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Avoiding Liability and Other Legal Land Mines in the Evolving Genomics Landscape

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Abstract

This article reviews evolving legal implications for clinicians and researchers as genomics is used more widely in both the clinic and in translational research, reflecting rapid changes in scientific knowledge as well as the surrounding cultural and political environment. Professionals will face new and changing duties to make or act upon a genetic diagnosis, address direct-to-consumer genetic testing in patient care, consider the health implications of results for patients' family members, and recontact patients when test results change over time. Professional duties in reproductive genetic testing will need to be recalibrated in response to disruptive changes to reproductive rights in the United States. We also review the debate over who controls the flow of genetic information and who is responsible for its protection, considering the globally influential European Union General Data Protection Regulation and the rapidly evolving data privacy law landscape of the United States.

INTRODUCTION

Our understanding of the contributions of genomic variation to human health and disease as well as to new interventions is expanding rapidly. The law, with its foundation in history and broader culture, will attempt both to shape and to respond to this growth. In this review, we discuss where we anticipate that significant legal changes will occur in response to advances in genomics as well as broader sociocultural forces, particularly for the legal issues that may directly affect healthcare practice and research. These issues fall into two major areas: expansion of liability—usually under the rubric of medical malpractice for clinicians using genetic information—and the ongoing debate about who controls the flow of genetic information.

MEDICAL MALPRACTICE: THE TREND TOWARD EXPANDING LIABILITY

Patients have long alleged that they suffered injuries as a result of the way that genetic information was or was not generated and used. Many of these tort claims fall under the general umbrella of medical malpractice, the requirements of which vary from state to state due to differences in case law, statutes, and regulations [details of recent state decisions, statutes, and regulations addressing genetics are available from the LawSeq^{SM} project (86)]. The elements of such claims are well defined—the clinician must have owed a duty to the patient and failed to comply with the standard of care, thereby causing the patient to suffer injuries that are attributable to the lapse and for which the law provides compensation. Common claims include failure to make or act upon a genetic diagnosis. In these cases, the standard of care is usually defined as that provided by reasonably prudent providers, often within the same specialty. Defining the level of care required is often informed by literature reviews and recommendations by professional organizations (13) and typically must be established by expert testimony. Most courts require claimants to show that they and other reasonably prudent people would have chosen a different course of care had they received appropriate information, a requirement imposed to mitigate fear of hindsight bias. Potential claims for this type of liability were comprehensively reviewed in 2020 by Marchant et al. (59).

The legal challenges for clinicians who use genetic information may well become more complex, in no small part because in the future, the price of genetic testing may be much lower than it is today. Some predict that it will soon be possible to sequence the whole genome for $100 to $200 (18, 69), although this price does not include the cost of interpretation and delivery of results. In addition, much more will be known about the clinical impact of particular variants individually and in combination both with each other and with a wide array of exposures. There is great enthusiasm about the potential of genomics to improve medical care, and many resources are being devoted to the implementation of this information in clinical practice. Yet gaps in knowledge remain, particularly regarding understudied populations (18, 76). Tools to interpret and integrate genomic information are constantly evolving as well. Thus, clinicians may not use these tools appropriately (52), and the tools themselves may not always deliver correct information for the particular patient.

What Test to Do and What Variants to Examine

In an era where broad-based sequencing is increasingly available, the first question may be which test to use. Where there is a known pathogenic variant in the family, for example, testing solely for that specific variant answers the clinical question—the patient does or does not have the variant. For patients with certain clinical problems, such as cancer or one of a variety of cardiac conditions, but where a particular variant is not already known to be present in the family, panels that examine many genes that may be implicated are increasingly available (74). These

strategies are often favored because they focus on the clinical issue at hand and do not provide findings pertinent to other disorders except in the case of pleiotropy, where a single variant affects multiple, sometimes seemingly unrelated, traits.

Yet many have suggested over the years that genome sequencing should become routine even for individuals who do not have a current indication for testing (19, 89). At present, whole-exome and whole-genome sequencing have an important role to play in understanding complex phenotypes experienced by patients, particularly those with rare diseases (50, 84). However, whole-genome sequences contain a broad array of other information, the clinical implications of which are not always well understood. This raises the question of how to handle the parts of the genome beyond those expected to answer the current clinical question.

