APPENDIX II

COALITION FOR GENETIC DATA PROTECTION

May 4, 2023

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

Dear Governor Gianforte:

The Coalition for Genetic Data Protection, which includes consumer genetic testing companies Ancestry and 23andMe, must respectfully request a veto of SB 351 (Zolnikov).

The bill would require important privacy protections for genetic testing data that our companies have implemented in practice and supported in legislation in other states.

Unfortunately, amendments adopted late in the legislative process make the bill unworkable and overreaching in its restrictions against the use of deidentified data for research and other uses in the public interest. The amendments also expand the applicability of the bill to numerous entities beyond consumer genetic testing companies.

Specifically, this bill:

- Imposes unrealistic requirements to obtain individual consent for use or transfer of data that is not linked to an identified person.
    - The latest amendments removed an exception to the separate express consent requirement for use of *deidentified* data, which by its very nature does not link data with a specific person. In other words, the bill would require a company to get consent from an individual for use of data, when the company does not know the identity of a person from which the deidentified data was derived.
    - Even if it were possible to associate the data with a specific person, that very reidentification would violate user privacy expectations, create unnecessary cybersecurity risks, and go against typical third party contracts that guard against such intrusions.
    - Data that is used in research is often deidentified data. Therefore, complying with the unwieldy requirements of this bill will unnecessarily impede research.

- Does not provide an exception for HIPAA-regulated entities such as hospitals and universities that collect, use and conduct research with genetic data in a different manner than consumer genetic testing companies, and are already subject to significant privacy regulations under state and federal laws.

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CGDP

- Impedes research by requiring the specific name of the third party to be disclosed and consented to for every transfer of any genetic data or biological sample.
    - While this seems reasonable on its face, it effectively requires an additional and duplicative consent process each time data is transferred – even if the consumer has already been informed and explicitly agreed to the use of their data in the research for which it is being transferred.
    - Under our current practices, an individual can separately consent to have their data shared for research purposes – but a separate consent is not required *each time the data is transferred for this same purpose*. This is clear to the research participant at the time of consent, and that consent may be revoked at any time.

Ancestry and 23andMe have worked extensively with policymakers, consumer advocates and nonprofits to contribute to the development of Privacy Best Practices for Consumer Genetic Testing, as published by the Future of Privacy Forum in 2018. We have already implemented these practices for informed, express consent, and support these principles becoming law.

We look forward to working with the Legislature and you to build a privacy protective framework to afford consumers of all genetic testing services with control over and protections for their data.

For these reasons, we must respectfully request that you veto SB 351.

Sincerely,

Ritchard Engelhardt
Head of Government Affairs
Ancestry

Jacquie Cooke
General Counsel and Privacy Officer
23andMe

cc: Sen. Daniel Zolnikov (Sponsor)

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TECHNET
THE VOICE OF THE INNOVATION ECONOMY

TechNet Northwest | Telephone 253.441.5272
P.O. Box 7036, Olympia, WA 98501
www.technet.org | @TechNet_NW

May 9, 2023

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

RE: SB 351 Veto Request

Dear Governor Gianforte,

On behalf of TechNet's member companies, we strongly urge the veto of Senate Bill 351 (Zolnikov). TechNet members place a high priority on consumer privacy. However, the current version of the bill poses significant challenges for Montana employers and will impede advancements in improving safety and security for consumers.

Our members have effectively implemented essential privacy protections for genetic testing data, as required by the bill. However, late amendments adopted during the legislative process have rendered the bill impracticable and excessively restrictive in terms of the use of deidentified data for research and other public interest purposes. Furthermore, the amendments have expanded the bill's coverage to include various entities beyond just consumer genetic testing companies.

The latest revisions to the bill mandate that companies must acquire authorization from individuals regarding the utilization or transfer of data that is not associated with any specific individual, even if it is de-identified. Essentially, this means that businesses must obtain consent before utilizing such data, regardless of whether they know the person from whom the data was obtained. This requirement is simply unworkable.

It's important to note that research data is commonly de-identified. Therefore, implementing all the requirements of this bill would hinder research progress.

Furthermore, it is absolutely crucial that the current legislation includes exemptions for HIPAA-regulated entities, such as hospitals and universities, from the privacy regulations imposed on consumer genetic testing companies. Failing to do so will undoubtedly present significant obstacles for research involving genetic data and biological samples, as explicit disclosure and consent will be required for every transfer of information to third parties.

