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 NIKKI BRATCHER-BOWMAN

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

1. I am the Deputy Assistant Secretary, Executive Management for Preparedness and Response ("ASPR"), at the U.S. Department of Health and Human Services ("HHS"), a position I have held since August 4, 2019. In that capacity, I am responsible for leadership and oversight of the Office of External Affairs and the Office of Management, Finance, and Human Capital. I advise the Assistant Secretary and provide communications strategy and budget, acquisitions and congressional oversight.

2. I make this declaration based on my personal knowledge, information acquired by me in the course of performing my official duties, information supplied 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 did not "[c]ompile 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 42 U.S.C. § 247d-3b(i), awardees of ASPR's Hospital Preparedness Program ("HPP") cooperative agreements are required to prepare and submit annual reports on their HPP activities. To date, this part of the statutory requirement has been satisfied by HPP awardees through their submission of annual progress reports, annual performance measure reports, and grants management federal financial reports. "Fact sheets" compiling information about each HPP awardee are compiled by ASPR with the awardees. The most recent fact sheets covering FY2018 are publicly available on ASPR's PHE.gov website.[1]

5. In 2020, ASPR's work with each awardee to complete updated fact sheets for FY2019 was temporarily suspended because the awardees were forced to redirect resources to COVID-19 response activities. Fact sheets for FY2019 would not have addressed COVID-19 response activities. ASPR plans to develop fact sheets early in 2021 for FY2020 with updated funding data, health care coalition membership data, and recipient highlights. Also, in 2021, the National Healthcare Preparedness Programs branch of ASPR is planning to publish an annual report that will provide recent data and an overview of accomplishments from CY2020 across its health care readiness portfolio, including the HPP. HPP awardees of COVID-19 emergency supplemental funding and administrative supplements to the existing HPP awards in 2020 will not report COVID-19 performance measures data until late 2021.

6. Plaintiffs allege that HHS did not "prepare and publish, by March 15, 2020, a

[1] https://www.phe.gov/Preparedness/planning/hpp/Pages/awardee-highlights.aspx

Strategy and Implementation Plan ('Countermeasures SIP') from the Public Health Emergency Medical Countermeasures Enterprise ('PHEMCE'), 42 U.S.C. § 300hh-10(d); Pandemic Preparedness Act § 402, 133 Stat. at 943." PI Mem. at 21-22; *see also* Compl. ¶ 44(b). By statute, the reporting obligation is to Congress. *See* 42 U.S.C. § 300hh-10(d). HHS has been slightly delayed in preparing and publishing the Countermeasures SIP as a result of significant demand placed upon the agency's resources in responding to the COVID-19 pandemic. As of the date of this declaration, a draft of the Countermeasures SIP has been prepared, and HHS expects that it will be finalized and transmitted to Secretary for promulgation to Congress by the end of CY2020, at which time it will also be made publicly available.

7. The Countermeasures SIP is a routine document that lays out strategic priorities for building preparedness against CBRN (chemical, biological, radiological, and nuclear) threats. Pandemic threats are not required to be included under the statute, but have been included in the past under preparedness against influenza. This year's Countermeasures SIP makes brief mention of COVID-19 as a pandemic exemplar, but is not focused on COVID-19 response enhancing activities as it is a plan for future efforts. The Countermeasures SIP focuses on medical countermeasure preparedness for all CBRN threats as well as pandemic threats and broadly addresses research and development, acquisition and stockpiling, expanding manufacturing, and planning for distribution and dispensing for all of these countermeasures. The Countermeasures SIP provides a strategy for future efforts across all of these capabilities and countermeasures. Prior Countermeasures SIPs are available online.[2]

8. Plaintiffs allege that HHS did not "prepare and publish, by March 15, 2020, a five-year budget plan based on the medical countermeasure priorities identified in the

[2] https://www.phe.gov/Preparedness/mcm/phemce/Pages/default.aspx

Countermeasures SIP" that "include[s] consideration of the entire medical countermeasures enterprise," pursuant to 42 U.S.C. § 300hh-10(b)(7). PI Mem. at 22; *see also* Compl. ¶ 44(c). By statute, the reporting obligation is to Congress. *See* 42 U.S.C. § 300hh-10(b)(7). *The* Public Health Emergency Medical Countermeasures Enterprise ("PHEMCE") *Multiyear* Budget Report (FY 2019-2023) has been delayed by the agency's focus on the COVID-19 response. The key personnel involved in providing data for the report are currently the key personnel guiding the agency's financial management of the COVID-19 response. Additionally, the multiyear budget's purpose is to forecast future resource needs for maintaining the country's preparedness capabilities or for increasing those capabilities to meet medical countermeasure requirements. The ongoing demands of the COVID-19 response have introduced a significant amount of uncertainty with regard to the financial resources agencies will need in future years. Additionally, the availability of supplemental appropriations, the annual appropriations in FY2021 that are still pending final Congressional action, and the status of enactment of a continuing resolution, all substantially increase the complexity of the agency's planning for FY2022 and FY2023. HHS will continue to fulfill its commitment to submitting a PHEMCE multi-year budget to Congress as required, although the timing of the submission remains dependent on meeting the priorities of the COVID-19 response. The multi-year budget describes plans for medical countermeasure development broadly and is not required to include new or specific areas of focus such as COVID-19. HHS has not yet made a decision regarding the inclusion of financial projections for out-year funding needed to support continued medical countermeasure development for COVID-19. Prior multi-year budget reports are available online.[3]