The American College of Genetics and Genomics has addressed the question of which parts of the test results need to be studied by identifying a set of actionable genetic variants that clinicians should offer to examine whenever they order a broad-based test regardless of the primary reason for testing (4, 5, 33, 65, 66). The motivations for developing this list are to ensure the well-being of patients, provide a practical and feasible strategy for handling genomic information, and reduce potential liability for practitioners by defining what does not need to be examined. This set has grown over time, but laboratories in the United States vary in how they manage secondary findings (3). It is important to note that the American College of Genetics and Genomics has made clear that its recommendations are intended to apply only to clinical care and not to research and are not intended to define the standard of care despite the fact that courts often rely on guidelines such as these for exactly that purpose (60). By contrast, the European Society of Human Genetics continues to take a cautious approach to what it refers to as "opportunistic" screening of patients who undergo whole-genome sequencing for genetic variants beyond those related to the patient's presenting condition. The European Society of Human Genetics proposes that any offers should be framed within pilot and evaluation studies to confirm a substantial clinical benefit and the appropriate and equitable use of limited public healthcare resources (21).

The Case of Polygenic Risk Scores

Most research to date has, understandably, focused on monogenic traits. However, much effort is currently devoted to interrogating genetic data to develop polygenic scores that involve dozens to hundreds of genes to improve prediction, diagnosis, and treatment of complex diseases. Much of this work involves machine learning, which increasingly seeks to integrate environmental and structural factors as well. The results of these efforts at present are not always equally applicable to all populations (49, 55) due to, among other things, gaps in the representativeness of underlying data, which may be attributable in part to unrecognized bias in ascertainment, as well as failing to frame the task appropriately.

Liability considerations for medical practitioners from the development of polygenic risk scores are likely to remain limited, although the direction of evolution in the future remains unclear (57). First, polygenic risk scores tend to focus on identifying healthy at-risk individuals rather than on diagnosing current symptoms. Thus, these scores are typically deployed in the context of preventive health programs to target screening and prevention efforts. Finally, the complexity of interpretation, limited actionability, and potentially long time periods between testing and realization of the harm all suggest that malpractice may play a limited role in regulating this area of genomics.

Machine Learning and Artificial Intelligence

At the same time, there has been much interest in the potential for liability for injuries resulting from the use of machine learning and artificial intelligence in healthcare (31, 57, 61, 67). Failure

to detect and respond to bias is a particular area of concern (51), as are questions about who should bear responsibility among physicians, institutions, and developers for injuries resulting from the use of these tools (31, 32, 48). What is more likely, however, is increased attention to regulating the quality of machine learning applications. Medical device regulations are expanding to cover software (28, 57), and many jurisdictions around the world are pursuing greater oversight of artificial intelligence (41).

(Re)examining, (Re)interpreting, and Returning Results

Whatever test is used, issues of interpretation can loom large since knowledge is expanding rapidly and currently available data are incomplete. Genomics laboratories do not always agree about which variants are present or their clinical significance (88). These differences have narrowed due to public resources such as ClinVar, a central database that defines the clinical relevance of genes and variants, and ClinGen, the network of expert groups interpreting disease risk of genomic variants (63). Laboratories are also establishing data-sharing networks, resolving differing interpretations as a quality control measure (62). Nonetheless, gaps in knowledge remain, which can leave open the possibility of liability (85). Of particular note is that currently existing data were obtained primarily from individuals of northern European or, to a lesser extent, East Asian ancestral origin and thus are less probative for individuals of other origins (49, 76). Laboratories also differ in their data-sharing practices for commercial or privacy reasons (11, 20).

Moreover, interpretations of clinical impact can change over time as knowledge advances, leading to questions about whether and to what extent clinicians and laboratories have a legal obligation to reexamine previously returned data and to provide new interpretations to patients and their physicians (79). Reinterpretation and communicating changes in genomic risk assessment may pose the greatest legal challenge for clinicians in the near future.