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TechNet members have successfully collaborated with state legislatures and consumer advocates to implement informed and express consent practices. We fully endorse these principles becoming law. At TechNet, we believe that privacy laws should provide strong safeguards for consumers while allowing the industry to innovate.

Therefore, we respectfully advise a veto of SB 351 and look forward to working with you to enact a genetic testing privacy framework that benefits all Montanans.

Please don't hesitate to reach out if I can be of further assistance.

Respectfully submitted,

Ashley Sutton
Executive Director
WA & the Northwest
TechNet
asutton@technet.org

May 17, 2023

The Honorable Greg Gianforte
Governor of Montana
State Capitol
1301 E 6th Ave.
Helena, MT 59601

Dear Governor Gianforte:

On behalf of the Montana BioScience Association and the Biotechnology Innovation Organization (BIO), we respectfully request your veto of SB 351, which would establish the Genetic Information Privacy Act. While this bill was introduced to regulate direct-to-consumer DNA and genetic testing companies, amendments were introduced in conference committee without input from stakeholders, including patient groups, that risk interfering with clinical trials and cutting-edge biomedical research in Montana.

The Montana BioScience Association is a network of biotechnology businesses, entrepreneurs, laboratories, hospitals, clinics, and universities. We work together to commercialize, grow, and sustain globally competitive bioscience enterprises. The Montana BioScience Association is dedicated to expanding the bioscience-based economy through the promotion of research, investment, education, and infrastructure. BIO is the world's largest advocacy association representing member companies, state biotechnology groups, academic and research institutions, and related organizations across the United States and in 30+ countries.

Our organizations and the bioscience companies we represent are concerned that SB 351, while well-intentioned, would inadvertently have a significant negative effect on research in Montana. The bill's requirements include provisions that would be unnecessarily burdensome for entities performing legitimate and innovative research using genetic materials and data. For example, the requirement in SB 351 that an entity which discloses genetic data or biological samples obtain consent identifying *by name* each third-party recipient of the genetic data or samples would be incredibly burdensome for researchers and patients. If a researcher is not able to disclose genetic data for secondary research beyond those identified specifically by name in the consent obtained during the research study, the parties collaborating towards innovative solutions would be dramatically limited, given that most research entities are simply not known at the time the data is collected. This would significantly curtail future research and product development of benefit to patients and limit the ability for biotech researchers to receive and analyze genetic data in coded or de-identified form for secondary research and product development. In addition, requiring a detailed list of third-party recipients may lead to an overwhelming consent process for the patients and may lead to less patient comprehension of consent, including as it relates to understanding the risks associated with a research study.

Furthermore, other provisions in SB 351 would be impossible to comply with while maintaining good scientific practices, such as the requirement for entities to maintain a process for consumers to access and delete their genetic data, revoke consent, or request destruction of

their biological samples – including for de-identified genetic data. This may deter researchers from storing data in a de-identified manner as this would allow researchers to be able to obtain future consent if necessary to honor an individual's rights to access or delete their genetic data. This could also subject patients to risks associated with data breaches or other unauthorized access of identifiable genetic data.

Adequate exemptions for research using de-identified genetic data, such as observational studies, are not provided in SB 351 and this will suppress important and innovative treatments for diseases such as cancer. The same requirements in SB 351 to obtain consent to use and share genomic data would therefore be imposed on de-identified genomic data. While some genetic data, such as the sequence of an individual's whole genome, is unique to an individual, SB 351 would regulate limited portions of sequencing data related to common genetic mutations. Researchers use this data to conduct observational studies or retroactive analyses to determine, for example, whether patients do better on certain therapies. Many of the significant medical breakthroughs in oncology and the field of precision medicine are based on these types of analyses. Because de-identified data is not associated with an identifiable individual, requiring consent to use de-identified data is impossible and in practice has the potential to foreclose important areas of research and clinical development, particularly for certain cancers and rare diseases. Removal of an exception for de-identified genetic data also creates potential challenges for researchers that leverage real world evidence and data to generate findings and investigate innovative therapies.

