

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

CONEY ISLAND PREP, *et al.*,

Plaintiffs,

- against -

UNITED STATES DEPARTMENT OF HEALTH
AND HUMAN SERVICES, *et al.*,

Defendants.

No. 20 Civ. 9144 (VM)

DECLARATION OF ILEANA ARIAS, Ph.D.

Pursuant to 28 U.S.C. § 1746, I hereby declare as follows:

1. I am the Acting Deputy Director for Public Health Science and Surveillance (“DDPHSS”) at the Centers for Disease Control (“CDC”), U.S. Department of Health and Human Services (“HHS”), a position I have held since January 2020. In that capacity, I am responsible for strengthening CDC’s scientific foundation by working across the Office of Science; the Office of Laboratory Science and Safety; the Center for Surveillance, Epidemiology, and Laboratory Sciences; and the National Center for Health Statistics. One of my primary areas of responsibility is to provide leadership for CDC’s Data Modernization Initiative. The Data Modernization Initiative marks the first comprehensive CDC strategy to create an integrated high-speed, networked health data system for laboratories, healthcare facilities, and public health authorities, paired with fast and reliable data in order to protect Americans from health threats.¹ This initiative supports public health surveillance, research, and ultimately, decision making.

¹ <https://www.cdc.gov/surveillance/surveillance-data-strategies/data-IT-transformation.html>

2. I make this declaration based on my personal knowledge, information acquired by me in the course of performing my official duties, information provided to me by federal government employees, and government records.

3. I have reviewed portions of documents filed in the above-captioned case, including the Complaint, Dkt. No. 1 (“Compl.”), and the Memorandum of Law in Support of Plaintiffs’ Motion for a Preliminary Injunction, Dkt. No. 7 (“PI Mem.”) in which Plaintiffs allege that HHS has not met certain statutory obligations. This declaration responds to several of those allegations.

4. Plaintiffs allege that HHS did not “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 national-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).” PI Mem. at 20; *see also* Compl. ¶ 39(a). Based on information and belief and HHS’s investigation to date, it does not appear that HHS yet convened this meeting and will work to address that oversight.

5. However, both HHS and CDC have taken multiple steps to engage and inform stakeholders, including states and local governments, with respect to ongoing, significant biosurveillance activities.² CDC held a listening session in July 2020 with federal, state, and local public health, healthcare, and technology stakeholders, to better understand how public health might leverage certification requirements required by the 21st Cures Act (P.L. 114-255) to

² <https://www.cdc.gov/surveillancepractice/index.html>

help provide richer and more real-time data to public health.³ More specifically, CDC has also identified and provided public access to a wide range of surveillance data activities related to COVID-19.⁴ A number of CDC's robust, long-standing biosurveillance systems have been leveraged to support the response to COVID-19, including, in particular: (a) the National Syndromic Surveillance Program; (b) the U.S. Flu Vaccine Effectiveness Network; (c) the COVID-19, Associated Hospitalization Surveillance Network (built on the Emerging Infections Program and the Influenza Hospitalization Surveillance Project); (d) the New Vaccine Surveillance Network; and (e) the National Healthcare Safety Network.

6. Plaintiffs allege that HHS did not, 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).” PI Mem. at 21; *see also* Compl. ¶ 39(c). That requirement has been partially satisfied. Specifically, as a first step, CDC has developed and published a variety of data vocabulary standards through its Public Health Information Network (“PHIN”) resources. These materials promote the use of standards-based vocabulary to support the exchange of consistent information among public health partners. Currently, there are 206 code systems and 1,506 value sets available on various platforms. These resources are available online.⁵

7. In addition, CDC is coordinating with the HHS Office of National Coordinator for Health Information Technology (“ONC”), which is responsible for promoting the adoption and use of standards and technologies that allow health information to be shared electronically between clinicians, patients, researchers, and others who are authorized to access the

³ <https://www.cdc.gov/surveillance/pubs-resources/index.htm>

⁴ https://covid.cdc.gov/covid-data-tracker/#cases_totalcases

⁵ <https://www.cdc.gov/phin/index.html>

information. By promoting this ability to share information, ONC's work will facilitate "interoperability" of relevant data, including for public health purposes and networks. ONC has promulgated by rulemaking the "Standards and Implementation Specifications for Health Information Technology," which are codified at 45 C.F.R. Part 170; these standards are used as appropriate for public health biosurveillance. As a follow-up to the above-mentioned July 2020 listening session, CDC is working with state, tribal, local, and territorial partners to propose further standard data elements to ONC for the U.S. Core Data for Interoperability, which is a standardized set of health data classes and constituent data elements for nationwide, interoperable health information exchange, and CDC will coordinate with appropriate standards development organizations as directed by Section 247d-4(b)(3)(B). Additional relevant public health data standards are displayed by ONC online.⁶