The case of *Williams v. Quest Diagnostics* (90) suggests what the future may hold. In that case, a child with a seizure disorder died due to inappropriate anticonvulsant treatment. The child received genetic testing for his seizure disorder at 18 months, at which time the family was told that the tests had revealed a variant of uncertain significance. It turned out, however, that the variant causes Dravet syndrome, which requires different medications. The parents later sued the laboratory director, alleging that he had already known at the time of testing that the variant was pathogenic (10, 38) and that even when the association with Dravet syndrome was later clarified (44), it was never communicated to the family.

While the courts never reached the merits of the parents' claim, deciding that their suit was barred by both the statute of limitations and the statute of repose, the trend is clear. Many laboratories are already returning at least some reinterpreted results to clinicians and sometimes to patients (14), and many clinicians feel an ethical responsibility to return these new interpretations to the patients to whom the results pertain, apparently no matter how much time has elapsed (6, 9). Challenges include determining what types of reinterpretations are significant enough to return, although actionability may diminish for individuals over time as health risks are realized (or not). Moreover, patients and research participants vary widely in their definitions of actionability, and some want all information regardless of impact on care (45). Reinterpretation is also compounded by the everyday challenges of paying for new analyses and communicating altered results to laboratories, clinicians, and patients. As a practical matter, it can sometimes be difficult to find patients who may have moved or changed providers in the interim. What laboratories and clinicians do about returning changes in interpretation will shape the standard of care, raising questions about how much effort must be made to recontact and how long the responsibility to do so lasts.

The Ongoing Challenge of Direct-to-Consumer Genetic Testing

It is estimated that more than 100 million people have pursued direct-to-consumer genetic testing (43). Of these, approximately 12 million have purchased health-related testing (1), and many consumers take genomic data about them from one source and submit it to another direct-to-consumer provider to identify disease-related variants (35). The quality of these tests and third-party interpretations may vary. Some of these individuals take their results to clinicians to help them understand the results or to provide follow-up care. Clinicians, however, may not always have the time or the skills to interpret results and provide adequate counseling (7). Insurers often will not pay for the repeat tests that professional organizations recommend or the follow-up care that may be warranted (58). Clinicians' choices, however, can expose them to liability (59) if they either decline to act on a potentially pathogenic variant or base care on a direct-to-consumer result that turns out to be incorrect (70).

Warning Relatives

Some legal concerns are long-standing. Relatives of patients with monogenic traits, particularly those that are dominantly inherited, may often be at risk of the same condition. Warning patients of these risks to their kin is standard practice, and indeed, many clinicians offer to help their patients warn at-risk relatives. In the 1990s, two courts reasoned that failure to warn their patients about familial risk could give rise to liability (72, 81). The Florida Supreme Court held that the physician had a duty to inform a patient with medullary thyroid cancer that her daughter shared a risk of the same disorder (72). In the other case, the father died of adenomatous polyposis in the 1950s. When his daughter developed the same disease in 1990, a New Jersey court went further and held that her father's physician had a duty to ensure that she personally had been informed (81), a decision overturned by the state's legislature. These decisions were roundly criticized (15) and largely superseded by the promulgation of the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA) (45 CFR part 160 and subparts A and E of part 164).

These early precedents were concerning, especially since some patients do not share information about genetic risk with their families. Indeed, physicians are often distressed when patients refuse to warn their families and want to reach out themselves to inform patients' relatives. Although some commentators argue that clinicians' decisions to contact relatives directly are ethically permissible and that legally effective work-arounds are possible in some cases (77), 45 CFR § 164.510 states that protected health information may not be shared with family members without the patient's consent except as needed to enable them to care for and pay for the patient (42, 78, 87). Thus, the better path is to work with patients to assist them in talking with their kin or getting permission for the clinician to share this information directly with the relatives, taking care to document these efforts.