Standard exemptions for clinical care are also not found in SB 351, even though entities that conduct these activities are generally already subject to federal and state health privacy laws. There is a partial and conditional exemption for HIPAA-regulated entities; however, even this exemption is problematic given the requirement to provide a process for an individual to delete their data without any express exemption for retention of data as necessary for treatment of the patient or to enable future research. This may result in a situation where HIPAA-regulated entities, such as physicians, are deterred from recommending genetic testing, even when clinically appropriate for the patient.

Furthermore, there is a limited exemption in SB 351 that is available to entities engaged "*only* in collecting, using, or analyzing genetic data [for research]." Most sites and sponsors do not *only* conduct research – they also provide standard of care treatment or, in the case of sponsors, manufacture and commercialize approved drugs and therapies. A strict interpretation of this exemption would preclude BIO members from relying on the exemption where an entity is, for instance, engaged in the disclosure of genetic data.

SB 351 would make clinical research in Montana more costly, inefficient, and less scientifically valuable. For these reasons and given your efforts to cultivate an environment in Montana for genomic-based research and development, we ask for your veto of SB 351. If you have any questions, please do not hesitate to contact Brian Warren at bwarren@bio.org.

Sincerely,

Sharon Peterson
Executive Director
Montana BioScience Association

Patrick J. Plues
Vice President, State Government Affairs
BIO

GSK

410 Blackwell Street
Durham, NC 27701

May 18, 2023

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

Dear Governor Gianforte:

As you know, GSK has a strong commitment to the state of Montana. We employ 200+ Montanans at our site in Hamilton, and, in the coming weeks, we are planning a ribbon cutting ceremony of our newly established $100 million expansion to accommodate the manufacture of important components for our Shingles vaccine and our recently approved RSV vaccine. Given our interest in conducting research and development within the state, we respectfully request a **veto of SB 351 (Zolnikov)**.

While we support the spirit of the original bill to institute privacy protections for genetic testing data, amendments were added very late in the legislative process without vetting from stakeholder groups – these amendments make the bill untenable and go well beyond regulating direct-to-consumer genetic testing companies. They impose new and uncertain obligations in the clinical care and medical research context that will make it harder for Montanans to get needed care and access to clinical studies.

Among other issues:

- **The bill lacks standard exemptions for clinical care and medical research even though these activities already are regulated under federal health privacy and human subject protection laws.**
    - For example, there is only a partial and conditional exception for HIPAA-regulated entities such as hospitals and universities that collect, use and conduct research with genetic data. HIPAA-regulated entities are already subject to significant privacy regulations under state and federal laws. SB 351 appears to create new obligations for HIPAA-regulated entities, including to have processes to honor deletion requests without express exemptions for retention of genetic data to enable future treatment or for the integrity of medical research. At best, it is confusing for consumers that the same information is protected under multiple different, overlapping privacy frameworks without a clear benefit to patients. At worst, these seeming inconsistencies may deter clinicians from standard of care genetic testing and may deter medical research investment in Montana.
- **The bill also imposes unrealistic requirements to obtain individual consent for use or transfer of data that is not linked to an identifiable person.**
    - The latest amendments could be read to extend the same level of protections to *deidentified* data, which by its very nature cannot be associated or linked with a specific person. This could be read to require consent to use and share even genetic data that has been de-identified, and the bill does not distinguish between different types of genetic data. While some genetic data may be unique to an individual or family, the scope of genetic data that is regulated includes individual genotypes and phenotypes – like the fact that an unknown individual's sample tested positive for relatively common genes, like BRCA1 or PMS2. Requiring consent to use de-identified insights about these genetic variations has the

GSK

410 Blackwell Street
Durham, NC 27701

potential to foreclose medical research hospitals and others from conducting observational research based on genetic data that has already been collected, stifling insights that have led to tremendous improvements and innovations in treatments and cures for cancers and other diseases.

- It also does not make practical sense to extend the same level of protections to de-identified data. For example, the bill seems to contemplate that a company would need to honor requests to revoke consent and to process deletion requests in relation to de-identified data. But where data has been de-identified, it typically is not possible to honor these requests because it is not possible to associate the requester with his or her data.

- Further, the bill creates bad incentives in that it deters researchers from de-identifying research data that is collected with a subject's consent. This is at odds with the privacy goals of the statute and creates unnecessary cybersecurity risks.

