

United States Senate

WASHINGTON, DC 20510

June 10, 2019

Ms. Joanne M. Chiedi
Acting Inspector General
U.S. Department of Health and Human Services
300 Independence Avenue, SW
Washington, D.C. 20201

Dear Acting Inspector General Chiedi:

According to a February 2019 report released by the U.S. Department of Health and Human Services Office of the Inspector General (OIG), the Federal Bureau of Investigation (FBI) has identified national security risks related to sharing genomic data, and recognizes China as a country as a primary source of those risks.¹ The report raises concerns that the National Institutes of Health (NIH) gave access to U.S. genomic data to for-profit companies from China, including WuXi Nextcode Genomics (WuXi) and Shenzhen BGI Technology Company (BGI), “even though the FBI has identified those companies as having ties to the Chinese Government.”² We agree with your office’s recommendations for the NIH to work with national security experts to assess the potential consequences of providing foreign entities access to Americans’ genomic information. We also support your efforts to bring this issue to the NIH’s attention and its recommendation that NIH work to mitigate these risks.

We are equally 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.³ Similarly, BGI has publicly announced partnerships with leading American health care systems, including those that accept Medicare and Medicaid patients.⁴ In 2013, BGI acquired Complete Genomics, a U.S. company which later became part of MGI Tech (MGI), a BGI subsidiary.⁵ In March 2019, MGI announced plans to expand into the U.S. market by the end of 2019, making it all the more necessary for the OIG to determine whether CMS has the proper security protocols in place to protect Americans’ genetic information.

¹ 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/region18/181809350.pdf>.

² *Id.* at 4.

³ *WuXi NextCODE Becomes the First and Only CAP, CLIA, and California Accredited Sequencing Laboratory in China*, PR 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://eurekaalert.org/pub_releases/2018-08/bch-bch080618.php.

⁴ *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/>.

⁵ *About Us*, Complete Genomics, available at <https://www.completegenomics.com/>. See also, <https://en.mgitech.cn/page/gsjj.html>.

Both BGI and WuXi also have publicly touted their partnerships with Huawei to expand genomic analytics.⁶ 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.”⁷ This is the same company that the U.S. recently charged with conspiring to defraud our nation and stealing trade secrets, among other crimes.⁸ WuXi and BGI’s U.S.-based partnerships give them unique access to genomic 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.⁹ Together, these two programs totaled more than \$1.1 trillion in federal outlays in 2018 – far more than federal funding to the NIH. Taxpayers cover the costs of CMS payments. Accordingly, they have every right to know if their money has gone to entities connected to the Chinese government.

We therefore request that the OIG, in coordination with relevant Intelligence Community agencies, review CMS payments to determine whether it has made payments for genetic testing to U.S. entities with partnerships to BGI, WuXi and any other company with ties to the Chinese government. We also request that the OIG determine whether the CMS considers national security risks when determining whether payments are permissible to providers with partnerships with these Chinese-affiliated companies. Finally, we ask that the OIG make recommendations to CMS and to Congress on ways to mitigate national security risks related to Americans’ genomic data with respect to CMS payments.

Thank you for your attention to this important issue. Please respond no later than June 24, 2019. Should you have questions please contact Joshua Flynn-Brown of Chairman Grassley’s staff at 202-224-4515 and Ansley Rhyne of Senator Rubio’s staff at 202-224-3041.

Sincerely,



Charles E. Grassley
Chairman
Committee on Finance



Marco Rubio
U.S. Senator

⁶Alex 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>.

⁷Sara 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-huawei-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/>

⁸*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>.

⁹*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.