

OFFICE OF THE GOVERNOR
STATE OF MONTANA

GREG GIANFORTE
GOVERNOR



KRISTEN JURAS
LT. GOVERNOR

June 6, 2025

The Honorable Brandon Ler
Speaker of the House
State Capitol
Helena, MT 59620

The Honorable Matt Regier
President of the Senate
State Capitol
Helena, MT 59620

Dear Speaker Ler and President Regier:

Montanans count on us to protect and uphold their privacy rights as explicitly provided in our Constitution, especially when it comes to safeguarding their personal, private, and sensitive data. Over the past four years, I'm proud of what we've accomplished together to enact strong data privacy protections aimed at preventing harm and ensuring individuals have more control over their personal data. With comprehensive consumer data privacy protections on the books, Montana is at the forefront of protecting residents' personal, private, and sensitive information.

Senate Bill 410 is well-intended legislation that aims to build on existing privacy protections and prevent foreign adversaries from gaining access to sensitive genetic information. I appreciate and agree with the intent of Senate Bill 410, but existing federal regulations already prohibit the sharing of Americans' genetic data with adversarial countries.¹

Unfortunately, some of the restrictions of Senate Bill 410 extend beyond our nation's adversaries, to our nation's allies who are critical partners in medical research that Montanans rely on. The unintended consequence of Senate Bill 410 is that it effectively prevents Montanans from participating in lifesaving clinical trials. By generically prohibiting the storage of genetic information outside of the United States, Senate Bill 410 puts ongoing lifesaving research with our international partners at risk, including research conducted in Montana.

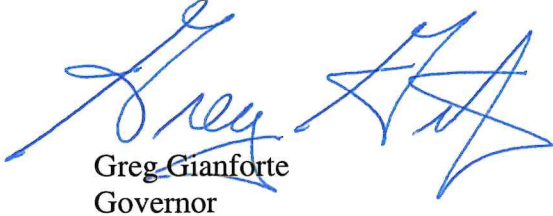
¹ "Executive Order 14117 of February 28, 2024, Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern," *Federal Register* 89, no. 42 (March 1, 2024): 15421, <https://www.govinfo.gov/content/pkg/FR-2024-03-01/pdf/2024-04573.pdf>.

Among the attached letters, Billings Clinic Logan Health highlights several clinical trials that Montana patients are participating in that Senate Bill 410 will jeopardize, including a cystic fibrosis study that involves sending samples to Italy, a multiple sclerosis trial based in Switzerland, and a breast cancer study that sends samples to Canada. Senate Bill 410 will eliminate the opportunity for Montanans to participate in clinical trials to address debilitating and life-threatening medical conditions they face, unless they are willing to travel to other states for care.

Other states across the country have worked to protect genetic data from foreign adversaries but have also allowed for ongoing research collaborations with international partners. While I believe there are strong, existing state and federal laws and regulations that protect the personal, private, and sensitive genetic data of Montanans, I look forward to working with legislators and industry stakeholders through the interim to further enhance protections for sensitive genetic information without hindering critical, lifesaving research that Montanans rely on.

Therefore, in accordance with the power vested in me as Governor by the Constitution and the laws of the State of Montana, I hereby veto Senate Bill 410: "AN ACT PROVIDING FOR THE MONTANA GENOMIC SECURITY ACT; PROHIBITING MEDICAL AND RESEARCH FACILITIES IN THE STATE FROM USING A GENETIC SEQUENCER OR GENETIC SEQUENCING SOFTWARE PRODUCED BY A FOREIGN ADVERSARY; PROHIBITING STORAGE OF GENETIC SEQUENCING DATA OF MONTANANS OUTSIDE OF THE UNITED STATES; REQUIRING WRITTEN CONSENT OF AN INDIVIDUAL TO REMOTELY ACCESS THEIR GENETIC SEQUENCING DATA THAT IS NOT OPEN DATA; PROVIDING GENETIC INFORMATION STORAGE REQUIREMENTS FOR FACILITIES; PROVIDING PENALTIES; AND PROVIDING DEFINITIONS."