8. Plaintiffs allege that HHS did not "provide adequate notice of and public comment with respect to those technical and reporting standards, as required by 5 U.S.C. § 533 [sic]." PI Mem. at 21; *see also* Compl. ¶ 39(d). I understand that ONC promulgates certain standards and implementation specifications through rulemaking; however, there is no requirement that CDC's technical and data standards be promulgated through a rulemaking process under the Administrative Procedure Act, 5 U.S.C. § 553.

9. Plaintiffs allege that HHS did not "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)." PI Mem. at 21; *see also* Compl. ¶ 44(a). Pursuant to this requirement, awardees of CDC's Public Health Emergency Preparedness ("PHEP") cooperative agreements are required to prepare and

⁶ https://www.healthit.gov/isa/isa-document-table-contents#blocktabs-isa_toc_new-5

submit annual reports on their PHEP activities. Awardees have been providing their annual reports to CDC as required under 42 U.S.C. § 247d-3a(i) pursuant to the notice of funding opportunity requirements. CDC has publicly posted the information concerning these submissions through 2018 in its 2018 CDC Preparedness Report.⁷ This Report highlights preparedness activities and investments at the federal, state, and local levels, and features stories that demonstrate the impact of these activities. There are two sections to this report: the Narrative and the PHEP Program Fact Sheets. The Narrative describes CDC preparedness and response activities in 2016 and 2017 and demonstrates how investments in preparedness enhance the nation’s ability to respond to public health threats and emergencies.⁸ The PHEP Program Fact Sheets provide information on PHEP funding from 2015 to 2017 and trends and progress related to the 15 public health preparedness capabilities defined in the PHEP Cooperative Agreement.⁹ CDC has also made available current information on awardee funding, including the PHEP Cooperative Agreement 2019-2024 Notice of Funding Opportunity (“NOFO”)¹⁰ and PHEP Funding and Other Recipient Information.¹¹

10. Plaintiffs allege that HHS did not “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).” PI Mem. at 22; *see also* Compl. ¶ 45(b)(i). The

⁷ <https://www.cdc.gov/cpr/pubs-links/2018/index.htm>

⁸ https://www.cdc.gov/cpr/pubs-links/2018/documents/2018_Preparedness_Report.pdf

⁹ https://www.cdc.gov/cpr/epf/index.htm?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2F%2Fpartnerships%2Fmap.htm; *see also* <https://www.cdc.gov/cpr/readiness/capabilities.htm>.

¹⁰ https://www.cdc.gov/cpr/readiness/00_docs/PHEP_Cooperative_Agreement_TP19-1901_RevisedMay3_508Compliant.pdf

¹¹ https://www.cdc.gov/cpr/epf/index.htm?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2F%2Fpartnerships%2Fmap.htm

statute states these reports are to be submitted to the President and Congress and that the Secretary of HHS shall disseminate statistics from these reports “on as wide a basis as practicable,” 42 U.S.C. § 242m(c), and this information is generally made publicly available. The National Center for Healthcare Statistics (“NCHS”) within CDC fulfills its statutory responsibilities under 42 U.S.C. § 242m(a)(1)-(2) and § 242p through publication of *Health, United States*, a series of reports on the health status of the nation submitted by the Secretary of HHS to the President and Congress.¹² *Health, United States* presents an annual overview of national trends in key health indicators. The 42nd edition of the report, *Health, United States, 2018* was released on October 30, 2019.¹³ This report presents trends and information on selected measures of morbidity, mortality, health care utilization and access, health risk factors, prevention, health insurance, and personal health care expenditures in a 20-figure chartbook. Preparation of the 43rd edition of the report is complete, and the report is in the final stages of review and publication is forthcoming. While the report is produced and submitted annually, both the report and complementary health information on the four health sectors, including trend tables on key indicators and an infographic on racial and ethnic disparities, are available throughout the year on the *Health, United States* website.

