

VIA EMAIL & PAL PORTAL

April 8, 2020

Michael Marquis
FOIA Officer
Department of Health and Human Services
Hubert H. Humphrey Building, Room 729H
200 Independence Avenue, SW
Washington, DC 20201
E-mail: FOIARequest@hhs.gov

Dear Mr. Marquis:

This letter constitutes an urgent request under the Freedom of Information Act (“FOIA”), 5 U.S.C. § 552, and is submitted on behalf of the Electronic Privacy Information Center (“EPIC”) to the U.S. Department of Health and Human Services (“HHS”).

EPIC seeks records about HHS’s efforts to collaborate with Oracle on a software database to study the effectiveness of unproven drugs to treat COVID-19, known as the “COVID-19 Therapeutic Learning System.”¹

Documents Requested

- (1) All records—including but not limited to communications, memoranda, and policy guidance—about HHS collaboration with Oracle regarding the “COVID-19 Therapeutic Learning System” and
- (2) The required privacy assessments for the “COVID-19 Therapeutic Learning System.”

Background

Oracle founder and Chief Technology Officer Larry Ellison has proposed to develop, on the Oracle platform, a database to track coronavirus cases of experimental drugs that have not yet been approved by the FDA for the treatment of COVID-19.² According to a report in Forbes,

Doctors will register every COVID-19 case being treated with a medication on the Oracle-built website. The system will then send daily emails, to the doctor or the patient, to ask for a

¹ See Oracle Corp., *COVID-19 Therapeutic Learning System*, <https://covid19.oracle.com/>.

² Angel Au-Yueng, *Larry Ellison Reveals His Big Data Battle Plan to Fight Coronavirus in Partnership with Trump White House*, Forbes (Apr. 1, 2020), <https://www.forbes.com/sites/angelaueyung/2020/04/01/exclusive-larry-ellison-reveals-his-big-data-battle-plan-to-fight-coronavirus-in-partnership-with-trump-white-house/>.

progress report on symptoms. As of press time, the team was working to get over legal hurdles and was hopeful the project would launch imminently.³

Earlier, two senior administration officials have stated that the Oracle platform may also be used to mail the experimental drugs to patients involved in the trial.⁴

In an April 3, 2020 press briefing, HHS Secretary Alex Azar confirmed that Oracle is establishing a web portal (COVID19.Oracle.com) and platform that gathers real-time information from healthcare providers and patients about experimental drug treatments for COVID-19.⁵ And on April 5, 2020, President Trump stated, “And this week, Oracle, a great company, donated a new web portal — Larry Ellison, amazing guy — and platform to the government to gather real-time data on how patients are responding to the various new treatments. And they have a very sophisticated site, we’ll be learning a lot from Oracle.”⁶

The “Oracle Therapeutic Learning System” will store detailed sensitive medical health information, including records regarding patient’s response to experimental COVID-19 drugs. According to Oracle, doctors and patients will be prompted to enter daily status updates, including the patient’s COVID-19 status, in the system.⁷ Oracle further states that the federal government will access this sensitive personal data concerning patient outcomes by treatment type and geography.⁸ Oracle states that the system is collecting real-world patient data throughout the U.S. but will eventually collect patient data “throughout the world soon thereafter.”⁹

According to Oracle, the Therapeutic Learning System involves HHS, the FDA, the National Institutes of Health, the Center for Disease Control and Prevention, and the Centers of Medicare and Medicaid Services.¹⁰

If federal agencies intend to use health data to address the COVID-19 crisis, or to collaborate with private firms to gather such data, they should first consider whether the planned uses are lawful.

³ *Id.*

⁴ Noah Weiland & Maggie Haberman, *Oracle Providing White House With Software to Study Unproven Coronavirus Drug*, N.Y. Times (Mar. 24, 2020), <https://www.nytimes.com/2020/03/24/us/politics/trump-oracle-coronavirus-chloroquine.html>.

⁵ President Donald J. Trump, et al., Remarks by President Trump, Vice President Pence, and Members of the Coronavirus Task Force in Press Briefing (Apr. 3, 2020), <https://www.whitehouse.gov/briefings-statements/remarks-president-trump-vice-president-pence-members-coronavirus-task-force-press-briefing-18/>.

⁶ President Donald J. Trump, et al., Remarks by President Trump, Vice President Pence, and Members of the Coronavirus Task Force in Press Briefing (Apr. 5, 2020), <https://www.whitehouse.gov/briefings-statements/remarks-president-trump-vice-president-pence-members-coronavirus-task-force-press-briefing-19/>.