Sincerely,



Greg Gianforte
Governor

Enclosures

cc: Legislative Services Division
Christi Jacobsen, Secretary of State

June 2, 2025

Honorable Greg Gianforte
Governor, State of Montana
State Capitol
Helena, MT 59620-0801

Re: S.B. 410 – Veto Request

Governor Gianforte:

On behalf of Billings Clinic Logan Health, we respectfully request your veto of S.B. 410 to avoid any potential unintended consequences this legislation may have on access to clinical research trials for the citizens of Montana.

We understand Senator Zolnikov's sincere intentions behind this bill and the need to protect the genomic information of Montanans. However, we fear that, as written, S.B. 410 will limit or possibly eliminate much of the medical research conducted by our facilities. Provisions within the bill limit the ability to access genetic information from outside of the United States and prohibit the storage of such data outside of the US. Much of the research done by Billings Clinic revolves around industry trials which involve some component of genetic information. As the field of medicine moves towards personalized precision care, we have become more dependent on genomic data to guide individual treatment plans. These studies are generally international in nature, meaning that there is a high probability that some genetic information is being stored and or accessed from outside the United States.

Examples of research done by Billings Clinic, likely to be impacted, include the following:

- Billings Clinic is currently participating in a cystic fibrosis study that involves sending samples to Italy. While this study only has a few participants in MT, it is impactful to their quality of life.
- Novartis, based in Switzerland, is one of our primary sponsors of research at Billings Clinic. We are currently participating in a Multiple Sclerosis trial with a small number of patients.
- We are currently screening candidates for a consortium study involving breast cancer that requires us to send tissue to Canada.
- One recently completed international study looked at early detection of cancer, offering high-risk individuals who have a family or personal history of cancer access to genetic testing for cancer susceptibility mutations in a randomized trial. This trial included more than 5500 Billings Clinic primary care patients.

In addition to those listed above, Billings Clinic participates in multiple studies in Oncology, Cardiology, Neurology, Infectious Disease and other specialties. We have also participated in studies where patients from other countries travel to us to participate in a study. These clinical trials allow our patients early access to cutting edge treatments which often become standards of care after completion of the trial. Many of these patients have exhausted other treatment options and these trials offer new hope to the Montanans we serve. SB 410 would severely impede our ability to do this work. Patients will likely be forced to choose between traveling to major metropolitan areas in other states such as Denver or Seattle or forgoing participation altogether.

Senator Zolnikov was gracious enough to come to Billings Clinic and meet with us regarding our concerns. We have committed to collaborating with him to fine tune the bill language in the interim to address the unintended consequences and produce a bill for next session that protects the genomic information of Montanans while allowing the valuable international collaborations around critical medical research.

Thank you for your consideration of our veto request.

Regards,

Heidi Duncan, M.D.

Heidi M. Duncan, M.D.
Physician Director of Health Policy
Billings Clinic Logan Health

May 12, 2025

Honorable Greg Gianforte
Governor, State of Montana
State Capitol
Helena, MT 59620-0801

Re: S.B. 410 – Veto Request

Governor Gianforte:

Johnson & Johnson (J&J) respectfully urges you to veto S.B. 410 due to the potential unintended consequences that its implementation may have on both clinical research and patient care.

We recognize and appreciate the sponsor's intent and concern regarding the utilization of foreign genetic sequencers. However, other provisions of S.B. 410, as passed by the legislature, would severely restrict the ability of companies to collaborate in research with international partners, including Canada. The potential signing of this legislation could hinder innovation, stall investment, and result in negative outcomes for patients in Montana.

Our primary concern lies in the data storage and access stipulations in Section 5, which mandates that "all genetic sequencing data from the state must be restricted to the geographic location of the United States. Except for open data, genetic sequencing data from the state may not be accessed remotely from outside the United States unless explicit written approval is obtained from the individuals whose data would be accessed."

Cutting edge biomedical research requires collaboration between some of the world's most knowledgeable scientists and physicians and consequently requires international collaboration among experts. At Johnson & Johnson, we take seriously the security of our research participants' data, and comply with a complex series of laws, regulations, and professional and company standards and policies to ensure protection of sensitive data. If enacted, we have concerns about our ability to continue to conduct cancer-related research in Montana.

