



Policy Analysis

Data Ownership and Consent in Direct-to-Consumer Genetic Testing

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ABSTRACT

Direct-to-consumer (DTC) genetic testing has built some of the largest genomic databases in existence outside clinical or research infrastructure, governed largely by consumer terms-of-service agreements rather than the informed-consent standards applied to clinical or research genomics.

This review examines the unresolved legal status of ownership over DTC genetic data, the empirical evidence on how customers actually understand what they have consented to, and the secondary uses -- research partnerships, corporate sale, and law-enforcement access -- that original consent language only loosely anticipated.

It then turns to a problem distinctive to genetic data: because a single person's test result also reveals information about parents, siblings, children, and more distant relatives, individual consent structurally cannot protect the interests of the family members a test simultaneously implicates.

We survey recent state-level legislative responses and the scholarly debate over property-based versus privacy-based frameworks for genetic data, finding neither fully adequate on its own.

We conclude that closing the gap between DTC consent's formal structure and its practical substance will require purpose-built genetic-privacy regulation, consent language specific enough to cover known secondary uses, and some structural acknowledgment of relatives' interests that does not depend solely on a customer's voluntary disclosure.

Keywords: *direct-to-consumer genetic testing; informed consent; data ownership; genetic privacy; familial implications*

Citation: Bakker Z, Ferraro E and Gallagher A (2023) Data Ownership and Consent in Direct-to-Consumer Genetic Testing. *Bioethics*. 1(2):01-06.

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Article History: Received 11 July 2023 | Accepted 04 October 2023 | Published 29 December 2023

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INTRODUCTION

A saliva kit purchased online for a modest fee has become one of the more consequential consent

transactions an ordinary consumer will ever complete, and most people who spit into the tube have only a hazy sense of what they have actually agreed to. Direct-to-consumer (DTC) genetic testing was marketed for years as a curiosity -- ancestry percentages, a handful of trait predictions, occasionally a health risk flag -- but the companies selling that curiosity are, functionally, building some of the largest genomic databases in existence, governed not by the research-ethics apparatus that oversees clinical genomics but by consumer terms-of-service agreements that few customers read and fewer still understand [1]. The result is a consent model that looks procedurally adequate -- a checkbox, a click-through privacy policy, an option to opt into "research" -- while doing very little of the substantive work informed consent is supposed to do in a research or clinical context [2].

This review examines two entangled problems in that model. The first is ownership: once a consumer's genetic data sits on a company's servers, who actually controls what happens to it, and does the language of "ownership" even map coherently onto information that is, biologically, shared with blood relatives who never agreed to anything? The second is consent: what would it mean for a DTC consent process to be genuinely informed, given that a customer at the point of purchase cannot anticipate the company's future business decisions, research partnerships, law-enforcement disclosures, or acquisition by another firm entirely. We look at the legal vacuum DTC genetic data sits in, the empirical evidence on how customers actually understand what they agreed to, the secondary uses that consent forms only loosely anticipate, and the distinctly DTC-specific problem of familial and third-party implications that individual consent structurally cannot resolve.

OWNERSHIP WITHOUT A FRAMEWORK

The most basic question -- who owns a customer's genetic data once a DTC company has it -- does not have a settled legal answer in most jurisdictions, and that ambiguity is doing a great deal of quiet work in the industry's favor. Genetic information generated through DTC testing typically falls outside HIPAA's reach because the companies collecting it are not "covered entities" providing treatment, leaving consumers' most sensitive biological information regulated, if at all, by general consumer-protection and state privacy law rather than by health-privacy law built for exactly this kind of data [3]. Proposals to close that gap by simply extending HIPAA to DTC companies have circulated for years without being adopted, and in the meantime the industry has grown large enough that retrofitting health-privacy rules onto it raises its own transition problems [4].

