**Title: Addressing the Lack of Regulation in Commercialized Genetic Services**

Strengthening Privacy Protections and Informed Consent for Genetic Data Collection

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**Current Issue**

Biotechnology has undergone remarkable advancements in recent decades, leading to a significant reduction in sequencing costs. Consequently, there has been an exponential increase in the number of genomes sequenced in the US. While medical diagnostic services utilize genetic information for health-related purposes, companies like 23andMe have emerged, collecting extensive user genetic data for recreational use.

In the recreational sector, where genetic data are gathered to inform users about their ancestries and other traits, regulatory oversight is lacking. Many users, when consenting to genetic testing, are often unaware that they are divulging more information than intended. This wealth of genetic data is primarily advantageous to companies, often being outsourced to medical research entities, posing risks to users' privacy.

**Key Research Findings**

The laws regulating the behaviors of large commercial genetic sequencing services for recreational purposes are inadequate. While laws such as the Genetic Information Nondiscrimination Act (GINA) and the Health Insurance Portability and Accountability Act (HIPAA) exist to protect genetic information, they primarily focus on health-related contexts. State-specific genetic privacy laws vary in their comprehensiveness, and telemedicine laws, though relevant, lack specific provisions addressing genetic counseling services. Additionally, informed consent laws vary by state and may not adequately address the complexities of genetic data usage.

User consent for biotech companies collecting genetic information is often insufficiently informative. Many users, despite attempting to review consent agreements, may not fully grasp the implications of granting access to their genetic information beyond ancestry or disease risk assessment.

There is an urgent need for government intervention, both at the state and federal levels, to strengthen regulations in this field. This should include:

**Standardized User Consent:** Implementing guidelines for comprehensive and transparent user consent processes, ensuring individuals are fully informed about the potential implications of sharing their genetic information.

**Enhanced Privacy Protections:** Expanding existing laws, such as GINA and HIPAA, to encompass recreational genetic services, safeguarding user privacy, and preventing misuse of genetic data.

**Uniform Regulation:** Establishing uniform regulations across states to address discrepancies in genetic privacy laws and ensure consistent protection for all individuals.

**Public Awareness Campaigns:** Launching educational initiatives to raise awareness among users about the importance of informed consent and the potential risks associated with sharing genetic information.

By taking proactive measures to regulate commercialized genetic services and prioritize user privacy, governments can uphold ethical standards and protect individuals in an era of rapidly evolving biotechnology.

A graph showing the number of genomics

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The graph illustrates the rapid increase in genomes sequenced in the US from 1995 to 2024, compared to the slow growth in relevant laws established. This disparity highlights the need for enhanced regulatory measures in genetic services, as discussed in the policy briefing on strengthening privacy protections and informed consent in the commercial genetic sector.