Alexandra Greenberg, who performed Biomedical Level 4 research at government facilities, Greenberg Decl. ¶ 3; and Health Committee Chair Mark Levine all have relevant experience and interests to qualify.

mitigation strategies, continually update its Covid-19 response plans, and share them with education partners and the public; this includes programs to support families economically impacted by the pandemic and ensure these disruptions do not unduly harm students' educations. Joseph Decl. ¶¶ 19-20. As they explain, Plaintiffs would not have to undertake these efforts—at least to the extent they do—or divert from other initiatives had Defendants fulfilled their duties.

More than mere "budgetary choice[s]," Opp. at 26, these are precisely the types of injuries that confer Article III standing on an organization. As this Court held just last month, diversion of resources gives rise to standing when defendants' conduct results in an organization spending resources on some initiatives at the expense of others: the "diversion of resources is an opportunity cost that constitutes a perceptible impairment of the organization's activities [which] satisfie[s] the injury-in-fact requirement." *Nat'l Coal. on Black Civic Participation v. Wohl*, 2020 WL 6305325, at *8 (S.D.N.Y. Oct. 28, 2020) (Marrero, J.); *see also Olsen v. Stark Homes, Inc.*, 759 F.3d 140, 158 (2d Cir. 2014) ("fair-housing advocacy and counseling" organization suffered Article III injury where, due to defendant's conduct, it expended resources investigating claims and preparing complaints on behalf of an individual tenant); *NRDC*, 410 F. Supp. 3d at 595 ("Plaintiffs would not have to expend these resources if not for the alleged [statutory] violations.").

B. Plaintiffs Have Standing Because Their Injuries Are Traceable to Defendants' Conduct and Redressable by the Relief Sought

In addition to injury-in-fact, the standing inquiry asks whether Plaintiffs' injuries are "fairly traceable" to Defendants and whether they would be redressed by a favorable decision. *Jones v. United States Postal Serv.*, 2020 WL 5627002, at *11-12 (S.D.N.Y. Sept. 21, 2020) (Marrero, J.). Rather than argue traceability and redressability, Defendants simply repeat that Plaintiffs have not been injured. *See* Opp. at 30, 31, 33. But Plaintiffs have amply established these elements.

To establish traceability, Plaintiffs need only show a "causal connection between the injury

and the conduct complained of." *Jones*, 2020 WL 5627002, at *11; *see also Rothstein v. UBS AG*, 708 F.3d 82, 91 (2d Cir. 2013). Even "indirect[]" injuries suffice. *Id.* at 91–92.[16] Plaintiffs' declarations detail how Defendants' failures to publish the requisite reports, improve the national biosurveillance network, and allow for public participation have directly injured each Plaintiff.[17]

Plaintiffs' injuries are also redressable, because they "seek[] relief directly from [Defendants] that is within the court's authority to order." *Cacchillo v. Insmed, Inc.*, 638 F.3d 401, 404 (2d Cir. 2011). *Cacchillo* is instructive, even though the Court denied injunctive relief on the merits. There, the Court held that the plaintiff had standing and her injuries were redressable because the Court could order the defendant to provide the relevant withheld document. *Id.* at 404. The same is true here: the court could redress Defendants' failure to receive provide reports from Defendants by ordering them to publish those reports.[18]

C. Plaintiffs Are Directly in Federal Public Health Laws' Zone of Interests.

In addition to the requirements of Article III, plaintiffs must show that they are within the "zone of interests" protected by the statutes simply a question of "whether the particular plaintiff has a cause of action under the statute." *Am. Psychiatric Ass'n v. Anthem Health Plans, Inc.*, 821

[16] Defendants' point about a "highly attenuated chain of possibilities," Opp. at 31 n.6, would have to involve the future actions of "third parties," and is irrelevant. *Bennett v. Spear*, 520 U.S. 154, 168–71 (1997). "Fairly traceable" does not mean "the defendant's actions are the very last step in the chain of causation." *Id.* at 168–69; *see also NCBCP*, 2020 WL 6305325, at *7 (Marrero, J.) ("traceability does not require proximate causation").

[17] Joseph Decl. ¶¶ 27-42; King Decl. ¶¶ 49-61; Levine Decl. ¶¶ 13-27; Greenberg Decl. ¶¶ 19-21. Plaintiffs' experts have corroborated that evidence. Redlener Decl. ¶¶ 13-19, Bassett Decl. ¶¶ 20-24, Oster Decl. ¶¶ 17-21.

