

Dear Congressional Leaders:

Earlier this year, before the House passed the **BIOSECURE Act, H.R. 7085**, I wrote to many members of Congress to raise significant Constitutional concerns with this legislation and the companion bill in the Senate, **S. 3558, the Prohibiting Foreign Access to American Genetic Information Act of 2024**.

These bills, which target Complete Genomics, a U.S.-based company I founded in 2005 in California, are based on false information about the ownership and business activities. The bills impose catastrophic market restrictions that would overwhelmingly restrict us from competing in the U.S. market, impacting nearly 200 jobs in the Bay Area, including at [our new manufacturing facility at our San Jose headquarters](#). We believe these flawed bills are unconstitutional and vulnerable to legal challenges.

Since I originally wrote to Congress, the House passed the **BIOSECURE Act** despite notable bipartisan opposition, including from Democratic leadership, that raised some of the same Constitutional concerns we communicated earlier and reprise below. Indeed, Congressman McGovern argued during floor debate: “I want to get it right in a way where we can’t be accused of just blacklisting companies because we don’t like their last name....If they don’t belong in the underlying legislation, there is no way to get off the list....This is not what we are supposed to do in the United States. Due process actually matters here. The truth matters here.”

The truth, indeed, does matter. The premise for the inclusion of Complete Genomics in these bills is that the company somehow poses a risk of sharing Americans’ sensitive genomic data with foreign parties. No supporting evidence has been presented in the Congressional Record for this allegation and it is patently false. Complete Genomics is in the instrument manufacturing business; we do not provide sequencing or any other data-related services. Our customers, whether academic, research-based or commercial, use our devices to sequence genetic material in the course of their research. Any personal genetic data created in this process is collected and controlled by these customers, and none of it is shared with or accessible to Complete Genomics – just as MRI images are not accessible by MRI instrument manufacturers.

The reality is that Complete Genomics has no access to genomic patient data and does not collect or maintain it, so the company has no such data that it could share with any external party. Our instruments operate without Internet links to our or any other servers, which has been proven. In 2023, former FBI cybersecurity experts at [FTI Consulting](#) validated the security of the Complete Genomics T7 state-of-the-art sequencer, as well as a separate ZTRON server used for local storage by customers. Their [report](#) concluded that, based on their assessment, our technology did not result in outbound, external IP communications during genomic sequencing, nor did our technology contain any immediately concerning source code or network vulnerabilities.

A second misconception that supporters of the pending bills have stated to justify naming Complete Genomics is that the company is a subsidiary of BGI – which is also named in the legislation. That claim is also false and not supported with evidence in the Congressional Record. While it is true that a Shenzhen BGI Genomics Technology Co., Ltd. entity purchased Complete Genomics in 2013, today Complete Genomics is

100% owned by MGI, which went public in 2022 on the Shanghai Stock Exchange Science and Technology Innovation Board, commonly referred to as the STAR Market, and is a separate company from BGI's parent and subsidiary companies with its own management, employees, and assets. MGI and Complete Genomics are no longer subsidiaries of any BGI entity, and no BGI entity has a direct investment in MGI.

The FAQ section of FixBiosecureAct.com contains a copy of the MGI prospectus filed with the Shanghai Exchange in connection with its IPO, which confirms, "MGI holds 100% equity of Complete Genomics US through MGI Tech."

MGI and its wholly owned subsidiary Complete Genomics also operate in different businesses than BGI. BGI is a sequencing services provider. MGI and Complete Genomics are manufacturers and sellers of genomic sequencing instruments and provide no sequencing services and have no access to genomic data.

The inclusion of Complete Genomics in the pending bills and the extreme market restrictions they impose, based on this false information and absent any documentary record to the contrary, provide most of the legal grounds for the concerns raised by our experts. We have three specific legal concerns:

- First, we believe that the legislation, if passed, would violate the U.S. Constitution's Bill of Attainder Clause as it singles out Complete Genomics and inflicts punishment on the Company by restricting its ability to enter into contracts with current and future customers. This Clause is intended to prevent legislatures from determining the guilt of, and punishing, specific individuals or entities in the absence of a judicial process. Specifically, a legislative act violates the Bill of Attainder Clause when it "(1) applies with specificity, and (2) imposes punishment," both of which apply here. The Congressional Record does not contain any evidence that Complete Genomics poses a national security risk, and in the absence of national security risk or any other legitimate basis for naming Complete Genomics, the law would be merely punitive and violate the U.S. Constitution.
- Second, the bills, if enacted, violate the Fifth Amendment's Due Process Clause. While they provide a process and multi-factor set of criteria for the Executive Branch to follow in listing additional entities for coverage under the law, Complete Genomics has been named from the start based on false information without any notice or reasonable process to support such a determination. Moreover, there is also no process identified in the law for Complete Genomics or any other entity to be delisted in the future, a concern voiced by Rep. McGovern.
- Third, the bills, if passed, likely constitute a 'taking' in violation of the Fifth Amendment. The Fifth Amendment requires just compensation for any government taking of property. Here, the legislation would severely reduce, if not shutter, Complete Genomics' U.S. business by effectively preventing the company from selling its instruments to the vast majority of U.S. customers and potential customers, which is effectively a taking. And the bill contains no mechanism for any type of compensation which meets the test of a taking.

We share the desire of many in Congress to protect personal DNA data and diversify the American supply chain, but singling out companies like ours that don't even have access to such data – and therefore cannot share it – has only a few % of US sequencing market and has started US manufacturing is not the way to

accomplish this, and eliminating a company that constitutes less than 5% of the US sequencing market will have serious and very real consequences:

- It will adversely impact customers whose labs receive federal funding or grants and conduct life-saving and cutting-edge research, including in fields such as public health, cancer, Alzheimer's and infectious diseases.
- It will disrupt the overall supply chain and ecosystem within the genomics industry, causing delays in critical research and putting future cures and treatments out of reach.
- It will further concentrate the already-concentrated sequencer market, leading to fewer choices and higher prices for labs with already tight budgets, as well as less innovation in the market overall.
- It will drive up costs for genomic research in the U.S., as our sequencers are the most cost efficient, giving a competitive advantage to labs and researchers outside the U.S. who will still be able to access the latest technology.
- Last, it will diminish confidence in Congress' ability to protect genomic data because, despite its promises, this legislation does little to protect genomic data and does not mention or cover many companies who control the largest pools of genomic data of Americans.

Indeed, if Congress is serious about protecting genomic data, it should prescribe uniform standards that apply consistently to all companies and parties that have access to personal DNA data – much as HIPAA does for healthcare data – rather than barring market access for select companies, some of which have no access to such data.

For all of these reasons and the serious Constitutional concerns raised here, we urge Congress to remove Complete Genomics from the aforementioned legislation.

Thank you for your consideration and please let me know if there is any further information we could provide to assist with your consideration of this legislation.

Sincerely,



Rade Drmanac  
Cofounder and Chief Scientific Officer, Complete Genomics