A separate line of scholarship has argued that the fix should not be extending health-privacy law at all, but recognizing a property interest in one's own genetic

data -- an approach that would give individuals an enforceable claim over data already collected and shared, rather than only prospective consent rights over data not yet given [5]. Property-based proposals face an obvious difficulty specific to genetics: a property right vested in one person over data that is partially shared with parents, siblings, and children does not obviously resolve who controls a hereditary information good, and most versions of the proposal have not fully worked through what happens when one relative wants disclosure and another wants secrecy. Commentary aimed at a general audience has increasingly framed the situation bluntly: consumers who assume they "own" their DNA data in any meaningful legal sense are, in practice, mistaken, because the company holding the data typically retains broad rights to use, de-identify, and share it under terms the consumer accepted without realizing how much latitude those terms contained [6].

WHAT CONSENT ACTUALLY CAPTURES

DTC consent flows are, formally, a form of informed consent -- there is a document, an acceptance click, sometimes a layered structure separating "testing" consent from optional "research" consent -- but the empirical literature on how customers actually engage with this process paints a considerably less reassuring picture than the formal structure suggests. Survey work examining how 23andMe customers understood the company's use of their data found meaningful gaps between what customers believed they had agreed to and what the company's policies actually permitted, alongside a broader finding that trust in the company, rather than close reading of the consent terms, was doing most of the work in customers' willingness to proceed [7]. That finding matters because it inverts the usual logic of informed consent: consent is supposed to substitute for trust by giving people the specific information they need to decide for themselves, but DTC consent appears in practice to function more as a trust signal than as a genuine transfer of decision-relevant information.

The Hastings Center's public-facing guidance on DTC privacy makes a related point in plainer terms: most consumers cannot meaningfully evaluate, at the point of purchase, what a privacy policy permits a company to do with their data five or ten years later, particularly regarding sale of the company itself, a bankruptcy, or a change of ownership that transfers the genetic database along with other corporate assets [8]. Legal commentary examining 23andMe specifically has treated the company's later difficulties as an illustration of exactly this risk -- that consent obtained under one set of corporate circumstances does not necessarily survive changes in those circumstances with its practical meaning intact [9]. A related strand of scholarship has scrutinized the boundary between "recreational" genetic testing and genuine research, arguing that when DTC companies recruit their own customers into research studies using data already

collected for a different, commercial purpose, the resulting consent occupies an uncomfortable middle ground that neither consumer-protection norms nor research-ethics norms were built to police cleanly [10].

SECONDARY USES: RESEARCH, SALE, AND LAW ENFORCEMENT

Table 1 summarizes the main categories of secondary use that DTC genetic data has been put to beyond the original ancestry or trait-prediction service, and the consent posture each one typically receives. What the comparison makes visible is that the categories requiring the most explicit, specific consent -- academic research partnerships -- are also the ones DTC companies have generally been most careful to formalize, while categories with larger population-level consequences, such as law-enforcement access and data transfer upon corporate acquisition, have often proceeded under consent language written broadly enough to cover them without ever specifically naming them.

Law-enforcement use of DTC genetic databases, most visibly through investigative genetic genealogy built on databases originally populated for ancestry purposes, has expanded well beyond what most early customers could have anticipated when they submitted a sample [11]. The Hastings Center's briefing on this issue frames the core tension plainly: investigative genetic genealogy has solved cold cases that conventional methods could not, but it does so by searching genetic data belonging to people who never consented to law-enforcement use and, in most cases involving distant relative matches, never consented to anything at all [12]. Legal scholarship examining the Fourth Amendment implications of this practice has argued that current doctrine, built around an individual's own reasonable expectation of privacy, does not straightforwardly protect a person whose genetic profile becomes searchable only because a distant relative uploaded their own data to a different platform [13].