[18] Defendants also claim, "[t]o the extent Plaintiffs desire access to government resources . . . there are publicly available resources, including data . . . that are much more relevant." Opp. at 31. That argument misses the mark. Plaintiffs are injured because of Defendants' admitted failure to publish mandatory reports and data. It is no defense to say that Defendants published *other* data or Plaintiffs need be satisfied anything shy of their legal rights.

F.3d 352, 359 (2d Cir. 2016).[19] Defendants claim that Plaintiffs do not qualify because they are not "public health officials, laboratories, hospitals, poison control centers, or even primarily health-related facilities." Opp. at 34. But Plaintiffs clear the threshold here for at least two reasons.

First, the test is not as narrow as Defendants contend; a plaintiff need only have interests among those "arguably to be protected" by the statute. *Nat'l Credit Union Admin. v. First Nat'l Bank & Trust Co.*, 522 U.S. 479, 492 (1988). On their face, the majority of the statutes here are explicitly relevant to pandemic preparedness and response. Moreover, the nation's public health laws consider public education and awareness, public input, transparency, and oversight integral to their goals.[20] They also repeatedly focus on emergency interventions, adverse health outcomes and risks to vulnerable racial and ethnic groups Plaintiffs serve. *See, e.g.*, 42 U.S.C. § 299a-1(a)(6). Far from being "marginally related" or "inconsistent with the purposes" of the relevant statutes, *Clarke*, 479 U.S. 389, 399 (1987), Plaintiffs are directly within the zone of interests.

Second, Plaintiffs satisfy even Defendants' narrow description of the zone of interests. Plaintiff Levine is, as Defendants require, a "local public health official." Levine Decl. ¶¶ 5, 15. Housing Works is not just a "housing" organization, *see* Opp. at 34, but is a primary healthcare provider with decades of experience with infectious diseases that has performed thousands of

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[19] "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)); *see also Fed. Defs. of N.Y., Inc. v. Fed. Bureau of Prisons*, 954 F.3d 118, 128 (2d Cir. 2020).

[20] Defendants must "assure that statistics [they] develop[] . . . are of high quality, timely, comprehensive" and "publish, make available, and disseminate such statistics on as wide a basis as is practicable," 42 U.S.C. 242m(c). The Pandemic Preparedness Act calls for some form of "report[ing]," "notif[ication]," "oversight" or "transparency" over 80 times in the legislative text, and for some form of "input," "expert[ise]," or "advi[ce]" over ninety times. "Arming the public with transparent and accurate public health information inoculates it against . . . public health threats . . . especially true in pandemics." Redlener Decl. ¶ 8.

Covid-19 tests. King Decl. ¶ 13. Plaintiff Greenberg is an infectious disease researcher, working and studying in the only city hospital to treat Covid-19 patients exclusively and has partnered with members of Congress to propose Covid-19 related legislation. Greenberg Decl. ¶ 20. CIP participates actively in the health and Covid-19 mitigation efforts of its students, families and staff and is an education sector leader in Covid-19 mitigation. Joseph Decl. ¶¶ 23-24.

Indeed, outside this court, Defendants and their colleagues have endorsed the importance of these actors in fighting the pandemic.[21] The law echoes this, repeatedly calling for the input of local officials, experts and other stakeholders. *See* P.L. 116-22 § 605, 133 Stat. 905, 958-59. Taken together, Plaintiffs fall well within the zone of interests of statutes concerning the same, and Defendants cannot pretend otherwise in order to avoid liability.

D. Plaintiffs' Section 706(1) Claims Are Substantially Likely to Succeed on the Merits Because Defendants Admit They Failed Statutorily-Required Duties.

Plaintiffs are substantially likely to succeed on their request for an injunction compelling Defendants to perform duties that they admit that they have unlawfully withheld or unreasonably delayed to date. *See* Mem. at 19-23. Defendants have "fail[ed] to promulgate a rule or take some action by a statutory deadline," *Norton v. Southern Utah Wilderness Alliance*, 542 U.S. 55, 62 (2004) ("*SUWA*")—which they admit is actionable under 5 U.S.C. § 706(1).

Plaintiffs are not levying a "broad programmatic attack" against agencies' policy decisions.