We propose an amendment that would restrict genetic sequencing data storage and access specifically in foreign adversary countries. This amendment would facilitate ongoing research collaborations with international partners while preventing the sharing of genetic sequencing data with foreign adversaries, aligning with what we believe is the original intent of the bill. Similar language has already been integrated into legislation in several states, including Utah, Texas, Kansas, Tennessee, Louisiana, and Arkansas.

In line with this approach, the U.S. Department of Justice issued a final rule on January 8, 2025, which addresses the safeguarding of Americans' personal data from "countries of concern" as mandated by Executive Order 14117. This rule prohibits the transfer of bulk sensitive data, including genetic information, to China and other designated countries of concern. Importantly, even in those instances, the DOJ rule incorporates carefully tailored exceptions to ensure that Americans' access to health care is not needlessly impacted as a result of these restrictions. These exceptions are not included in Senate Bill 410.

Lastly, we have concerns regarding Section 6 (Penalties for non-compliance) in that cutting-edge healthcare companies may be forced to invest their clinical research, precision medicine and advanced technology dollars in states where doing so does not risk a significant monetary penalty each and every time data is accessed to do their job to advance patient care.

In conclusion, if enacted, this legislation may position Montana as an outlier and lead to unintended consequences that could negatively impact critical, lifesaving research and patient treatment options.

For these reasons, we respectfully request that you consider vetoing Senate Bill 410. Thank you for considering our perspective.



Christine Maroulis
Director, State Government Affairs
Worldwide Government Affairs & Policy

May 29, 2025

Honorable Greg Gianforte
Governor, State of Montana
State Capitol
Helena, MT 59620-0801

Re: SB 410 – Veto Request

Governor Gianforte:

This correspondence will serve as a follow up to our initial letter dated May 12, 2025, which respectfully requested your veto of SB 410 due to the potential unintended consequences that its implementation may have on both clinical research and patient care.

We appreciated the opportunity to meet with Rachel Green and Mark Blasdel on May 27, 2025, and hope that the information contained in this letter will offer some additional follow up information regarding some excellent questions raised during our discussion.

As we stated in our initial letter, we very much appreciate the sponsor's intent and concern regarding the utilization of foreign genetic sequencers, as we take the protection of patient data to be of the utmost importance. While SB 410 would establish that genetic sequencing data must be secured by "reasonable encryption methods, restrictions on access, and other cybersecurity best practices," Montanans can rest assured that existing state and federal law already protect their genetic data to this standard.

- Section 7(b) of the **Montana Consumer Data Privacy Act** already requires that a company "(b) establish, implement, and maintain *reasonable* administrative, technical, and physical data security practices to protect the confidentiality, integrity, and accessibility of personal data *appropriate to the volume and nature of the personal data at issue*." Genetic data is universally considered to be among the most sensitive types of data, subject to the highest security requirements. The Attorney General is empowered to enforce this law.
- At the federal level, most genetic data collected by and through health care providers is covered by the **HIPAA Security Rule**, which is widely regarded as among the most strict and prescriptive security standards. In addition, the FTC regularly brings enforcement actions under **Section 5 of the FTC Act** against companies for failing to secure health data, including genetic data.

Moreover, at both the state and federal level, **breach notification laws** place significant pressure on companies to secure genetic and other health data in order to avoid the consequences of a data breach. Indeed, when a data breach occurs, companies must notify individuals, State regulators, and Federal regulators, giving rise to enforcement risks and class actions.

Lastly, it is important to note that US Department of Justice published a Final Rule (**28 CFR Part 202 "Access to U.S. Sensitive Personal Data and Government-related Data by Countries of Concern or Covered Persons," which was made effective on April 18, 2025**) which criminalizes the transfer of covered genetic data (100 records or more) to countries of concern and individuals working in those countries or for companies domiciled there. This means that – with certain narrow exceptions, including importantly for FDA-regulated clinical trial activity – existing federal regulations already prohibit the sharing of genetic data of Montanans with people in adversarial countries."

If SB 410 is signed into law, these restrictions will extend to non-adversarial countries, including Canada and the European Union, and to contexts where such restrictions are likely NOT in the best interest of those whose data is being used (eg, clinical trials).