[3] https://www.phe.gov/about/aspr/Pages/Budget.aspx

9. Plaintiffs allege that HHS did not "prepare and publish annually 'all current material threat determinations' as to and related assessments of the sufficiency of the [Strategic National Stockpile ("SNS")] of public health emergency countermeasures, as required by 42 U.S.C. § 247d-6b(c)(2)(C), (3)(A)–(B)." PI Mem. at 22; *see also* Compl. ¶ 45(a). The Material Threat Determination Report ("MTD Report"), which is to be provided to Congress by the Secretary of HHS and the Secretary of the Department of Homeland Security ("DHS") on an annual basis pursuant to § 247d-6b(c)(2)(C), is considered extremely sensitive by HHS and DHS and, as a result, is deemed "for official use only" and not publicly available. Likewise, notice that a material threat determination has been made, which is to be provided to various Congressional subcommittees under § 247d-6b(c)(2)(C), is considered extremely sensitive information by HHS and DHS and is also deemed "for official use only and not publicly available. There is no statutory requirement to make the report or notices public. As of the date of this declaration, HHS has prepared a draft of the 2020 MTD Report, and the agency expects that the report will be provided to Congress by the end of CY2020.

10. Likewise, assessments made by HHS and DHS regarding the availability and appropriateness of countermeasures to address any material threats in accordance with § 247d-6b(c)(3)(A)-(B) typically contain highly sensitive information which may reveal public health vulnerabilities, and contain "source selection information" (FAR 2.101) prepared for use by the agency for the purpose of evaluating a bid or proposal to enter into an agency procurement contract, such that disclosure of these assessments would jeopardize the integrity or successful completion of the Federal agency procurement to which the information relates. Thus, the results of these assessments are procurement sensitive-protected from disclosure, typically deemed "for official use only" or classified and are not publicly available. Under § 247d-

6b(c)(3)(B), the Secretary is required to institute a process for making publicly available the results of the assessments, but the statute does not dictate the particular process and provides that the Secretary may withhold information that tends to reveal public health vulnerabilities or would otherwise be exempt from disclosure under 5 U.S.C. § 552. HHS makes some of the assessments of countermeasures public through the Countermeasures SIP and multi-year budget documents submitted to Congress (which are also made public as discussed above). These documents highlight medical countermeasures that have been developed or acquired as well as the outcomes of medical countermeasure research and development. The Countermeasures SIP contains a table that lists prioritized threats for medical countermeasure preparedness activities. Additionally, completed acquisitions and advancements are announced on SAM.gov.

11. Ongoing assessments have been made and continue to be made on an as-needed basis. The assessments themselves are withheld from public disclosure as they would fall under Exemption 1 (classified information) or 4 (proprietary information) to public disclosure under 5 U.S.C. § 552. The assessments may be classified by DHS as containing vulnerability information that, if made public, would jeopardize national security and are subject to derivative classification or determination by ASPR that consequence assessments are protected information. The assessments contain outcomes of modeled terrorist attacks including death and injury, as well as assessments of the fitness of available or future medical countermeasures to curtail death and injury. Further, the determination as to whether a medical countermeasure is suitable to address a threat is a necessary step in acquisition of the countermeasures under 42 U.S.C. § 247d-6b(c) and are procurement-sensitive source selection information under Federal Acquisition Regulations (FAR) 2.101.

12. Plaintiffs allege that HHS did not provide "notice to Congress of use of various

emergency powers and funds to address the pandemic" under 42 U.S.C. §§ 247d-4a, 247d-6b(c)(6), and 247d(e)(4). PI Mem. at 22 n. 9; *see also* Compl. ¶ 47(a). No determination has been made regarding the sufficiency or selection of medical countermeasures specific to COVID-19 for expenditure of the Special Reserve Fund under § 247d-6b(c)(3)-(5), and therefore there is no requirement to satisfy the statutory requirements of § 247d-6b(c)(6). With respect to § 247d(e)(4), HHS has not yet notified Congress of the reassignment requests and renewals made pursuant to this subsection. Because states had not previously requested to use this authority during prior public health emergencies declared under section 319 of the Public Health Service Act, HHS had to establish a process for evaluating and approving the renewals at the outset of the COVID-19 pandemic. HHS has focused on evaluating and approving requests from states expeditiously to respond to the ongoing public health emergency, rather than compiling information for Congress but will address that oversight.