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[21] Declaring Covid-19 a public health emergency, Defendant Azar described "local authorities," like Levine, as "the backbone of our public health infrastructure," while federal agencies play a "backup" role. *Press Briefing by Members of the President's Coronavirus Task Force*, Jan. 31, 2020. Local hospitals and healthcare providers, like Housing Works and Greenberg, were told to source their own supplies and not rely on Defendants. Ctrs. for Disease Control and Prevention, *Blueprint for Testing Plans and Rapid Response Programs*, Apr. 16, 2020, at 2 (arguing the federal government is a "supplier of last resort"). Defendants and other members of the White House Coronavirus Task Force singled out "education leaders" like CIP and Joseph for their role in pandemic response: every school "has unique capabilities, unique facilities," requiring "individual" decisions and a "right mixture of strategies for them." *Press Briefing by Vice President Pence and Members of the Coronavirus Task Force*, July 8, 2020.

Opp. at 35. Instead, Plaintiffs are suing to compel Defendants to perform 19 specific statutory duties. The requested injunctive relief adequately applies to "*discrete* agency action that [they are] *required to take*." *SUWA*, 542 U.S. at 64. And Plaintiffs' other remedies seek only to ensure performance of Defendants' "discrete" statutory obligations.[22]

Defendants also contend that Plaintiffs' attack is too *narrow*, claiming that Plaintiffs "fail to show how any of [the failures] has a direct bearing on the Government's Covid-19 response." Opp. at 38; *see also id.* at 3, 5, 8, 10, 13 (referring to the "Government's Covid-19 response"). But Plaintiffs allege that the failures have harmed *Plaintiffs'* Covid-19 response. *See supra* Part I.B. Plaintiffs are not asking the Court to implement their preferred Covid-19 policy. They are asking the Court to order the Government to convene the required meetings, collect necessary data, and publish mandated reports. Plaintiffs are not making any substantive claim—beyond the statutory mandates—about how the meetings, data collection, or publication should be conducted.[23]

E. Plaintiffs Section 706(2) Claim is Substantially Likely to Succeed on the Merits Because the Shift to HHS Protect Denied the Public Access to Information.

Plaintiffs are likely to succeed on their claim that Defendants' July decision to switch hospital reporting of Covid-19 data away from NHSN to HHS Protect is "arbitrary and capricious." Defendants' lengthy discussion, Opp. at 38-47, fails to address Plaintiffs' fundamental objection: the action resulted in data being withheld from the public.[24]

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[22] Defendants over-read the request that they be ordered "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. Plaintiffs are not asking the Court to devise surveillance and data collections methods; they simply ask the Court to ensure that Defendants take the steps necessary to prepare the reports that Defendants admit have not been prepared. *Cf. NRDC v. EPA*, 595 F. Supp. 1255, 1269-70 (S.D.N.Y. 1984) (holding that an agency could not rely on voluntary testing by private parties instead of promulgating their own testing rules).

[23] Defendants' only other argument that reports to Congress are not reviewable under the APA is incorrect as explained *supra* Part I.A.1.

[24] Defendants refer to the program as HHS TeleTracking, *e.g.*, Opp. at 14, the private vendor now

Defendants claim that the decision reflected in the July 13 guidance ("July Decision") that Plaintiffs cite is not a final, reviewable agency action. But the analysis does not turn on what the action is labeled. The determination of whether an agency action is "final," thereby subject to the Court's review, is a "pragmatic one" and fact-specific. *NRDC v. United States DOI*, 397 F. Supp. 3d 430, 446 (S.D.N.Y. 2019). Here, the shift to HHS Protect "has all of the hallmarks of APA finality . . . . Through the [July Decision], the [agency] determined rights or obligations," *Sackett v. EPA*, 566 U.S. 120, 126 (2012), and the guidance lacks "the kind of qualification-laden, guideline-offering, advice-giving, recommendation-making, or discretion-preserving language that courts have held signifies a lack of finality," *NRDC*, 397 F. Supp. 3d at 446.[25] There is nothing "tentative or interlocutory," Opp. at 40, about the hard cutoff of hospitals' participation in NHSN and the permanent change to public access to NHSN data.[26] Nor does a subsequent revision mean the July Decision was itself not final; "[t]he mere possibility that [the agency] might reconsider . . . does not suffice to make an otherwise final agency action nonfinal." *Sackett*, 566 U.S. at 127.[27] In fact, despite the September 2 Interim Final Rule ("September Rule") that Defendants claim

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managing the program. But more than who manages the data, Plaintiffs' concern is the public-facing HHS Protect site and whether it transparently shares data as the CDC had done before.