State legislatures have responded unevenly. A wave of new genetic-privacy statutes in 2024 attempted to impose stricter consent and deletion requirements specifically on DTC companies, following earlier state-level laws that established similar frameworks [14], and additional bills introduced in early 2026 suggest the legislative activity has not slowed [15]. Legal commentary tracking this landscape has noted that the resulting patchwork -- different consent, retention, and deletion rules in different states, layered on top of no comprehensive federal standard -- leaves companies operating nationally with a genuinely difficult compliance picture and leaves consumers with meaningfully different protections depending on their state of residence [16]. Earlier legal analysis of the privacy risks specific to the two largest DTC platforms had already anticipated much of this regulatory activity, arguing that self-regulation by the companies

themselves was unlikely to be sufficient given the commercial incentives to monetize genetic data through partnerships and data licensing [17]. A broader survey of privacy problems across the genetic testing industry reached a similar conclusion about the limits of voluntary industry standards [18], and legal scholarship proposing more structural fixes has argued that regulating DTC data as a distinct category, rather than folding it into general consumer-privacy or health-privacy frameworks, is necessary precisely because it does not fit either category cleanly [19].

Table 1. Categories of secondary use of direct-to-consumer genetic data and the consent posture each has typically received.

Secondary use	Typical consent mechanism	Specificity at point of purchase	Regulatory attention to date
Academic/industry research partnerships	Separate opt-in research consent, often layered	Relatively specific	Moderate; governed partly by research-ethics norms
Corporate sale, merger, or bankruptcy transfer	Covered by general terms-of-service language	Low; rarely named explicitly	Limited; addressed unevenly by recent state statutes
Law enforcement / investigative genetic genealogy	Covered by broad terms-of-service or third-party platform terms	Very low; often not anticipated by the original consumer	Growing, but inconsistent across states and absent federally
Disclosure to genetic relatives	No formal consent mechanism; left to the customer's discretion	Not addressed by consent at all	Minimal; treated as a private, not regulatory, matter

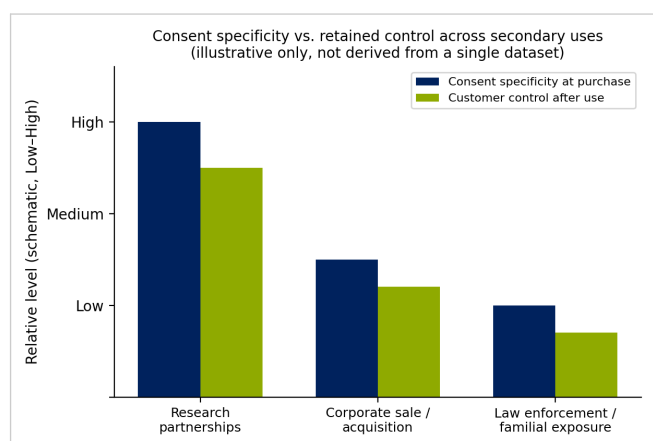
FAMILIAL AND THIRD-PARTY IMPLICATIONS

The property and consent problems discussed above become sharper once the analysis moves from the individual customer to the network of people connected to that customer by descent. A DTC test necessarily reveals information about parents, siblings, children, and more distant relatives who never purchased a kit, never signed a consent form, and in many cases never knew a family member's data had been submitted at all -- a structural feature of genetic information that ordinary individual-consent frameworks were not built to accommodate [20]. Ethical analysis of this problem going back over a decade identified the tension clearly: an individual's right to explore their own genetic ancestry or health risk sits in permanent tension with relatives' interest in controlling disclosure of information that is, in a meaningful sense, also theirs [21].

This tension has produced genuinely difficult clinical

and ethical questions where a DTC test surfaces an actionable health finding. Scholarship examining whether a genetic counselor or clinician learns of an actionable risk through a DTC result has an obligation to inform the tested individual's genetic relatives has generally concluded that some duty exists in principle, but that DTC testing's structure -- no clinical relationship, no genetic counseling built into the purchase, and no established mechanism for family notification -- makes that duty far harder to discharge in practice than the equivalent duty in a clinical genetics setting [22]. Legal commentary on the familial privacy implications specifically has argued that a consent model organized entirely around the person who purchased the kit cannot, by construction, protect the interests of the relatives whose genomes are also partially revealed by the results, and that this gap has received far less regulatory attention than the individual-level privacy questions that dominate public debate [23].

Figure 1. Schematic comparison of consent specificity at the point of purchase versus the customer's retained control after data has been used, across three categories of secondary use discussed in this review. Illustrative only; not derived from a single empirical study.