⁷ *Frequently Asked Questions*, Oracle COVID-19 Therapeutic Learning System (2020), <https://www.oracle.com/corporate/covid-19-tls-faq.html>.

⁸ *Id.*

⁹ Press Release, Oracle, Oracle Therapeutic Learning Systems Records Effectiveness of COVID-19 Drugs (Apr. 1, 2020), <https://www.oracle.com/corporate/pressrelease/oracle-records-effectiveness-covid-19-drugs-040120.html>.

¹⁰ *Id.*

Agencies should then follow all appropriate steps, including the completion of the requisite privacy impact assessments, before collection occurs and new uses are undertaken. In this instance, the word “privacy” appears nowhere among Oracle’s “Frequently Asked Questions.”

The use of aggregate and statistical data should be encouraged. That is the material of evidence-based policy. But the collection of health data that identifies particular individuals can pose a real threat to well established safeguards that safeguard medical privacy.

It is worth noting that shortly after the 9-11 attacks on the United States, Larry Ellison proposed to establish a system of national identification, using Oracle software.¹¹ Congress rejected Ellison’s proposal when the Department of Homeland Security was established with a clear prohibition on the creation of a national identity card in the United States. Congress said explicitly, “Nothing in this Act shall be construed to authorize the development of a national identification system or card.”¹²

The public has the right to know whether Oracle’s Therapeutic Learning System is lawful and whether the federal agencies working have conducted the necessary review.

PIA Requirement

Under Section 208 of the E-Government Act, an agency must undertake a Privacy Impact Assessment (“PIA”) when a federal agency (1) “develop[s] or procur[es] information technology that collects, maintains, or disseminates information that is in an identifiable form,” and (2) when an agency “initiat[es] a new collection of information” that “includes any information in an identifiable form.”¹³ This identifiable information, referred to as personally identifiable information (“PII”), is any information in a program or system that allows the identity of an individual to be directly or indirectly inferred.¹⁴ The Office of Management and Budget (“OMB”), for the purposes of the E-Government Act, follows the Clinger-Cohen Act definition of information technology: “any equipment, software or interconnected system or subsystem that is used in the automatic acquisition, storage, manipulation, management, movement, control, display, switching, interchange, transmission, or reception of data or information.”¹⁵

¹¹ Sumner Lemon, *Ellison Offers Free Software for National ID*, Computerworld (Sept. 24, 2011), <https://www.computerworld.com/article/2583197/ellison-offers-free-software-for-national-id.html> (“Ellison said the U.S. government should issue a national ID card that contains a photograph and digitized thumbprint for each U.S. citizen” . . . the Electronic Privacy Information Center (EPIC) in a statement urged Congress to carefully consider any legislation that could significantly erode a person's constitutional rights. The Washington-based EPIC and 150 other organizations said there is a ‘need to consider proposals calmly and deliberately with a determination not to erode the liberties and freedoms that are at the core of the American way of life.’”).

¹² See Homeland Security Act of 2002, Pub. L. No. 107-296 § 1514, 116 Stat. 2135, 2311.

¹³ E-Government Act of 2002, Pub. L. No. 107-347, § 208 (b)(1)(A)(i)-(ii), 116 Stat. 2899, 2921.

¹⁴ U.S. Dep’t of Homeland Sec., *Privacy Impact Assessments: The Privacy Office Official Guidance* 4 (2010), https://www.dhs.gov/sites/default/files/publications/privacy_pia_guidance_june2010_0.pdf.

¹⁵ Clinger-Cohen Act of 1996, 40 U.S.C. § 11101(6) (2011) (emphasis added); see also Exec. Office of the President, Office of Mgmt. and Budget, M-03-22, OMB Guidance for Implementing the Privacy Provisions of

The OMB further states: “In general, PIAs are required to be performed and updated as necessary where a system change creates new privacy risks.” Such system changes include, but are not limited to, “when agencies adopt or alter business processes so that government databases holding information in identifiable form are merged,” “when agencies work together on shared functions involving significant new uses or exchanges of information in identifiable form,” and “when new information in identifiable form added to a collection raises the risks to personal privacy.”¹⁶ Lastly, the OMB states: “Agencies should commence a PIA when they begin to develop a new or significantly modified IT system or information collection.”

