U.S. Department of Justice

United States Attorney
Southern District of New York

86 Chambers Street
New York, New York 10007

December 30, 2020

By ECF
Cary McClelland, Esq.
Siegel Teitelbaum & Evans, LLP
260 Madison Avenue, Suite 22nd Floor
New York, NY 10016

Re: *Coney Island Prep, et al. v. HHS, et al.*, 20 Civ. 9144 (VM)

Dear Mr. McClelland:

We write pursuant to Section II.B of the Court's Individual Rules to explain why the Government intends to file a motion to dismiss Plaintiffs' complaint.[1]

A. The Complaint Should Be Dismissed Because Plaintiffs Lack Standing

For the reasons given by the Court when concluding that Plaintiffs have not established irreparable harm with respect to their preliminary injunction motion, Plaintiffs have also not alleged a concrete, particularized, and imminent injury-in-fact or a causal connection between the injury and the Government's conduct, as required to establish standing. *See Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560-61 (1992); ECF No. 47, Court's Decision and Order on PI Motion ("Order").

First, Plaintiffs have failed to sufficiently allege that they "ha[ve] sustained or [are] immediately in danger of sustaining a direct injury as a result of [the challenged] action." *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1552 (2016). Plaintiffs allege informational injuries in the form of allegedly withheld reporting obligations under the Pandemic and All-Hazards Preparedness and Advancing Innovation Act ("PAHPAIA") and Public Health Service Act (the "PHS Act") and COVID-19 data through the HHS Protect system. *See* Compl. ¶¶ 5-7, 39-48, 58-65, 68-71, 121-31, 139-141, 152. However, Plaintiffs have not been deprived of any information to which they are entitled. PAHPAIA and the PHS Act specify that the vast majority of the required reports must be provided to Congress rather than made publicly available. *See* ECF No. 33 ("PI Opp.") 22-23. Further, there is no statutory provision requiring that National Healthcare Safety Network ("NHSN") or HHS Protect data be made publicly available. Therefore, for most of the allegedly withheld information, Plaintiffs have failed to allege an essential element of informational standing—*i.e.*, that they have been deprived of information that a statute requires the government to disclose to them. *Fed. Election Comm'n v. Akins*, 524 U.S. 11, 21 (1998); *NRDC v. Dep't of the Interior*, 410 F. Supp. 3d 582, 597 (S.D.N.Y. 2019); *see also, e.g., W. Virginia Highlands Conservancy v. Johnson*, 540 F. Supp. 2d 125, 143 n.12 (D.D.C. 2008) (no informational injury

[1] The Government understands that the time to file its motion to dismiss will be preserved pending completion of the Court's pre-motion requirements.

where report was to Congress rather than to the public); *Elec. Privacy Info. Ctr. v. Presidential Advisory Comm'n on Election Integrity*, 878 F.3d 371, 378 (D.C. Cir. 2017); *Am. Farm Bureau v. U.S. E.P.A.*, 121 F. Supp. 2d 84, 99 (D.D.C. 2000) (same). Regarding the few reports that do require reporting to the public, Plaintiffs have not shown an injury because these reports have already been provided or do not directly relate to COVID-19—the hook by which Plaintiffs seek to show injury. *See* PI Opp. 24-25; Order 14 ("[T]he vast majority of information at issue does not pertain directly to the COVID-19 pandemic."); *see also* Order 16-26 (no informational harm).

Plaintiffs have further failed to demonstrate an injury-in-fact with respect to their other two alleged injuries—procedural injury and the diversion of resources. Although Plaintiffs allege procedural injury as a result of several allegedly "withheld participation duties," Compl. ¶ 8, they have sustained no injury. These allegedly withheld participation opportunities have already occurred, are not required to be provided, or would not include Plaintiffs as participants, and moreover, Plaintiffs have not demonstrated any "concrete interest that is affected" by the alleged procedural violations. *See* PI Opp. 28-30; *Spokeo*, 136 S. Ct. at 1549; Order 26-30 (no procedural harm). Nor have Plaintiffs established standing based on a diversion of resources theory as they have failed to identify resources that were diverted as a result of the allegedly withheld reports and opportunities. *See Havens Realty Corp. v. Coleman*, 455 U.S. 363, 379 (1982). In fact, Plaintiffs allege that they were already devoting resources to respond to COVID-19 irrespective of the Government's actions. *See* Compl. ¶¶ 86-88, 95-97, 102-05, 115, 133, 145, 153; Order 31 ("Plaintiffs' diversion of resources is not due to Defendants' conduct—rather, it is due to the pandemic."); *New York v. DHS*, 969 F.3d 42, 61 (2d Cir. 2020) (no showing of diverted resources where organization was already devoting resources to the same goals).