Experiences have differed internationally. A UK court found liability for a physician's failure to warn a family member of a dementia variant (which would have informed her reproductive decisions) over the patient's objection (2). In Germany, a physician's decision to inform a child of a dementia variant (late onset) led to liability for illegal genetic "testing" (25). In the Canadian civil law province of Quebec, a court of first instance found that a physician had a duty to warn family members of the heritability of a serious neurological condition, but an appeal court upheld the primacy of patient confidentiality (56). Nevertheless, the risks of legal disputes can be greatly reduced in clinical genomics through clear, documented recommendations to patients that they share information with relatives who may share their risk variant as well as offers to provide letters or other tools to facilitate sharing.

The Blurring of Research and Clinical Care

The discussion above focuses on claims arising from clinical activity. Notably, however, many genetic tests and interventions are offered to participants in the context of translational research in order to learn more about the benefits and risks of these interventions (91). In research, however, the interventions can rest on a shakier foundation of evidence so that the results and advice may be less well founded and follow-up may be less available (37). Researchers have rarely been held liable to participants injured in the course of research, often on the ground that the researchers did not have a fiduciary duty to the participants unless the investigator was the participant's treating physician, with only a few exceptions (34, 46). Translational research, however, blurs these lines as it seeks to integrate with and inform clinical care and as investigators increasingly assume obligations to notify and care for participants. For example, a number of genetics organizations have recommended returning results in translational research projects (54), highlighting the importance of capacity building through up-front planning and resourcing. Research recommendations have even extended to a narrow set of circumstances in which updated interpretations of genomic results should be offered to research participants (12), recommendations that if not heeded could support liability, given the weight accorded to professional guidance (13).

The One Area Where Liability Will Be More Limited: Challenges to Reproductive Genetic Testing

The earliest wave of efforts to impose liability for inadequate genetic counseling was for failure to warn pregnant women that the fetus they were carrying had a genetic disorder in time for them to decide whether to continue the pregnancy (92). These claims for "wrongful birth" usually depended on the availability of abortion, unless they were founded on assertions of inadequate preconception counseling or failure to diagnose an affected older sibling in time to forgo further childbearing. While many states permitted these causes of action, some courts ruled that such claims violated public policy, especially when the claimant asserted that she would have chosen to terminate the pregnancy. Less commonly, legislatures limited such claims (73).

The landscape in the United States, however, has changed dramatically with the decision in *Dobbs v. Jackson Women's Health Organization* (23), which held that women have no constitutional right to abortion. Anticipating the rejection of existing precedent, many states passed highly restrictive abortion laws, including many with so-called reason bans, which eliminate claims of inadequate prenatal counseling in those jurisdictions (36). A few states have made it a crime to "aid or abet" a woman seeking an abortion, which could include physicians and counselors who perform prenatal diagnosis or provide counseling about options (75). A smaller number of states, notably including Texas, have enacted laws that enable citizens to obtain damages and attorneys' fees from anyone who aids or abets an abortion (Texas Senate Bill 8), a strategy designed to evade judicial review. Although no state has forbidden providers who receive government funding to mention abortion, the Supreme Court previously made clear that such bans are constitutionally permissible (80). It seems clear that legislatures are going to be very active in this space in coming years and that some will adopt even more restrictions, a course of action that would go against the trend in much of the world. These restrictions raise questions about what role remains for prenatal diagnosis even to inform pregnant women about fetal condition in the states with restrictive abortion laws.

Another notable trend is the enactment of statutes and introduction of bills that define protected human life as beginning at the moment of fertilization, which could limit in vitro fertilization when more embryos are created than are planned to be implanted. Indeed, since 1986, Louisiana has forbidden the intentional destruction of viable in vitro fertilized embryos, which it

defined as juridical persons (La. Rev. Stat. 9 §§ 121–133, Act 1986, No. 964). There has been much debate about whether some of the language in bills in Louisiana and states with similar restrictions will lead providers not to provide these services (40).

One situation in which parents may be able to pursue wrongful birth claims in some states that have strictly limited access to abortion is if they claim they would have forgone childbearing altogether or used donor sperm had their physician offered preconception genetic testing or diagnosed a genetic condition in an older child prior to their conceiving another child (68). Using donor ova might still be foreclosed if in vitro fertilization is not an option. Here as well, however, courts and legislatures may step in to preclude such claims.