A recent systematic review of healthcare professionals' knowledge and views on DTC testing found that clinicians themselves frequently feel unprepared to counsel patients who arrive with DTC results, particularly regarding the familial and psychological implications of unanticipated findings, which suggests the problem is not confined to the initial consent transaction but extends into how DTC information gets handled downstream, often by people with no direct relationship to the testing company at all [24]. Broader epistemic analysis of the DTC testing process has raised a related concern: because DTC results are typically delivered without the interpretive scaffolding a clinical genetics visit would provide, consumers -- and by extension their relatives, once results are shared within families, as they very often are -- may draw conclusions about risk or ancestry that overstate what the underlying data actually supports [25].

Figure 1 sketches, schematically, how the consent burden shifts across these three categories of

secondary use -- research, corporate/commercial transfer, and law enforcement/familial exposure -- relative to how much control the original consenting customer retains once each use occurs. The pattern is not derived from a single dataset; it is intended to illustrate the general shape of the problem this review has traced: control declines fastest in precisely the categories of use that were least explicit in the original consent transaction.

TOWARD BETTER GOVERNANCE

No single fix closes the gap between what DTC consent formally captures and what a genuinely informed transaction would require, but the literature reviewed here converges on a few overlapping directions. First, genetic data collected outside clinical settings needs a privacy framework built for its specific features -- shared inheritance across relatives, durability across a customer's lifetime and beyond, and value to law enforcement and researchers that a generic consumer-privacy statute does not anticipate -- rather than continuing to rely on either health-privacy law that formally excludes it or consumer-protection law that was not designed with heritability in mind [3,19]. Second, meaningful consent for secondary uses, particularly law-enforcement access, likely requires consent language specific enough that a customer at the point of purchase can actually anticipate the use, rather than broad language that becomes retroactively applicable to uses invented later [11,13]. Third, because DTC results are structurally familial rather than purely individual, governance frameworks -- whether regulatory or internal to the companies themselves -- need some mechanism for acknowledging relatives' interests that does not depend entirely on the original purchaser choosing to share results voluntarily [23,22].

The uneven state-by-state legislative response documented above suggests this is an area where federal harmonization would reduce, rather than create, complexity, but the political path to a comprehensive federal genetic-privacy statute remains unclear given how the issue currently gets litigated piecemeal across state legislatures [14,15,16].

CONCLUSION

Direct-to-consumer genetic testing sits at an uncomfortable intersection of consumer commerce, clinical genetics, and law-enforcement investigation, governed by a consent model built for the first of those three contexts and stretched, often past its actual capacity, to cover the other two. The ownership question remains legally unresolved in most jurisdictions, empirical work on customer understanding suggests the consent process functions more as a trust signal than a genuine information transfer, and the field's distinctive familial structure means that individual consent -- however well designed -- cannot fully protect the relatives whose

genetic information is also, unavoidably, disclosed by a single person's decision to test. Closing these gaps will likely require purpose-built genetic-privacy regulation rather than continued reliance on general consumer-protection frameworks, consent language specific enough to cover the secondary uses that have already emerged, and some acknowledgment, structural rather than voluntary, of the interests held by relatives who never clicked accept on anything.

DECLARATIONS

Acknowledgements

The authors are grateful to colleagues in their respective bioethics and clinical ethics departments for helpful discussion during the preparation of this review.

Funding

This review received no external funding.

Conflict of Interest

The authors declare no conflicts of interest relevant to this work.

Author Contributions

Zsofia Bakker conceived the review and drafted the sections on ownership and the legal framework. Erik Ferraro conducted the literature synthesis on consent and secondary uses and critically revised the manuscript. Anneke Gallagher contributed the analysis of familial and third-party implications and provided final approval of the submitted version. All authors read and approved the final manuscript.

Ethics Statement

As a literature review synthesizing previously published, publicly available research, legal analysis, and policy commentary, this article did not involve new data collection from human participants and did not require institutional ethics committee approval.

Data Availability

No new data were generated or analyzed for this review. All sources discussed are cited in the reference list and are publicly available through their respective publishers.

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