Second, Plaintiffs have entirely failed to link the purported absence of any report, data, or participation opportunity to any specific injury. *See Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 03 (1998). Most of the reports are not related to COVID-19, and the Biosurveillance Network itself is, by statute, not required to be completed until September 2023. *See* PI Opp. 30-31. Further, Plaintiffs have not alleged that they used NHSN or how the switch to HHS Protect impacted their COVID-19 response, and in fact, none of Plaintiffs have requested or been denied access to these systems. *See* PI Opp. 31. Therefore, the Government's conduct could not have caused any injury to Plaintiffs with respect to their COVID-19 response. *See* Order 16-31 (describing why Plaintiffs' allegations are "speculative," "conclusory," and not concrete).[2] For these reasons, the complaint should be dismissed in its entirety due to lack of standing.

B. <u>Plaintiffs' Claims Should Be Dismissed For Additional Reasons</u>

Plaintiffs' Section 706(1) claims challenging alleged agency inaction or delay should be dismissed for two additional reasons. First, some of these claims should be dismissed because they are moot. If a court is no longer capable of granting a judgment that will affect the parties' legal rights, the case is moot, and the court lacks jurisdiction over the action. *See ABN Amro Verzekeringen BV v. Geologistics Americas, Inc.*, 485 F.3d 85, 94 (2d Cir. 2007). Here, the Government has already met many of its statutory obligations. *See* PI Opp. 36. As a result, with

[2] Plaintiffs have also not shown that their injuries would be cured by a favorable ruling by the Court or that they are within the zone of interests protected by the statute. *See* PI Opp. 32-35.

respect to these duties, because this Court is no longer capable of granting a judgment that would practically affect the parties' legal rights, those claims are moot and should be dismissed for lack of subject matter jurisdiction. *See NRDC v. U.S. Nuclear Regulatory Comm'n*, 680 F.2d 810, 814 (D.C. Cir. 1982) ("[W]e can hardly order the [defendant] at this point to do something that it has already done."). Second, Plaintiffs' Section 706(1) claims as to reports that by statute are due only to Congress should be dismissed because they are not judicially reviewable. Unless Congress has indicated otherwise—which, in this case, it has not—congressional reporting requirements are not susceptible to judicial review. *NRDC v. Hodel*, 865 F.2d 288, 317-19 & n.31 (D.C. Cir. 1988); *see also NRDC v. Lujan*, 768 F. Supp. 870, 882 (D.D.C. 1991); *Greenpeace USA v. Stone*, 748 F. Supp. 749, 765 (D. Haw. 1990).

Plaintiffs' Section 706(2) claim alleging that a July 13, 2020 document (the "July 13 Guidance") directing hospitals to report COVID-19-related data to the HHS Protect system instead of NHSN was arbitrary and capricious should also be dismissed for two additional reasons. First, the July 13 Guidance does not constitute final agency action and is not reviewable under the APA because it fails both prongs of the *Bennett v. Spear* finality test. 520 U.S. 154 (1997) (interpreting 5 U.S.C. § 704). The July 13 Guidance is merely interim guidance that has been revised several times and as such does not mark the consummation of any agency's decision-making process. Additionally, the July 13 Guidance does not determine the rights or obligations of any party and it has no legal consequences. It merely provided the guidelines applicable at the time for hospitals choosing to voluntarily report COVID-19 data to the Government; it created no obligation that they do so. As such, Plaintiffs cannot seek review of the July 13 Guidance under the APA.

Second, the Government's decision to request that hospitals report COVID-19 data to a specific portal (and later to make that reporting mandatory, *see* 85 Fed. Reg. 54,820, 54,822, 54,872-73 (Sept. 2, 2020) (adding 42 C.F.R. §§ 482.42(e), 485.640(d))) are matters committed to agency discretion that cannot be reviewed under the APA. 5 U.S.C. § 701(a)(2); *Heckler v. Chaney*, 470 U.S. 821, 830 (1985). Under *Heckler*, the starting point of any analysis under Section 701(a)(2) is whether there is a "meaningful standard" provided in the governing statute. *Lunney v. United States*, 319 F.3d 550, 558 (2d Cir. 2003). There is no "meaningful standard" that applies here. The recently issued regulations that made hospitals' COVID-19 data reporting mandatory were promulgated pursuant to the Secretary's broad authority under the Social Security Act, which authorizes the Secretary to prescribe such regulations "as may be necessary to carry out the administration of the insurance programs under this subchapter," 42 U.S.C. § 1395hh(a)(1), and "as may be necessary to the efficient administration of the functions with which [the Secretary] is charged under this chapter," 42 U.S.C. § 1302(a). *See* 42 C.F.R. §§ 482.42(e), 485.640(d). The administration of Medicare and Medicaid—including by requiring data reporting as a condition of participation in those programs and specifying the manner of reporting—is left to the Secretary's discretion. Therefore, the Secretary's decisions as to what data to collect for use by CDC and other federal decision-makers and how to collect it are not judicially reviewable.

Finally, Plaintiffs are also not entitled to relief under the All Writs Act or the Mandamus Act, *see* Compl. ¶¶ 149-58, as neither of these statutes creates an independent right of action where a plaintiff may also bring an APA claim. *See* PI Opp. at 48-49.

Very Truly Yours,

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