Attached to this letter is a spreadsheet created from clinicaltrials.gov which lists all planned and currently enrolling clinical trials (n=258), as well as recently completed studies (n=2,724), which include patients and sites in Montana. These are examples of clinical research (and patient care) that will – very unfortunately - be at risk to continue/move to completion upon the enactment of SB 410 (or are examples of studies in Montana that would have been impacted by enactment).

Lastly, in our previous correspondence, we noted our commitment to work with the bill sponsor on an amendment that would restrict genetic sequencing data storage and access specifically in foreign adversary countries but would allow for ongoing research collaborations with international partners. We mentioned several states' legislative activity in our May 12, 2025 correspondence that could be considered, but one specific example for reference is Tennessee (HB25-395), which was enacted on April 4, 2025.

68-30-205. (a) A medical facility or research facility shall not store genetic sequencing data within a foreign adversary. The medical facility or research facility shall not allow remote access to genetic sequencing data storage within its direction or control, other than open data, to a foreign adversary, unless approved in writing by the commissioner of health.

Cutting edge biomedical research requires collaboration between some of the world's most knowledgeable scientists and physicians and consequently requires international collaboration among experts. At Johnson & Johnson, we take seriously the security of our research participants' data, and comply with a complex existing series of laws, regulations, and professional and company standards and policies to ensure protection

of sensitive data. If enacted, we have concerns about our ability to continue to conduct cancer-related research in Montana.

I hope this additional information is useful to you and your staff in your consideration of our veto request of SB 410. Thank you for considering our perspective.

A handwritten signature in cursive script, reading "Christine Maroulis".

Christine Maroulis
Director, State Government Affairs
Worldwide Government Affairs & Policy



MONTANA
BioSCIENCE
ALLIANCE

PO Box 6464
Bozeman, MT 59771
406-253-8297
director@montanabio.org
05/29/2025

The Honorable Greg Gianforte
Governor of the State of Montana
State Capitol
P.O. Box 200801
Helena, MT 59620-0801

RE: Veto Request for Senate Bill 410 – Montana Genomic Security Act

Dear Governor Gianforte,

On behalf of the Montana Bioscience Alliance and the many researchers, entrepreneurs, and small businesses we represent across our state, I respectfully urge you to **veto Senate Bill 410**.

Montana has long been a quiet leader in bioscience innovation. From the foundational work of Dr. Maurice Hilleman to the world-class infectious disease research at NIH's Rocky Mountain Laboratories in Hamilton, our state has contributed to global health breakthroughs while supporting the growth of local companies working on diagnostics, therapeutics, and public health solutions.

SB 410, as currently written, threatens to undermine that progress.

While we support the bill's intent to protect sensitive data from foreign adversaries, its overly broad data storage and access restrictions, particularly the mandate that genetic sequencing data from Montana cannot be stored or accessed outside the United States, would have immediate and harmful effects on Montana's research and business community.

Across our state, small companies and startups depend on international collaboration to remain competitive and to scale innovation. Many of our bioscience entrepreneurs are engaged in research partnerships and clinical trials with trusted institutions and companies in Canada, the United Kingdom, Spain, Australia, Denmark, Japan, Taiwan, and other allied nations. SB 410 would abruptly disrupt these joint efforts, cutting off access to shared genetic data platforms, delaying research, and jeopardizing both public and private investments in Montana's bioscience sector.

Montana cannot afford to isolate itself from global scientific advancement. These partnerships are not only vital to curing disease and improving health outcomes—they also bring federal grants, foreign investment, and high-wage jobs to our communities. Emerging companies in places like Bozeman, Missoula, Hamilton, and Great Falls rely on cloud-based tools and

data-sharing platforms that span international boundaries. Limiting them to only U.S.-based systems places them at a disadvantage, particularly against competitors in other states that have taken a more targeted approach.

Furthermore, SB 410 could inadvertently undermine Montana's recently expanded Right to Try Act, which aims to provide patients with access to experimental therapies that have passed Phase I clinical trials but are not yet approved by the FDA. Many of these investigational treatments are developed through international collaborations and may involve data storage or analysis outside the United States. By restricting such data interactions, SB 410 could limit the very access to experimental treatments that the Right to Try Act seeks to provide, thereby conflicting with the state's commitment to patient autonomy and access to cutting-edge medical care.