CONTROL AND USE OF GENETIC INFORMATION: MOVING TOWARD GREATER PERSONAL CONTROL?

In addition to claims that they were harmed by inappropriate use of genetic information for their clinical care, people have also expressed many concerns about the ability to control where data, whether collected in the course of clinical care, research, or beyond, go as well as more general suspicions about both invasions of privacy and discrimination—that is, being treated less well based on genetic information. These areas of law were recently reviewed by Clayton et al. (17), but here as well, the risk of liability is in flux.

The Important Precedent of the European Union General Data Protection Regulation

It is important to begin this discussion with the European Union (EU) General Data Protection Regulation (GDPR) [Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016], which gives individuals quite a bit of control over where data about them go. The GDPR has a direct impact on organizations that are based in the EU or that offer goods/services or monitor individuals within the EU. It also has spillover as a global privacy standard, affecting developments in US law as well as international research collaboration. It insists that all processing of personal data have a lawful basis. The six legal bases under the GDPR include processing with the individual's consent and processing that is necessary for the performance of a contract, compliance with a legal obligation, the protection of the vital interests of the individual or another person, the performance of a task in the public interest, or an organization's legitimate interest. Where consent is the legal basis, the GDPR establishes a rigorous standard that consent be freely given, informed, specific, and unambiguous.

The GDPR establishes robust transparency (notice) requirements and data subject rights, including rights to withdraw or object to processing of personal data, rights of access and portability, and in some cases a right of erasure. Personal data are defined broadly and extend to pseudonymized (coded) data where a link is retained to the individual's identity. Health and genetic data are special categories that are subject to stricter limitations on processing and more rigorous accountability obligations on the responsible organizations. High standards of confidentiality and security apply, which, in combination with significant potential liabilities for a breach, are an increasingly significant legal preoccupation for healthcare providers and researchers.

While the GDPR explicitly aims to facilitate personal data flows within the EU market, it places strict constraints on transfers to third countries and international organizations to ensure such transfers do not diminish protection for EU citizens. Implementation of legal mechanisms for international transfer has been limited, and some existing mechanisms have been invalidated by the European Court of Justice, citing concerns over mass surveillance practices in the United States. Particular challenges for EU researchers are transferring data to US-based government agency researchers and cloud providers, limits that undermine important scientific partnerships (8).

The contours of organizational responsibility for and individual control over personal data under the GDPR remain uncertain and are subject to significant fragmentation across Member State implementations (22). This can exacerbate legally conservative approaches to data management and hamper international collaborations. The available or preferred lawful bases for processing health and genetic data in healthcare and health research contexts differ across countries, with consequences for the scope of potential secondary use of data as well as the scope of applicable data subject rights. The scope of a valid consent and the opportunities for secondary use of data beyond the initial purpose remain narrow and contested, limiting opportunities for reusing genomic data for multiple health and research applications. A standard for anonymization remains elusive, particularly where a code linking back to individual identities is maintained. As whole-genome sequence data are unique to the individual, they tend to be treated in almost all circumstances as personal data and thus subject to the GDPR.

Building on this strong data protection foundation, the EU is turning to unlocking the value of data across sectors in a responsible way, including through the proposed European Health Data Space regulation (27). This regulation establishes a general obligation for holders of electronic health data to register these datasets in national data catalogs and to provide access to data for secondary use purposes, including research, healthcare, and artificial intelligence innovation. Importantly, access would be mediated by national data access bodies and provided in secure processing environments, with attention to data minimization and transparency. Thus, this regulation provides a legal framework for data access and secondary use that does not rely on individual consent.

