United States Senate
WASHINGTON, DC 20510

October 30, 2019

The Honorable Alex M. Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Secretary Azar and Administrator Verma:

We write in regards to the Centers for Medicare and Medicaid Services' (CMS) failure to comply with a congressionally mandated report which requires CMS to detail the circumstances in which CMS may be funding entities that process Americans' genome or exome data in China or Russia.

Specifically, the Joint Explanatory Statement ("Statement") accompanying legislation appropriating funding for the Department of Health and Human Services for Fiscal Year 2019 (P.L. 115-245) states, "Each department and agency funded in this Act shall follow the directions set forth in this Act and the accompanying statement, and shall not reallocate resources or reorganize activities except as provided herein."[1] The same Statement directed the Secretary of Health and Human Services to issue a report within 90 days of the bill's enactment detailing instances in which CMS may have provided funding to entities that process Americans' genome or exome data in China or Russia.[2] This congressionally-mandated report also directed the Secretary to coordinate with other relevant agencies to examine the potential effect of allowing beneficiaries' genome or exome data to be processed in China or Russia on U.S. national security, U.S. intellectual property protections, HIPAA privacy protections, future biomedical development capabilities and competitiveness, and global competitiveness for U.S. laboratories.[3]

More than a year has passed since this appropriations bill was enacted. Yet, CMS has failed to submit the report.

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[1] Joint Explanatory Statement of the Committee of Conference accompanying H.R. 6157, the Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019.
[2] *Id.* at 47.
[3] H.R. 6157, the Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019, Engrossed Senate Amendment, Section 251 (August 23, 2018).

As you may know, the Federal Bureau of Investigation (FBI) Weapons of Mass Destruction Directorate has identified national security risks related to sharing genomic data, and recognizes China as a country that is a primary source of those risks. The FBI also identified the Shenzhen BGI Technology Company (BGI) and WuXi Nextcode Genomics (WuXi) as companies that have ties to the Chinese Government.[4]

As we previously noted to the Inspector General, we are concerned that CMS may be providing payments for genetic testing or analysis to U.S. entities that have domestic partnerships with WuXi, BGI, and other genomics companies with ties to the Chinese government. In 2016, WuXi was the first genetic sequencing facility in China to gain CLIA (Clinical Laboratory Improvement Amendments) certification from CMS. It has since gained a foothold in the U.S.[5] Similarly, BGI has publicly announced partnerships with leading American health care systems, including those that accept Medicare and Medicaid patients.[6] In 2013, BGI acquired Complete Genomics, a U.S. company which later became part of MGI Tech (MGI), a BGI subsidiary.[7] In March 2019, MGI announced plans to expand into the U.S. market by the end of 2019, making it all the more necessary to determine whether CMS payments are negatively impacting the interests of the United States.

Both BGI and WuXi also have publicly touted their partnerships with Huawei to expand genomic analytics.[8] As you know, Huawei is a State-directed Chinese telecommunications company that, according to the heads of six U.S. intelligence agencies including the CIA, FBI, NSA, and the Director of National Intelligence, possesses the capabilities to "maliciously modify or steal information" and "to conduct undetected espionage."[9] This is the same company that the U.S. recently charged with conspiring to defraud our nation and stealing trade secrets, among other crimes.[10] WuXi and BGI's U.S.-based partnerships give them unique access to genomic

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[4] Department of Health and Human Services Office of the Inspector General, "Opportunities Exist for the National Institutes of Health to Strengthen Controls in Place to Permit and Monitor Access to Its Sensitive Data" Report No. A-18-18-09350 (February 2019), *available at* https://oig.hhs. gov/oas/reports/region 18/ 181809350.pdf.

[5] *WuXi NextCODE Becomes the First and Only CAP, CLIA, and California Accredited Sequencing Laboratory in ChinaPR*, Newswire (Feb. 23, 2016), *available at* https://www.prnewswire.com/news-releases/wuxi-nextcode-becomes-the-first-and-only-cap-clia-and-california-accredited-sequencing-laboratory-in-china-300224420.html; *WuXi Biologics to Invest $60 Million to Establish a Biologics Production Facility in the United States*, WuXi Biologics (Jun. 11, 2018), *available at* https://www.wuxibiologics.com/wuxi-biologics-invest-60-million-establish-biologics-production-facility-united-states/; *Boston Children's Hospital accelerates genomic sequencing to expand existing genomic database*, EurekaAlert! (Aug. 7, 2018), *available at* https://eurekalert.org/pub_releases/2018-08/bch-bch080618.php.