Key Statistics Highlighting the Impact:

- Since 2004, **over 1,287 clinical trials** have been conducted or are ongoing in Montana.
- As of 2022, **116 clinical trials** are currently open in the state.
- In 2017 alone, **133 active trials** supported an estimated **3,242 Montanans** participating in clinical research.
- The biopharmaceutical industry supports **more than 4,600 jobs** across Montana.
- It contributes to **\$1.1 billion in annual economic activity**, including direct industry output and local supplier and vendor spending.

As drafted, SB 410 would send a chilling signal to our research institutions and innovators: that Montana is not a safe or practical place to conduct bioscience work with global impact. This bill would make Montana an outlier, isolated at a time when collaboration and data-sharing are key drivers of medical and scientific progress.

We respectfully ask that you veto SB 410 for the future of our bioscience industry and for the health and economy of all Montanans.

Sincerely,



Cassandra Sunell

Executive Director

Montana Bioscience Alliance

Executive Director

406-253-8297 | director@montanabio.org



WE MEAN BUSINESS

Governor Gianforte:

The Montana Chamber of Commerce respectfully requests that you veto S.B. 410 due to the potential unintended consequences this legislation may have on clinical research and the entrepreneurship it supports.

We acknowledge and appreciate Senator Zolnikov's genuine concerns regarding the use of foreign genetic sequencers. However, other provisions within S.B. 410 would significantly limit the ability of some of our members, including hospitals and manufacturers, to engage in research collaborations with international partners, including those in Canada. The enactment of this legislation could stifle medical-technology entrepreneurship and innovation in Montana.

SB 410's rigid data restrictions could create significant barriers for small companies and startups looking to establish or expand in Montana. These companies often rely on global research collaborations and flexible data-sharing to bring innovative technologies to market.

By imposing strict limitations on data access and storage, the bill creates an environment that could disincentivize emerging medical technology companies from investing or locating in Montana, ultimately stifling job growth and economic development.

Our foremost concern involves Section 5, which prohibits storing data outside the US, and stipulates that "genetic sequencing data from the state may not be accessed remotely from outside the United States unless explicit written approval is obtained from the individuals whose data would be accessed."

Advancements in biomedical research rely heavily on collaboration among some of the leading scientists and physicians globally, necessitating international partnerships with experts. Our member providers and companies are committed to safeguarding the data of our research participants and adhere to a comprehensive array of laws, regulations, and company standards to ensure the protection of sensitive information. If this bill is enacted, they have concerns about their capacity to continue conducting research in Montana.

SB 410 may not only harm patients by preventing Montanans from accessing lifesaving research and treatment options, it will also stymie your efforts and our own to promote entrepreneurship and startups in our state.

We have discussed our concerns with Senator Zolnikov and shared enacted language from other states that should address his concerns while keeping Montana open for business.

Todd O'Hair
President & CEO



Biotechnology Innovation Organization
1201 New York Ave, NW, Suite 1300
Washington, DC, 20005
202-962-9200

May 28, 2025

The Honorable Greg Gianforte
Governor, State of Montana
P.O. Box 200801
Helena, MT 59620

RE: Senate Bill 410: Montana Genomic Security Act

Dear Governor Gianforte:

The Biotechnology Innovation Organization (BIO) **urges you to VETO Senate Bill (SB) 410**, which is currently on your desk. BIO shares the goal of protecting sensitive data from nefarious access by foreign adversaries. However, as currently written, SB 410 would inadvertently block vital, legitimate partnerships and scientific advances that depend on lawful, regulated international data access. This will slow access to innovative and life-saving health solutions for patients in Montana.

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, delay their onset, or prevent them in the first place. In that way, our members' novel therapeutics, vaccines, and diagnostics not only have improved health outcomes, but also have reduced healthcare expenditures due to fewer physician office visits, hospitalizations, and surgical interventions. BIO membership includes biologics and vaccine manufacturers and developers who have worked closely with stakeholders across the spectrum, including the public health and advocacy communities, to support policies that help ensure access to innovative and life- saving medicines and vaccines for all individuals.