The Complicated Landscape in the United States

The situation in the United States is more complex and differs dramatically from that in Europe. On the federal level, HIPAA provides some protection for personal protected health information, including genetic information, as defined by the Genetic Information Nondiscrimination Act [Pub. L. 110-233, 122 Stat. 881 (2008)], but it has numerous exceptions. First, it applies only to most health plans, healthcare clearinghouses, and healthcare providers and their business associates, which excludes a host of entities—ranging from direct-to-consumer genetic testing and interpretation companies to law enforcement—that collect genetic information. Even within its purview, HIPAA permits protected health information to be accessed without patient permission for numerous purposes, including by public health agencies and law enforcement. Data that are deidentified according to its strict criteria are not covered by HIPAA at all. The Regulations for the Protection of Human Research Participants [the Common Rule; 45 CFR part 46 (2018)], through a variety of definitions, exemptions, and waivers, permit use of quite a bit of genetic and clinical information, including some that is identifiable, for research without consent so long as results are not going to be returned (17). Moreover, as of January 2023, the National Institutes of Health (NIH) will require broad data sharing as a condition of funding research as well as submission and compliance with data management and sharing plans for all NIH research that generates scientific data (71). As a result, many data flow relatively freely in the United States.

Yet there is reason to think that some individuals may soon have more control over where genetic information about them goes. When the Common Rule requires consent, researchers are expected—and, in some cases, mandated [45 CFR § 46.116(d)(3)]—to notify the participant about data sharing to inform choices about participation. Many states have passed laws attaching conditions to the conduct of clinical genetic testing (64). These restrictions fall into three large groups. A focus of many of these statutes is ensuring informed consent for the collection, use, or transfer of genetic data, although the definition for what constitutes informed consent varies (83). This inconsistency is particularly true for minors (16). Another group includes antidiscrimination laws

(82). Most important for present purposes are laws that limit redisclosure of genetic information without consent (e.g., Ariz. Rev. Stat. title 12, chap. 19, § 12-2802; Colo. Rev. Stat. § 10-3-1104.6; 410 Ill. Compiled Stats. 513; S. Car. Code § 38-93-40). Most of these laws contain various exceptions, such as for criminal law enforcement, newborn screening, and medical, scientific, or clinical research and education purposes [e.g., N. Mex. Stat. § 24-21-3 (2020); Alaska Stat. § 18.13.010(b); 410 Ill. Comp. Stat. Ann. §§ 513/1 et seq.]. In particular, some of these laws specifically do not seek to offer greater protections than those provided by HIPAA [Cal. Civ. Code § 179.81.5 (2022); 410 Ill. Comp. Stat. Ann. § 513/31.7].

More recently, there has been an increase in bills targeted specifically to direct-to-consumer genetic testing companies [H.B. 502, Gen. Assemb., Reg. Sess. (Ky. 2022); H.B. 866, Gen. Assemb., Reg. Sess. (Md. 2022); H.B. 86, 66th Leg., 2022 Budget Sess. (Wyo. 2022) (now Wyo. Stat. Ann. § 35-32-101); S.B. 227, Gen. Assemb., Reg. Sess. (Utah 2021); S.B. 178 Gen. Assemb., Reg. Sess. (SD 2021); A.B. 825, Gen. Assemb. (Cal. 2021)]. These laws, as well, differ in their breadth, protections, exceptions, enforcement schemes, and constraints on disclosure.

The more dramatic change is the growing effort by states, and now Congress, to regulate personal data flows more generally. So far, five states have enacted comprehensive consumer privacy laws: California [California Consumer Protection Act, S.B. 1121 (2018); California Privacy Rights Act, Prop. 24, 1879 (19-0021A1) (2020)], Colorado [Colorado Privacy Act, C.R.S. §§ 6-1-1301 et seq. (2021)], Connecticut [Connecticut Data Privacy Act, S.B. 6 (2022)], Utah [Utah Consumer Privacy Act, Utah Code Ann. §§ 13-61-101 et seq. (2022)], and Virginia [Virginia Consumer Data Protection Act, S.B. 1392 (2021)]. The first and still most influential of these is the California Consumer Protection Act of 2018. This law and its newer version, the California Privacy Rights Act, took inspiration from, and have much in common with, the GDPR but have substantive and important differences. Each of the five statutes includes genetic data under its definition of sensitive data, and each one also has explicit exemptions for obligations regarding the collection, retention, and transfer of data when used for verified research purposes.