11. Plaintiffs allege that HHS did not “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.” PI Mem. at 22; *see also* Compl. ¶ 45(b)(2). The statute requires that this report be provided only to Congress, 42 U.S.C. § 242p, although this report is made publicly available. This directive is being addressed holistically through the Department’s *Healthy People* initiatives

¹² <https://www.cdc.gov/nchs/hus/index.htm>

¹³ <https://www.cdc.gov/nchs/data/hus/18.pdf>

with updated goals and objectives every ten years. The *Healthy People 2020 End of Decade Summary*, developed by the Office of Disease Prevention and Health Promotion and NCHS, is being finalized, and the *Healthy People 2020 Final Review* will follow next year. Work on *Healthy People 2030* has already been initiated. The *Healthy People* website provides access to the *Healthy People 2020* databases, which integrate tracking data from many diverse data systems into an interactive data tool that can be accessed via healthypeople.gov. This platform allows users to explore data and technical information related to the *Healthy People* program.¹⁴ In addition, NCHS maintains a Healthy People website housing all statistical and methodological reports, statistical information and technical materials from progress reviews, webinar slides, and technical documentation related to the initiative.

12. Plaintiffs allege that HHS did not give “notice to Congress of [the Secretary’s] use of various emergency powers and funds to address the pandemic, *see* 42 U.S.C. §§ 247d-4a.” PI Mem. at 22 n. 9. CDC activated the Infectious Diseases Rapid Response Reserve Fund and provided the required notifications to Congress as directed. This notice document is for Congressional purposes and is not required to be made public.

13. Plaintiffs allege that HHS did not “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).” PI Mem. at 22; *see also* Compl. ¶ 47(b). Section 262a(k) requires HHS to report to Congress annually on the number and nature of notifications received concerning the theft, loss or release (“TLR”) of select agents and toxins regulated by HHS. HHS and the United States Department of Agriculture jointly submitted a TLR report to Congress on July 6, 2020. This report is not made publicly available due to the sensitive nature of the information contained in

¹⁴ https://www.cdc.gov/nchs/healthy_people/hp2020.htm

the report.

14. In response to the COVID-19 pandemic, CDC has developed and publicly posted a plethora of data, reports, guidance, and educational materials intended to assist the public and other sectors in visualizing, preparing for, and responding to the COVID-19 pandemic.¹⁵ This includes national, state, and county level data to which CDC has access.¹⁶ These postings provide information on a range of COVID-19-related issues that may be of interest to individuals, communities, organizations, and state, local, tribal, and territorial governments. For example, there is guidance on effective mitigation strategies, social distancing, business and school operations, and travel. These tools provide information to the public that is more likely to be directly related to COVID-19 than many of the reports identified in Plaintiffs' Complaint. Many of the milestones and reports identified in Plaintiffs' Complaint and described in this declaration would not have captured COVID-19-related information, as they were based on information and data collected before the pandemic.

15. In addition, on March 27, 2020, Congress passed the Coronavirus Aid, Relief and Economic Security Act ("CARES Act") (P.L. 116-136), which appropriated an additional \$500,000,000 to CDC for public health data surveillance and analytics infrastructure modernization. CARES Act funding is supporting the development of changes at CDC and at state, tribal, local, and territorial public health entities to improve data sharing across the public health ecosystem, enhance CDC systems and services for ongoing data modernization, and develop new standards and approaches for public health reporting. In conjunction with the Data Modernization Initiative, activities performed pursuant to the CARES Act will modernize public

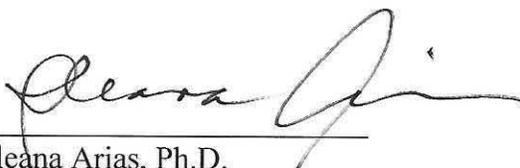
¹⁵ <https://www.cdc.gov/coronavirus/2019-nCoV/index.html>

¹⁶ https://covid.cdc.gov/covid-data-tracker/#cases_totalcases

health surveillance and data collection by accelerating integration of health systems, laboratory, and case-based data to a common operating platform with real-time analytic capability at federal, state, and local levels. CDC is also developing relationships with private-sector technology leaders for the rapid integration and scale-up of relevant data streams, innovative methods, and tools to process, analyze, and use those data, and to build the technological infrastructure to support these actions. CDC has also entered into a new collaboration with the U.S. Digital Service to help bolster the capacity of our public health partners at the state and local levels. While the immediate focus of this collaboration is on collecting data needed to improve the public health response to COVID-19, the approaches being adopted, and the tools being developed, are scalable to our ongoing public health needs. CDC is prioritizing enhancing and modernizing data systems related to COVID-19 as well as modernizing the public health data systems for the future.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: Atlanta, Georgia
November 16, 2020



Ileana Arias, Ph.D.