- **The bill also impedes research in various additional ways, including by requiring consent to the transfer of genetic data or a biological sample that identifies the specific name of each third-party recipient.**

  - SB 351 lacks clear and workable consent standards. The bill is not clearly drafted and could be read broadly to require additional and duplicative consents for both a medical researcher's internal use of genetic data for research purposes and its transfer of genetic data or samples to third parties that are involved in the research. There are often research opportunities that involve more than a single entity, such as research involving both a pharmaceutical sponsor and a medical research center or involving collaborators. These are traditionally handled as part of a single informed consent form.

    The bill also contemplates that separate express consent for the transfer of genetic data or a sample to a third party include the name of each such third party. While this may have some appeal, it would require detailed and overwhelming consent forms that list by name collaboration partners, diagnostics companies, ethics committees and regulators, and other standard recipients of pseudonymized research data. This would be at odds with the efforts that medical researchers take – typically in conjunction with ethics commitments (also known as institutional review boards) to ensure informed consent forms are plainly drafted, simple, and clear.

We look forward to working with the Legislature and you to build a privacy protective framework to afford consumers of all genetic testing services with control over and protections for their data, however we feel this bill does not meet that goal. We therefore respectfully request that you **veto SB 351**.

Sincerely,

Maya Martinez-Davis
President, US Commercial

AdvaMed
Advanced Medical Technology Association

1301 Pennsylvania Avenue, NW
Suite 400
Washington, D.C. 20004
P :: 202.783.8700
F :: 202.783.8750
W:: AdvaMed.org

May 19, 2023

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

Re: SB 351 – Veto Request

Governor Gianforte:

On behalf of AdvaMed, the medtech association, I am writing to request your veto of Senate Bill 351. AdvaMed recently became aware of this legislation following significant amendments added via conference committee very late in the legislative process.

Your veto is necessary to prevent the disruption of critical, lifesaving genetic research. Senate Bill 351 effectively excludes Montanans from participating in groundbreaking genetic research, unnecessarily restricting otherwise properly safeguarded data used in high value discoveries such as new human diseases, the impact of new or established diagnostic tests, and disease biomarkers, as well as treatments and cures for a wide range of conditions and diseases, including cancer.

The success stories of treatments and cures emerging from high quality medical research, including, critically, genetic research, are legion. Children with cystic fibrosis are living longer than ever before because treatments have emerged over generations. Biomarker tests identifying the genomic alterations driving cancer are enabling the development of cutting-edge targeted therapies that help patients live longer than was ever possible with chemotherapy and radiation alone.
Those are just two of the many examples.

Montana families with children experiencing a disease for which there is no treatment or cure may wish to participate in genetic research to try to help their children and other families and children. Senate Bill 351 will deprive them of the opportunity to contribute to society and build hope around what can be devastating diagnoses and difficult daily life. Further, in curbing the ability of Montanans to help others, Senate Bill 351 is also curtailing individual freedom. These impediments are contrary to the spirit of community paired with the elevation of individualism over government edict – whenever practical and sensible – for which Montana is known.

Specifically, AdvaMed has three key concerns with Senate Bill 351:

- It applies to any organization that "collects, uses, or analyzes genetic data", not just to companies providing consumer genetic testing products and, in turn, broadly defines genetic data.
- There are no exceptions for de-identified data.
- Exceptions for scientific research were removed or neutered, rendering them essentially unusable.

The lack of an exception for de-identified data makes it impractical or impossible to comply with the law. By not having a de-identification exception and preserving an unconditioned right to delete/access/opt-out or destroy, the law is prohibiting entities from de-identifying genetic data. This de-identification (as defined under the Common and Privacy Rule) is generally done to preserve the privacy of individuals. Paradoxically, the bill likely results in less privacy protection for Montanans – not more.

No exception for de-identified data also inhibits the use of applicable data in research. Clinical labs often rely on "IRB Waivers", which require the samples to be de-identified prior to use in research; a requirement for which Senate Bill 351 renders compliance impossible.

Other restrictions on use of genetic data likely result in the exclusion of Montanans from genetic data sets. The mandate for individual consent for transfer to third parties is unworkable in virtually all existing sharing frameworks. While it may work in certain one-to-one sharing agreements, it severely impacts biobank and genetic databases used for research.