13. Plaintiffs allege that HHS did not "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)." PI Mem. at 22; *see also* Compl. ¶ 47(a). By statute, the reporting obligation is to Congress. *See* 42 U.S.C. § 247d-6b(a)(2). Publication of the annual Threat-Based Review of the SNS for 2020 has been as slightly delayed as a result of significant demand placed upon the agency's resources in responding to the COVID-19 pandemic. A draft of the report is awaiting reasonable deliberation and review by key PHEMCE personnel who are also responsible for guiding the agency's COVID-19 response. HHS anticipates that the report will be promulgated to Congress by the end of CY2020/Q1CY2021. The Threat-Based Review of the SNS has no bearing on the COVID-19 response, as the review is a routine, five-year projection of budgetary priorities for expenditures to maintain current or acquire future medical countermeasure for all

threats. This deliverable is "for official use only" and is not made publicly available as it contains vulnerability and capability information that if exposed could jeopardize national planning and capabilities. SNS contents and locations are protected from FOIA disclosure under section 319F-2(d) of the Public Health Service Act, 42 U.S.C. § 247d-6d.

14. Plaintiffs allege that HHS did not "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." PI Mem. at 22; *see also* Compl. ¶ 47(c). By statute, the reporting obligation is to Congress. 133 Stat. 905, 959. HHS has been slightly delayed in preparing and publishing the PAHPAIA Reporting Requirements: Vaccine Development Report as result of the significant demand placed upon the agency's resources in responding to the COVID-19 pandemic. As of the date of this declaration, a report covering the period of 2019 to early 2020 (April) has been prepared, and HHS expects that it will be finalized and published by the end of CY2020. Based on the time period covered by the Vaccines Development Report, it will not address any issues related to vaccines for COVID-19.

15. Plaintiffs allege that HHS did not "solicit the formal input of experts and stakeholders in public health emergency countermeasures planning in the PHEMCE [Countermeasures] SIP process, as required by 42 U.S.C. § 300hh-10(d)(2)(H)." PI Mem. at 23; *see also* Compl. ¶ 49(a). The agency has complied with this requirement. Specifically, input was solicited from private sector partners as well as state, local, tribal, and territorial ("SLTT") partners throughout the year regarding enhancing SLTT capabilities and addressing any gaps in health emergency countermeasures planning. That input was analyzed and incorporated into PHEMCE strategy planning. Participants were selected to engage based on professional background, and these engagements are ongoing and inform both assessments for preparedness

as well as PHEMCE Countermeasures SIP activities.

16. Plaintiffs allege that HHS did not "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." PI Mem. at 23; *see also* Compl. ¶ 49(b). HHS has taken steps to comply with this requirement. Specifically, in October 2019 the nation's foremost bioeconomy leaders from industry, academia, and government met at the White House for a discussion on maintaining leadership in bioeconomy that addressed advanced biotechnology techniques such as genome editing (many innovators in this area were present at the meeting). This meeting focused on strengthening and safeguarding the U.S. bioeconomy, laying the groundwork for future action, and identifying opportunities for private-public partnerships. HHS and other relevant departments and agencies planned to engage a subset of the meeting attendees for more focused discussion on applying such advanced biotechnology to health security and medical countermeasures development. This plan was delayed by the COVID-19 pandemic and response, however, as many of the persons who would participate in the discussion are currently focused on COVID-19 response. Interagency discussions are now restarting, and a medical-focused meeting is anticipated to take place in 2021 when vaccine and therapeutics begin playing a greater role in COVID-19 mitigation. "Relevant stakeholders" who would participate in this discussion are limited to those people, companies, academicians and government personnel that are actively involved in advanced biotechnology work. The absence of a more strategic longer-term planning meeting on genomic engineering is not directly related to, and thus did not hinder, HHS's COVID-19 response or preparedness activities.

17. Plaintiffs allege that HHS did not "[p]repare and publish, also by December 21, 2019, a 'Biological Threat Detection Report . . . on the state of Federal biological threat detection efforts,' 'the capabilities of 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." PI Mem. at 22; *see also* Compl. ¶ 39(b). By statute, this reporting obligation is to Congress. P.L. 116-22 § 205(c), 133 Stat. at 924-25. HHS has not yet prepared this report and will work to address that oversight by January 2021.

18. Plaintiffs allege HHS has failed to report on the implementation of the recommendations of the Federal Experts Security Advisory Panel concerning the select agent program, (related to dangerous biological agents and toxins and their countermeasures), which pursuant to 42 U.S.C. § 262a(k)(2) was due "[n]ot later than 1 year after June 24, 2019." *See* PI Mem. at 22; *see also* Compl. ¶ 47(b). HHS has prepared this report, but to date has not yet submitted it to Congress as result of delays due to the COVID-19 response. HHS expects to issue the report to Congress by the end of CY2020.

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

Dated: Washington, D.C.
November 16, 2020

Nikki Bratcher-Bowman