[25] Defendants' cited *Golden & Zimmerman v. Domenech*, 599 F.3d 426, 432-33 (4th Cir. 2010) is not to the contrary. It held that "Frequently Asked Questions" regarding a statute were not final agency action. Here, the July Decision is also titled "FAQs." But *Golden* does not stand for a *per se* rule about FAQs. The FAQs in *Golden & Zimmerman* merely provided information about a statute; the July Decision substantively altered data collection and public access.

[26] The July Decision mandated that hospitals' participation was a prerequisite to federal distribution of "supplies, treatments and other resources," including vital treatments for Covid-19, like remdesivir. Williams Decl. Ex. C at 1. The fact that some hospitals may not have complied with those requirements, Opp. at 40-41, is irrelevant to the mandatory nature of the requirements and Defendants' decision to withhold certain data from the public.

[27] Though new regulations can moot an APA case, mootness only occurs where "the issues presented are no longer 'live' or the parties lack a legally cognizable interest in the outcome." *Ala. Hosp. Assoc. v. Beasley*, 702 F.2d 955, 961 (11th Cir. 1983). Here, the issue of the lack of public access to previously available information is very much "live," and the September Rule did not reinstate the public's prior access to the hospital data.

superseded the July Decision, Opp. at 16-17, the HHS Protect website still directs users to the July Decision "[f]or information about hospital Covid-19 reporting." *See* Williams Decl. Ex. N.

The July Decision also was not, as Defendants claim, Opp. at 41-44, an action "committed to agency discretion." The CDC has had duties to perform "biosurveillance" in service of the nation's "near real-time" "situational awareness" of public health emergencies since 2013, *see* 42 U.S.C. § 247d-4(c), (g) (Mar. 13, 2013), and HHS generally—and the National Center for Health Statistics within the CDC specifically—must "disseminate" the data it collects on "as wide a basis as possible," 42 U.S.C. §242(m)(c). This is not one of those *rare* circumstances where a statute is so vague as to provide no standards against which to measure agency action, *Lincoln v. Vigil*, 508 U.S. 182, 191 (1993), nor is it, as evidenced by the robust scheme of mandatory data collection and reporting at issue in Plaintiffs' Section 706(1) claim, an area "traditionally" left to an agency's discretion. *Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1905 (2020).

Finally, Defendants cannot rebut Plaintiffs' evidence that the July Decision was arbitrary and capricious.[28] *See Nat'l Ass'n of Home Builders v. Defs. of Wildlife*, 551 U.S. 644, 658 (2007) (factors considered in 706(2) claims). Agencies must defend their conduct on the "the grounds . . . invoked *when [they] took the action*," *Michigan v. EPA*, 576 U.S. 743, 758 (2015)—at the time HHS to public's interest in Covid-19 data. They cannot now offer a "*post hoc* rationalization" to rehabilitate that reasoning via unrelated justifications for the September Rule. *Regents of the Univ. of Cal.*, 140 S.Ct. at 1908 (2020). Whether HHS Protect offers "flexibility," "CDC staff have access to all of the Covid-19 data," and whether NHSN continues to serve "non-Covid-19 reporting

[28] The switch shifted data control to political appointees and their vendor, away from career CDC staff with the scientific expertise to manage the data and a demonstrated commitment to the legal requirements and norms of public education and transparency. HHS Protect is less timely, less reliable and provides less information to fewer people than before. Mem. at 27.

purposes," Opp. at 47, all are irrelevant to Plaintiffs' claim that HHS Protect effectively conceals nation-wide Covid-19 datasets that were previously available to the public via NHSN.

Defendants do not deny this. They acknowledge the full dataset underlying HHS Protect is only available to: (1) the Coronavirus Task Force and select federal officials, Opp. at 14-15; Ashmore Decl. ¶ 12; (2) "states, localities, and tribal partners," with only "information on their *local* situation," Opp. at. 16; Ashmore Decl. ¶ 21; and (3) individuals at the government's unbridled discretion, apparently limited to "entrepreneurs, researchers and policymakers," Ashmore Decl. ¶ 22. In short, by admission, but for those few with limited access, HHS Protect prevents public access to the full data set that gives regional or nationwide perspective on Covid-19. Martinez Decl. ¶ 27-31.[29] The decision to withhold such data must be reversed.