Genome sequencing and gene editing are critical tools in modern biotechnology. Researchers are now exploring the use of genome editing to treat or prevent genetically defined diseases, such as sickle cell disease, and many others. The human genome – our biological instructional manual - contains about 20,000 genes. More than 6,000 human diseases are currently known to have genetic basis. Restricting responsible access to genetic sequencing data will stifle promising research aimed at tackling these diseases.

BIO has concerns regarding provisions in SB 410 that mandate domestic storage of all genetic sequencing data and prohibit access to this data from outside of the United States.

This overly broad restriction would hinder essential biomedical research by our members by impeding data sharing and collaboration with trusted research partners and institutions located outside the United States. BIO's members are global companies that rely on international collaboration, including the use of secure data platforms developed by domestic and global

partners, to conduct cutting-edge research that benefits patients in Montana and the rest of the United States.

We urge a more narrowly tailored approach that protects data from nefarious access by foreign adversary governments while preserving the ability to engage with trusted international research partners.

For these reasons, we respectfully oppose SB 410 in its current form and urge you to VETO this measure. If you have any questions, please do not hesitate to contact me at pcastro@bio.org.

Sincerely,

A handwritten signature in black ink that reads "Primo J. Castro". The signature is written in a cursive, flowing style.

Primo J. Castro
Director, State Government Affairs – Western Region

April 29, 2025

Honorable Greg Gianforte
Governor, State of Montana
State Capitol
Helena, MT 59620-0801

Re: SB 410 – Veto Request

Governor Gianforte:

On behalf of AdvaMed, the medtech association, I am writing to request your veto of Senate Bill 410. We understand the goal behind this bill, however as currently drafted there are major unintended consequences for clinical research.

AdvaMed is the largest medical technology association, representing the innovators and manufacturers transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. Our over 600 members range from emerging companies to large multinationals, and include traditional device, diagnostic, medical imaging, and digital health technology companies.

We appreciate the author's intent and concern around the use of foreign genetic sequencers and agree this is an important issue. SB 410, as passed by the legislature, would have a significant impact on a company's ability to conduct research with partners outside of the United States. The impact of this legislation being signed could stifle innovation and lead to unintended consequences for Montana patients.

Specifically, our concern is the data storage and access requirements in Section 5 that requires "*storage of **all genetic sequencing data from the state must be restricted to the geographic location of the United States. Other than open data, genetic sequencing data from the state may not be remotely accessed from outside the United States unless approved in writing by the individuals whose data would be accessed.***"

Genetic information and data used in medical research is often deidentified and shared with clinical research partners in other countries. The sharing of this information is incredibly important for clinical trials needed for FDA device approvals and continuing the important work to advance medical technology innovations.

Our suggested amendment would have prohibited genetic sequencing data storage in and access by foreign adversary countries. This would have allowed research to continue with partners outside of the United States but would have prevented genetic sequencing data from being shared with foreign adversaries, which we believe was the goal of the bill. This language has been incorporated into similar legislation in states like Utah, Texas, Kansas, Tennessee, Louisiana, and Arkansas.

Consistent with this approach, the U.S. Department of Justice recently issued a final rule,¹ carrying out Executive Order 14117, which addresses Americans' personal data and access by "countries of concern" that became effective on April 8, 2025. Specifically, the Data Security Program prohibits the transfer of bulk sensitive data, including genetic data, to China and other countries of concern.

In closing, this legislation makes Montana an outlier and may have unintended consequences on data used for critical, lifesaving research. For these reasons, we respectfully request that you veto Senate Bill 410.

Sincerely,



Darbi Gottlieb
Director, State Government and Regional Affairs
AdvaMed

¹ Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons, 90 Fed. Reg. 1636 (Jan. 8, 2025) (to be codified at 28 C.F.R. pt. 202), available at <https://www.federalregister.gov/documents/2025/01/08/2024-31486/preventing-access-to-us-sensitive-personal-data-and-government-related-data-by-countries-of-concern>.