A notable recent development in federal privacy regulation was the American Data Privacy and Protection Act (ADPPA) [H.R. 8152 (Committee Print)], which was introduced in the 117th Congress. The ADPPA is a bipartisan, bicameral comprehensive privacy bill that has garnered far more support than its predecessors. Legislators have found compromises on the majority of the key issues and provisions of the bill. However, the two primary issues of contention are the inclusion of a private right of action and preemption of state law. If the ADPPA were enacted in its current form, it would supersede all existing comprehensive state privacy laws and prevent future ones, setting a single national standard [§ 404(3)(b)]. Opponents, including legislators in California and some privacy advocates, would prefer a federal law that sets a federal floor for protections but allows states to set higher standards should they choose (53, 93). However, the ADPPA includes some exceptions to its preemption clause—including for state laws that protect medical and health information and Illinois' Genetic Information Privacy Act—that cover many existing genetic privacy laws [§§ 404(b)(2)].

In the version of the ADPPA current as of this writing, genetic data are categorized as "sensitive covered data" [§ 2(24)(A)(v)] and warrant extra protections. In general, sensitive data may not be transferred to a third party without affirmative express consent of the individual [§ 102(a)(3)]. However, transfer of genetic information may be acceptable if "the transfer is necessary to perform a medical diagnosis or medical treatment specifically requested by an individual, or to conduct medical research" under limited circumstances [§ 102(3)(F)]. Section 101 covers the conditions under which a covered entity may collect, process, or transfer covered data, which, if "limited to what is reasonably necessary and proportionate to such purpose," include "conduct[ing] a public or peer-reviewed scientific, historical, or statistical research project" [§ 101(b)(10)]. The bill

additionally instructs the Federal Trade Commission to issue guidelines specific to the risks and context of researchers storing and transferring covered data [§ 101(b)(10)(B)].

The ADPPA was reported out of committee in the US House of Representatives in July 2022, and although it was not enacted in that form, it will serve as a precedent for any subsequent iterations and proposals in future sessions. Given the heightened attention that data privacy has received, many advocates are optimistic that a federal privacy law will ultimately be passed (26, 47).

Additionally, the Federal Trade Commission has published an Advance Notice of Proposed Rulemaking on commercial surveillance and data security (30). The agency is advancing the rule under its newly updated Magnuson–Moss authority (29), which entails a complex process that would likely take years. While the proposed rule is sweeping and comprehensive, many aspects would likely be challenged as overstepping the agency's authority. At this stage of the process, the details and extent of the obligations and restrictions that would result are uncertain.

CLOSING THOUGHTS

The rapid expansion of genetic testing in the clinic and in translational research, combined with advances in our understanding of the clinical implications of variants individually and together, surely creates the opportunity for claims by patients, research participants, and their family members that they were harmed by inaccurate, outdated, or poorly applied results. The genetics community needs to anticipate these issues and strive to create the systems needed to ensure that correct results are returned with appropriate support and follow-up care. Meeting these goals will be a major challenge no matter what, given the extraordinary growth of knowledge about genomics and the development and deployment of new and more focused preventive and therapeutic interventions around the world. This challenge will be particularly daunting in the United States, with its fractured healthcare system and complex federalism.

Two major developments may, however, limit the use of genomic information in some contexts. First, the role of reproductive genetic testing, including ultrasonography and prenatal genetic testing, must be reexamined, particularly in states that have enacted strict limits on access to abortion. Prenatal diagnosis of a fetal anomaly may not always help families prepare for the child's birth even in cases in which alteration in perinatal management can improve fetal outcome (24). Indeed, foreknowledge can come with significant emotional cost to parents both before and lasting well after delivery (39). Thus, it will be more important than ever to counsel pregnant women prior to performing prenatal diagnosis to allow them to decide whether to proceed with testing.

More broadly, healthcare providers and investigators may face stricter regulations about sharing and obtaining access to genomic data in the future, particularly outside the United States. Although the Common Rule, the NIH data-sharing and management policy, and the proposed European Health Data Space support broad access in many ways, the GDPR has tremendous practical and expressive impact, and some states and Congress are interested in providing individuals with greater control over data about them. If researchers are to obtain permission to use these data, they must redouble their efforts not only to demonstrate compliance but also to engage and build trust with communities.

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