The creation of the Oracle Therapeutic Learning System triggers Section 208 obligations. Through its coordination with Oracle, the HHS “initiat[ed] a new collection of information” that was “collected, maintained, or disseminated using information technology.” The system “includes . . . information in a tangible form,” including but not limited to biographic information, geographic information, and health information. A PIA should have been completed at before the database began collecting information.

EPIC has successfully litigated against federal agencies that have unlawfully failed to conduct required privacy impact assessments. In *EPIC v. Presidential Advisory Commission on Election Integrity*,¹⁷ EPIC brought suit against a federal advisory committee that sought to collect the personal data of every voter in the country without first conducting a PIA. The Commission was later disbanded and forced to delete the voter data it had unlawfully obtained. In *EPIC v. DHS*,¹⁸ EPIC brought suit against the Department of Homeland Security after the agency began developing a system for monitoring journalists without completing any privacy documentation. EPIC reached a settlement with the DHS halting the system. And in *EPIC v. Department of Commerce*,¹⁹ EPIC brought suit against the Commerce Department for failing to conduct required PIAs before adding the citizenship question to the 2020 Census. The citizenship question was subsequently withdrawn.

Request for Expedition

EPIC is entitled to expedited processing of this request under the FOIA and HHS’s FOIA regulations. 5 U.S.C § 552(a)(6)(E)(v)(II); 45 C.F.R. § 5.27(a). Specifically, this request is entitled to expedited processing because: first, there is “an urgent need to inform the public about an actual or alleged Federal Government activity,” and second, because the request is “made by a person primarily engaged in disseminating information to the public.” 45 C.F.R. § 5.27(b)(2).

First, there is “an urgent need to inform the public about an actual or alleged Federal Government activity.” 45 C.F.R. § 5.27(b)(2). The “actual . . . Federal Government activity” is the HHS’s coordinated efforts with Oracle to launch an online platform to study the effectiveness of experimental drugs on COVID-19 patients. The HHS has acknowledged its role in these efforts and

the E-Government Act of 2002 (Sept. 26, 2003), <https://www.whitehouse.gov/wp-content/uploads/2017/11/203-M-03-22-OMB-Guidance-for-Implementing-the-Privacy-Provisions-of-the-E-Government-Act-of-2002-1.pdf>.

¹⁶ *Id.* at 4.

¹⁷ 878 F.3d 371 (D.C. Cir. 2017).

¹⁸ No. 18-1268 (D.D.C. settled July 11, 2019).

¹⁹ 928 F.3d 95 (D.C. Cir. 2019).

will access the data collected from this system. The urgency to inform the public about these government activities is clear from the extensive press coverage and extraordinary privacy implications of collecting personal health data in connection with experimental drug treatments in the midst of a global pandemic.²⁰

Second, EPIC is an organization “primarily engaged in disseminating information to the public.” 45 C.F.R. § 5.27(b)(2). As the Court explained in *EPIC v. DOD*, “EPIC satisfies the definition of ‘representative of the news media’” entitling it to preferred fee status under the FOIA. 241 F. Supp. 2d 5, 15 (D.D.C. 2003). EPIC’s primary purpose is to focus public attention on emerging privacy and civil liberties issues and frequently disseminates information obtained through the FOIA on its website, EPIC.org.

In submitting this request for expedited processing, EPIC certifies that this explanation is true and correct to the best of its knowledge and belief. 5 U.S.C. 552(a)(6)(E)(vi); 45 C.F.R. § 5.27(a).

Request for “News Media” Fee Status and Fee Waiver

EPIC is a “representative of the news media” for fee classification purposes. *EPIC v. DOD*, 241 F. Supp. 2d 5 (D.D.C. 2003). Based on EPIC’s status as a “news media” requester, EPIC is entitled to receive the request records with only duplication fees assessed. 5 U.S.C. § 552(a)(4)(A)(ii)(II).

Further, any duplication fees should also be waived because disclosure because (1) “disclosure of the requested information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government;” and (2) “disclosure is not primarily in the commercial interest” of EPIC, the requester. 5 U.S.C. § 552(a)(4)(A)(iii); 45 C.F.R. § 5.54(a). EPIC’s request satisfies this standard based on the HHS’s three-factor consideration for granting a fee waiver. 45 C.F.R. § 5.54(b)(1)–(3).

(1) Disclosure of the requested information would shed light on the operations or activities of the government.