II. Defendants' Failures Have Caused Plaintiffs Irreparable Harm.

Defendants concede that they did not comply with their statutory obligations; as established, Plaintiffs have suffered direct and actionable injuries as a result. The informational, procedural, and diversion-of-resources injuries caused, and continue to cause, irreparable harm. Defendants do not directly respond to Plaintiffs' arguments; instead, in a single paragraph, they simply repeat the claim that Plaintiffs have not been harmed. Opp. at 49. There is ample case law that Plaintiffs' injuries are irreparable and should be remedied with an injunction. Where a harm "cannot be remedied if a court waits until the end of trial to resolve the harm," it is irreparable.[30]

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[29] For example, prior to July, NHSN provided daily updates to its information; HHS Protect only provides weekly updates. *See* Compl. ¶ 23. Visitors to HHS Protect who wish to access the underlying dataset for "detailed hospital reporting" or "percentage of hospitals reporting by state" are directed to tables of information as to how frequently and comprehensively hospitals report data to the federal government, but no information as to the substance of what they report. Also, visitors to the site who wish to access the underlying dataset for "COVID-19 Diagnostic Laboratory Testing" are directed to log in. Nowhere does the site direct users how to request access to the underlying substantive data or to obtain log-in credentials of their own.

[30] *Freedom Holdings, Inc. v. Spitzer*, 408 F.3d 112, 114 (2d Cir. 2005); *see also, e.g.*, *Lawyers'*

III. In the Midst of Another Potentially Devastating Wave of the Pandemic, the Balance of Equities and the Public Interest Point Decisively in Plaintiffs' Favor.

Defendants argue that requiring them to fulfill their mandatory obligations—the vast majority of which Congress considered necessary to Defendants' pandemic preparations and response—would somehow undermine Defendants' ability to prepare for and respond to the ongoing Covid-19 pandemic, which has infected more than three million Americans and killed nearly 30,000 since Plaintiffs filed their papers. The argument fails for multiple reasons.

First, as a result of Defendants' longstanding pattern of dereliction, the majority of the duties in question were due *before* the onset of the pandemic: (1) most predate the onset of major US cases that arrived in late March and April;[31] (2) others were due in 2019;[32] and (3) some duties have been neglected for a number of years.[33] Their prior failure cannot justify their continued failure and doubly violate Congress's intent and undermine the express purpose of the APA.[34]

Second, the Government argues that in many cases, "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." Opp. at 38, but cite to no authority granting them permission

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Comm. for Civil Rights v. Pres. Advisory Comm'n on Elec. Integrity, 265 F. Supp. 3d 54, 70 (D.D.C. 2017) (denial of access to information constitutes irreparable harm); *Nat. Res. Defense Council v. Lujan*, 768 F. Supp. 870, 890 n.36 (D.D.C. 1991) (denial of participation rights constitutes irreparable harm); *Ctr. for Biological Diversity*, 571 F. Supp. 2d at 1134 (same); *Nat'l Venture Capital Ass'n v. Duke*, 291 F. Supp. 3d 5, 13-14 (D.D.C. 2017) (lost procedural opportunities cause irreparable harm); *NCBCP*, 2020 WL 6305325, at *11 (Marrero, J.) (diversion of resources constituted irreparable harm and warranted TRO).

[31] See 42 U.S.C. § 242m (a)(1-2) (four public health reports); *id.* § 242p(a) (national disease prevention data profile); *id.* § 247d-6b(a)(2) (SNS Threat Based Review); *id*. § 300hh-10(d) (Countermeasures SIP); *id*. § 300hh-10(b)(7) (Countermeasures SIP budget); *id.* 300hh-10(d)(2)(H) (soliciting public input for Countermeasures SIP).

[32] *See id.* § 247d-4(c)(5)(B) (biosurveillance public meeting); P.L. 116-22, 133 Stat. 905, 924–25 (Biological Threat Detection Report); 42 U.S.C. § 300u-6(f)(1) (OMH Report).

[33] *Id*. § 300hh-10(d) (last dated 2017); *id.* § 242m(a)(1)-(2) (not since 2018); *Id*. § 300u-6(f) (not since 2015); *id.* §§ 247d-3a(i)-(j), 247d-3b(i) (since 2018).

[34] The six duties that were due mid-pandemic are all newly from the Pandemic Preparedness Act.

simply to ignore their legal obligations. If Congress wanted to give agencies a free pass during an emergency, it knew how to do so.[35] But it chose the opposite here.