[6] *BGI Announces New Partnerships and 8th Anniversary Milestone in US*, BGI (May 4, 2018), *available at* https://www.bgi.com/us/company/news/bgi-announces-new-partnerships-8th-anniversary-milestone-us/.

[7] *About Us*, Complete Genomics, *available at* https://www.completegenomics.com/. See also, https://en.mgitech.cn/page/gsjj.html.

[8] Alex Esson, *Tech giant Huawei enters genomic arena with China Precision Medicine Cloud*, Front Line Genomics (May 24, 2016), *available at* http://www.frontlinegenomics.com/news/5285/tech-giant-huawei-enters-genomic-arena-wuxi-nextcode/; *Huawei and BGI Sign Joint Development Agreement on Big Data Storage Systems for Genetic Research at HCC2015*, BGI (Sep. 23, 2015), *available at* https://www.bgi.com/%E5%85%B3%E4%BA%8E%E6%88%91%E4%BB%AC/careers/huawei-and-bgi-sign-joint-development-agreement-on-big-data-storage-systems-for-genetic-research-at-hcc2015.

[9] Sara Salinas, *Six top US intelligence chiefs caution against buying Huawei phones*, CNBC (Feb. 13, 2018), *available at* https://www.cnbc.com/2018/02/13/chinas-hauwei-top-us-intelligence-chiefs-caution-americans-away.html (last updated Feb. 15, 2018). See also, White House Executive Order on Securing the Information and Communications Technology and Services Supply Chain (May 15, 2019), https://www.whitehouse.gov/presidential-actions/executive-order-securing-information-communications-technology-services-supply-chain/

[10] *Chinese Telecom Conglomerate Charged with Multiple Crimes*, Federal Bureau of Investigation (Jan. 28, 2019), *available at* https://www.fbi.gov/news/stories/chinese-telecom-firm-huawei-indicted-012819.

data, including Americans' genomic data. Therefore, it is particularly alarming that these two companies have partnered with Huawei.

As of March 2019, the Congressional Budget Office estimates that the federal government's gross spending on Medicare in 2018 was $712 billion, while federal Medicaid expenditures were $389 billion, not including the states' Medicaid spending.[11] Together, these two programs totaled more than $1.1 trillion in federal outlays in 2018. Taxpayers cover the costs of CMS payments and have every right to know if their money has gone to entities connected to the Chinese or Russian governments.
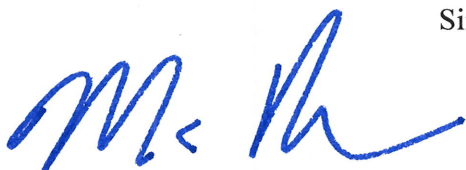
Accordingly, we request that you provide an update on the status of this report by November 14, 2019. In addition, we request that you expand the scope of this report to include payments for genome or exome analysis to domestic Medicare and Medicaid providers that have partnerships with Chinese genomics companies, including but not limited to BGI and WuXi.

Along with the update on the status of the report, please provide responses to the following questions no later than November 14, 2019:

1. Does CMS require providers to notify CMS of all labs it contracts with for services covered by Medicare or Medicaid? If not, why not?

2. Does CMS require providers to notify CMS if beneficiaries' genetic information is sent or stored outside of the United States? If not, why not?

3. As a condition of obtaining or retaining CLIA certification, does CMS require labs to notify CMS of all partnerships it maintains to perform services covered by Medicare or Medicaid? If not, why not?

Thank you for your attention to this important issue. Should you have questions, please contact Ansley Rhyne of Senator Rubio's staff at 202-224-3041 and Joshua Flynn-Brown of Chairman Grassley's staff at 202-224-4515.

Sincerely,

Marco Rubio
U.S. Senator

Charles E. Grassley
Chairman
Committee on Finance

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[11] *Medicare—CBO's May 2019 Baseline*, Congressional Budget Office (May 2, 2019), *available at* https://www.cbo.gov/system/files?file=2019-05/51302-2019-05-medicare_0.pdf.