First, disclosure of the requested documents concern “identifiable operations or activities of the Federal Government.” 45 C.F.R. § 5.54(b)(1). HHS’s coordination with Oracle in developing an

²⁰ See e.g., Sarah Owerhohle & Dan Diamond, *Trump’s Push for Risky Malaria Drugs Disrupts Coronavirus Response*, Politico (Mar, 27, 2020), <https://www.politico.com/news/2020/03/27/trump-malaria-coronavirus-152498>; Peter Baker, Katie Rogers, David Enrich, & Maggie Haberman, *Trump’s Aggressive Advocacy of Malaria Drug for Treating Coronavirus Divides Medical Community*, N.Y. Times (Apr. 7, 2020), <https://www.nytimes.com/2020/04/06/us/politics/coronavirus-trump-malaria-drug.html>; Avery Hartmans, *Oracle Billionaire Larry Ellison Reportedly Urged Trump to Explore a Malaria Drug to Treat the Coronavirus*, Business Insider (Apr. 7, 2020), <https://www.businessinsider.com/donald-trump-malaria-drug-oracle-larry-ellison-hydroxychloroquine-coronavirus-report-2020-4>; Justine Coleman, *Trump Pushed Health Officials to Make Anti-Malaria Drugs Available As Coronavirus Treatment: Report*, The Hill (Apr. 5, 2020), <https://thehill.com/policy/healthcare/public-global-health/491251-trump-pushed-health-officials-to-make-anti-malaria>.

online platform to track the efficacy of experimental drugs against COVID-19 is an identifiable activity. HHS will access this data in its response efforts against the pandemic.

(2) Disclosure of the requested information is likely to contribute significantly to public understanding of the operations or activities of the government.

Second, disclosure of the requested documents would be “likely to contribute significantly to public understanding of [government] operations or activities.” 45 C.F.R. § 5.54(b)(2). The HHS evaluates two factors to determine whether this requirement is met: (i) disclosure “must be meaningfully informative about government operations or activities;” and (ii) “disclosure must contribute to the understanding of a reasonably broad audience of persons interested in the subject.” *Id.*

On the first factor, disclosure is “meaningfully informative about government operations or activities” because the release of the requested information will contribute to the public debate on over the government’s decision to collect personal health data and crowdsource clinical trials of experimental drugs without ordinary FDA controls. 45 C.F.R. § 5.54(b)(2)(i). This decision has also resulted in the establishment of a large database of sensitive health information that may be prone to data breaches and overcollection of information.

On the second factor, disclosure “contribute[s] to the understanding of a reasonably broad audience of persons interested in the subject.” 45 C.F.R. § 5.54(b)(2)(ii). As provided in HHS FOIA regulations, HHS shall “presume that a representative of the news media will satisfy this consideration.” *Id.*

(3) Disclosure of the information is not primarily in the commercial interest of the requester.

Third, disclosure is not “primarily in the commercial interest of” EPIC, the requester. 45 C.F.R. § 5.54(b)(3). EPIC has no commercial interest in the records. EPIC is a registered non-profit organization committed to privacy, open government, and civil liberties.²¹ EPIC consistently publishes critical documents obtained through the FOIA and through litigation on its robust website, EPIC.org, and its online newsletter, *EPIC Alert*.²² Under HHS FOIA regulations, the agency “will presume that when a news media requester has satisfied factors (b)(1) and (2) of [the fee waiver section], the request is not primarily in the commercial interest of the requester.” 45 C.F.R. § 5.54(b)(3)(ii). Again, EPIC is a news media requester and, as set out above, this request satisfies the public interest factors (b)(1) and (2).

For these reasons, EPIC’s request for a full fee waiver should be granted.

Conclusion

²¹ EPIC, *About EPIC*, <https://www.epic.org/epic/about.html>.

²² See EPIC.org, <https://www.epic.org/>; EPIC, *EPIC Alert*, <https://www.epic.org/alert/>.

Thank you for your consideration of this request. EPIC anticipates your determination on its request within ten calendar days. 5 U.S.C. § 552(a)(6)(E)(ii)(I); 45 C.F.R. § 5.27(c). For questions regarding this request contact Enid Zhou at Zhou@epic.org, cc: FOIA@epic.org.

Respectfully submitted,

/s Enid Zhou

Enid Zhou

EPIC Open Government Counsel

/s John Davisson

John Davisson

EPIC Counsel