As the name suggests, the *Pandemic Preparedness Act* is oriented precisely toward the present crisis. Ironically, Defendants argue that the requested injunction would "divert[] resources" from Covid-19 response, Opp. at 38, *and* that their duties will be completed in "weeks or months," *id.* at 36-37. If the obligations can be completed shortly, they should consent to the requested injunction. But Defendants cannot unilaterally convert mandatory duties into discretionary ones.

Finally, the balance of equities and public interest cannot favor Defendants where, as here, they acknowledge they failed to comply with their statutory duties *and* represent that they will meet them on a timeline substantially similar to what Plaintiffs propose and this Court can so order.

CONCLUSION

For all of the foregoing reasons, Plaintiffs respectfully request that the Court grant their Motion for a Preliminary Injunction.

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[35] Notably, upon notice to Congress, Defendants may waive certain reporting requirements of third parties, 42 U.S.C. § 247d(d), but this provision does not apply to Defendants' *own* obligations.

Attachment A: Chart of Statutory Duties at Issue in Plaintiff's Proposed Order

This chart summarizes Defendants' representations as to their statutorily-required duties, with columns for: (1) the statute; (2) a description of the duty; (3) the statutory deadline; (4) Defendants' proposed date of completion or, if none is proposed, their response, citing the opposition page or declarations paragraph. The chart follows the duties as listed in Plaintiffs' Proposed Order, Dkt. [6].

Statute	Duty	Stat. Deadline	Defendants' Date
Biosurveillance Duties			
42 U.S.C. § 247d-4(c)(5)(B)	Public Meeting	By Dec. 21, 2019	"Taken multiple steps" (5)
P.L. 116-22 § 205(c), 133 Stat. 905, 924–25	Biological Threat Detection Report	By Dec. 21, 2019	Jan. 2021 (6)
42 U.S.C. § 247d-4(b)(2)-(3)	Technical and Reporting Stds.	By Jun. 24, 2020	"Partially met" (5)
Id.	Notice and Comment	By Jun. 24, 2020	"No requirement" (Arias Decl. ¶ 8)
Reporting Duties			
42 U.S.C. § 242m(a)(1)-(2)	Four Public Health Reports	By Mar. 15, 2020	"Forthcoming" (12)
Id. § 242p(a)	Nat'l Disease Prev. Data Profile	On Mar. 15, 2020	"Being finalized" (12)
Id. §§ 247d-3a(i)(1)(E), (j) and 247d-3b(i)(1)	Reports from state/local emergency funding recipients	"Timely manner"	"Early in 2021" (9 n.1)
Id. § 247d-6b(a)(2)	Stockpile Threat Based Review	By Mar. 15, 2020	Dec. 31, 2020 or Q1 2021 (10)
Id. § 247d-6b(c)(2)	Stockpile MTD Report	"Annual"	Dec. 31, 2020 (11)
Id. § 247d-6b(c)(3)(A)-(B)	Stockpile Assessments	"Ongoing"	Not "required to be made public" (11)
Id. § 262a(k)(2)(A)	FESAP Report	By Jun. 24, 2020	Dec. 31, 2020 (8)
Id. § 299a-1(a)(6)	AHRQ Disparities Report	"Annual"	Dec. 31, 2020 (13)
Id. § 300hh-10(d)	Countermeasures SIP	By Mar. 15, 2020	Dec. 31, 2020 (8)
Id. § 300hh-10(b)(7)	Countermeasures SIP Budget	By Mar. 15, 2020	"Delayed" due to COVID-19 (8-9)
Id. § 300u-6(f)(1)	Office of Minority Health Report	By Feb. 1, 2019	"Under development" (13)
P.L. 116-22 § 209, 133 Stat. 905, 929	Report on National Blood Supply	By Jun. 24, 2020	Jan. 2021 (6)
P.L. 116-22 § 606, 133 Stat. 905, 959	Report on Int'l Vaccine Efforts	By Jun. 24, 2020	Dec. 31, 2020 (7)
Participatory Duties			
P.L. 116-22 § 605, 133 Stat. 905, 958-59	Genomic Countermeasures Meeting	By Jun. 24, 2020	2021 (7)
42 U.S.C. § 300hh-10(d)(2)(H)	Input to Countermeasures SIP	By Mar. 15, 2020	Completed (8)