The human subject research exemptions appear to be available only for research conducted with the express consent of the individual. Specifically, the final version of Senate Bill 351 would not apply to:

> "…[A]n entity when it is engaged only in collecting, using, or analyzing genetic data or biological samples in the context of research as defined by 45 C.F.R. § 164.501 conducted with the express consent of the individual and in accordance with: (i) [the Common Rule, the International Council for Harmonisation Good Clinical Practice Guideline, or (ii) the FDA Policy for the Protection of Human Subjects]."

This creates confusion about whether a sponsor can rely on current informed consent forms to secure the "express consent" required by Senate Bill 351. For example, the bill can be read to require "express consent" only for the research

itself, but there is an alternative reading that would require "express consent" for each activity for which consent is required under Senate Bill 351.

The practical reality of Senate Bill 351 is stark. Genetic disease research is done using de-identified data. If Montana locks scientists out of said data, it is limiting the possibilities of new discoveries. If the genetic material for discovery of a new biomarker is present in a Montanan, the discovery will not be made. The confirmation of a new, rare disease will not be found if the second or third case happens to live in Montana.

Overall, this legislation makes Montana an outlier and unnecessarily restricts data used for critical, lifesaving research. Limiting the genetic research used to drive innovation and discover therapies and cures benefiting patients, while also failing to improve privacy protections, benefits no one.
Please veto Senate Bill 351.

Sincerely,

Bobby Patrick

Bobby Patrick
Vice President, State Government and Regional Affairs
AdvaMed

NWABR
Northwest Association for Biomedical Research

May 23, 2023

The Honorable Greg Gianforte
Governor of Montana
State Capitol
1301 E 6th Ave.
Helena, MT 59601

Dear Governor Gianforte:

The Northwest Association for Biomedical Research (NWABR) is writing to express concerns over SB351, which revises privacy laws related to biometric data. NWABR is the leading voice for understanding biomedical research and its ethical conduct, recognizing that public trust in the integrity of research is essential to the future of medical discovery in our region. It is with this mission in mind that we share concerns over some of the unintended consequences of SB351 and ways in which this bill could limit participation in essential clinical trials.

We applaud the legislature's commitment to protecting the genetic privacy of patients throughout Montana and recognize that this bill mirrors concepts that have passed in several other states. However, this bill deviates from other state laws in that it does not include an exemption for the collection of de-identified data in medical and clinical research.

Without this exemption, it will be extremely difficult for researchers throughout Montana to conduct trials. Medical research groups share collected data with trial sponsors and regularly partner with data organizations on joint research projects. As currently written, SB351 would require de-identified data to be re-identified in order to patient/participant to be reconsented to allow this de-identified sharing. Reidentifying this data is contrary to the patient-first privacy protections that our biomedical research partners practice and actually exposes patient medical data instead of protecting it, which we believe to be the intent of the bill.

This becomes even more concerning with HIPAA covered entities, who are legally bound to protect patient health information. One of the many benefits of HIPAA's federal privacy standards is that there is a common set of national standards for clinical researchers and hospitals to adhere to in protecting the privacy of patients. According to the HIPAA Privacy Rule[1], a covered entity may use a patient's personal health information (PHI) for research as long as the PHI has been de-identified. Once the patient's health information has been de-identified in accordance with the Privacy Rule standards, HIPAA clearly states that the patient does not need to reauthorize the use or disclosure of that de-identified information for research purposes. We are highly concerned that SB351 conflicts with federal HIPAA requirements and will cause serious confusion for research institutions if this bill were to be signed into law without a HIPAA exemption.

Instead, we recommend that the state include a de-identification safe harbor clause as originally included in the bill and which mirrors the Federal Trade Commission's de-identification standards. We also strongly recommend a HIPAA exemption to ensure consistent privacy standards for all patients.

[1] U.S. Department of Health and Human Services. National Institutes of Health. "Clinical Research and the HIPAA Privacy Rule."

PO Box 18067, Seattle, WA 98118 | 206.957.3337 | www.nwabr.org
The Northwest Association for Biomedical Research. NWABR is a 501(c)3 organization.

The Northwest Association for Biomedical Research strongly supports genetic privacy protections. However, we have serious concerns that SB351, as written, will halt the careful sharing of data between entities for the understanding of that genetic data and potential new treatments. We appreciate your consideration of these unintended consequences that may fail to protect biomedical research and the patients we serve.

Sincerely,

Ken Gordon
Executive Director