**Title:** Rethinking Regulation in the Wild West of Direct-to-Consumer Genetic Services

Elevating Privacy and Informed Consent in Genetic Data Sharing

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**Introduction**

In recent decades, biotechnology has seen remarkable advancements, dramatically reducing the costs associated with DNA sequencing. This has led to a surge in the number of human genomes sequenced in the U.S., from medical diagnostics that utilize genetic information to pinpoint diseases and tailor treatment plans, to companies like 23andMe that analyze DNA for insights on not only curious traits such as taste preferences, height, and ancestry, but also highly medically relevant traits such as disease risks.

However, in the recreational domain where companies gather genetic data to tell you about your ancestry or predict your ability to smell asparagus, regulatory oversight is scant. Many individuals, in agreeing to these tests, unknowingly provide more information than they intended. This data often benefits the companies far more than the consumers, being potentially sold to third parties, including for-profit research organizations, without clear consent or knowledge of the users.

**Key Issues and Findings**

The regulatory landscape for commercial genetic sequencing used for recreational purposes is troublingly sparse. Existing protections like the Genetic Information Nondiscrimination Act (GINA) and the Health Insurance Portability and Accountability Act (HIPAA) mainly cover clinical settings. This leaves a significant gap when it comes to recreational genetic testing. State laws on genetic privacy are inconsistent, with some states offering robust protection and others hardly any, creating a patchwork of regulations that is confusing and often ineffective.

For example, while California has stringent laws requiring explicit consent for genetic data usage, other states have minimal or no such requirements, leading to potential exploitation of genetic information without proper user consent. The consequences of these disparities can be significant, affecting everything from privacy breaches to unauthorized data sharing.

A graph showing the number of genomics

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*This graph shows the dramatic increase in the number of human genomes sequenced in the U.S. from 1995 to 2024, juxtaposed against the slow pace at which relevant laws (GINA, HIPAA, the Genetic Privacy Laws, the Telemedicine Laws, and the Informed Consent Laws featured) have been enacted. This stark contrast underscores the pressing need for strengthened regulations in the genetic services industry.*

Moreover, the process of obtaining consent from users is often flawed. Many individuals struggle with the complexity of consent agreements and do not fully understand the implications of sharing their genetic information. Studies suggest that a substantial majority of users feel confused by the terminology used in these agreements, with only about 20% fully understanding the terms to which they agree.

The blurred lines between recreational and medical use of genetic tests are particularly concerning. Increasingly, patients are bringing their direct-to-consumer genetic results to medical appointments, expecting health professionals to integrate this information into their medical care, which is often not feasible or appropriate.

**Urgent Actions Needed**

The urgency for governmental action at both state and federal levels is clear. The following steps are essential:

**Standardized User Consent:** Clear, understandable user consent guidelines are crucial. A diverse task force will design consent forms detailing data usage, risks, sharing policies, and withdrawal options. The U.S. Department of Health and Human Services, through the Office for Civil Rights, will enforce compliance across genetic testing companies. This initiative will enhance transparency, increase user trust, and promote ethical practices in genetic testing. Standardizing User Consent would require an initial outlay of around $500,000 for development, plus $1 million annually for enforcement. Genetic testing companies might each spend about $100,000 annually on compliance.

**Enhanced Privacy Protections:** We need to expand the scope of existing laws like GINA and HIPAA to cover recreational genetic services. This expansion should be spearheaded by a coalition of lawmakers, privacy experts, and biotech leaders, focusing on safeguarding privacy and preventing misuse of genetic data. Enhancing Privacy Protections could cost approximately $300,000 for legislative development, with an ongoing enforcement cost of $1 million annually.

**Uniform Regulation:** Implementing uniform regulations across all states is necessary to eliminate the current discrepancies in genetic privacy laws, ensuring consistent and effective protection for all individuals.

**Public Awareness Campaigns:** Launching public education campaigns is vital to enhance awareness about the significance of informed consent and the risks associated with sharing genetic information. Raising public Awareness Campaigns might reach $2 million for comprehensive national initiatives.

Knowingly, enabling these changes can be a financially significant endeavor. The cost of inaction, however, could be significantly higher. Legal liabilities from privacy breaches, public distrust resulting in market contraction, and increased healthcare costs due to inappropriate medical decisions could total over $2.1 billion. This includes tens of millions in potential fines and settlements, a 25% loss in market revenues (around $2 billion annually), and an estimated $100 million in unnecessary healthcare expenses.

Investing in these regulatory measures not only prevents hefty financial losses but also enhances public trust and safety, promoting broader acceptance and beneficial outcomes from genetic testing. By addressing these critical issues, we can ensure that the expansion of biotechnology benefits all, safeguarding privacy and enhancing informed consent in an age where genetic information is becoming increasingly accessible and increasingly sensitive.