Received: 27 April 2020 | Revised: 1 June 2020 | Accepted: 2 July 2020

DOI: 10.1002/mgg3.1414

ORIGINAL ARTICLE

Molecular Genetics & Genomic Medicine Open Access WILEY

Genetic testing and employer-sponsored wellness programs: An overview of current vendors, products, and practices

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FUNDING INFORMATION
This study was supported by National Institutes of Health (NIH) National Human Genome Research Institute (NHGRI) Award No. R01HG009694-03S1 to Vanderbilt University (as prime) and Geisinger Clinic as a subaward.

Abstract

Background: Employer-sponsored corporate wellness programs have spread despite limited evidence of effectiveness in improving health or reducing costs. Some programs have offered genetic testing as a benefit to employees, but little is known about this practice.

Methods: In December 2019, we conducted a systematic Google search to identify vendors offering corporate wellness programs involving genetics. We performed qualitative content analysis of publicly available information about the vendors' products and practices disclosed on their websites.

Results: Fifteen vendors were identified. Details regarding genetic testing offered within wellness programs were difficult to decipher from vendors' websites, including which specific products were included. No evidence was provided to support vendor claimed improvements in employer costs, employee health, and job performance. Only half offered health and genetic counseling services. Most vendors were ambiguous regarding data sharing. Disclaimer language was included in vendors' stated risks and limitations, ostensibly to avoid oversight and liability.

Conclusion: We found a lack of transparency among corporate wellness program vendors, underscoring challenges that stakeholders encounter when trying to assess (a) how such programs are using genetics, (b) the potential benefits of such applications, and (c) the adequacy of protections to ensure scientific evidence support any health claims and genetic nondiscrimination.

KEYWORDS
ELSI, employees, GINA, population genetics, wellness

1 | INTRODUCTION

Employer-sponsored wellness programs have proliferated in the United States since the 1990 s. Projections have estimated that the corporate wellness industry could exceed $12 billion US sometime in 2020 (Roberts & Fowler, 2017; Wolfe, 2018). In 2018, 82% of large firms and 53% of small employers in the United States offered a wellness program, with key health and wellness components, including nutrition, physical activity, stress reduction, and preventive services (Song & Baicker, 2019). Despite the high prevalence of employer-sponsored wellness programs (Roberts & Fowler, 2017),

the concept has no universally accepted definition. Generally-speaking, wellness programs offer employment-based activities to employees to promote healthy behaviors, prevent and/or manage disease. Congress encouraged wellness programs when it passed the Affordable Care Act (ACA; Patient Protection & Affordable Care Act, 2010), which sets statutory standards for two categories of wellness programs: "participatory" wellness programs and "health contingent" wellness programs (the latter of which may be either activity-only condition management or outcome-based). The ACA defines a "participatory" wellness program as one in which "none of the conditions for obtaining a reward under a wellness program is based on an individual satisfying a standard that is related to a health factor (or if a wellness program does not provide a reward)" [26 CFR § 54.9802-1(f)(ii); 29 CFR § 2590.702(f)(ii); and 45 CFR § 146.121(f)(ii)] and defines a "health contingent" wellness program as "a program that requires an individual to satisfy a standard related to a health factor to obtain a reward (or requires an individual to undertake more than a similarly situated individual based on a health factor in order to obtain the same reward)" [26 CFR § 54.9802-1(f)(iii); 29 CFR § 2590.702(f)(iii); and 45 CFR § 146.121(f)(iii)].

It has long been promised that employee wellness programs would provide health benefits and also reduce healthcare costs, but evidence for this is scant (Song & Baicker, 2019). An 18-month cluster randomized trial of 32,974 employees at 160 work sites run by Harvard Medical School and the National Bureau of Economic Research aimed to determine if corporate wellness programs improved employee health and reduced healthcare costs. Although the results showed an improvement in employee self-reported positive health behaviors, there was no significant change in healthcare spending, healthcare utilization, or clinical measurements of health for employees, and no significant impact on employment outcomes such as absenteeism and work performance (Song & Baicker, 2019).

Over the last decade, genomic medicine has been promoted as providing the ability to individualize care and improve health outcomes (Manolio et al., 2019). A major challenge to genomic medicine implementation has been the lack of evidence of clinical utility (net benefit of testing) and lack of reimbursement by insurers (Peterson et al., 2019). While privacy concerns remain an important consideration in any genetic service delivery setting, in the context of employer/employee relationships and access to genetic data, these privacy concerns are magnified (Song & Baicker, 2019). Recognizing these challenges, there has been increased interest in exploring the responsible integration of genetic technologies and genetic information in employer-sponsored health and wellness programs. In March 2019, the National Human Genome Research Institute (NHGRI) sponsored a "Genomics in Health and Wellness Meeting" to discuss the potential benefits and barriers to offering pre-emptive testing for genetic conditions in the workplace. Meeting recommendations included development of a framework for implementing and evaluating employee genetic testing, including assessment of outcomes of relevance to employers and employees such as impact on health status, productivity, and health care costs (Tamburro, 2019).

Proponents assert that genetic testing offered in this way (i.e., voluntary, health-related testing for employees, and their dependents with or without a personal or family history of genetic disease) might improve the identification of evidence-based and medically actionable risks, help participants be more actively engaged in their health and well-being, improve genetic and health literacy broadly, identify health risks earlier, and promote safer and more effective medication use. Knowledge of genetic risk could inform a variety of preventive measures, leading to the avoidance or mitigation of disease and associated costs. This possibility was anticipated by Congress when the Genetic Information Nondiscrimination Act (GINA; Genetic Information Nondiscrimination Act of 2008) was debated and passed more than a decade ago. GINA strictly forbids employers from obtaining or even requesting genetic information from employees (i.e., the statute includes a privacy mechanism as a means to preclude discriminatory uses of genetic information), but there is a statutory exception for employer-sponsored wellness programs that meet enumerated criteria (42 U.S.C§, 2000ff-1). Nevertheless, integration of genetic technologies in employer-sponsored wellness programs has been and continues to be controversial. Scholarly discussion has focused on several controversial aspects of corporate wellness programs, for example, the coercive pressures that financial incentives for wellness program participation exert upon potential participants (thereby undermining voluntariness), the statutory interpretation and implementation (e.g., Blue, 2014; Madison, 2015; Rothstein, Roberts, & Guidotti, 2015; Sarata, DeBergh, & Staman, 2011); and the intensifying concerns about employee privacy (Ajunwa, Crawford, & Ford, 2016; Ajunwa, Crawford, & Schultz, 2017; Areheart & Roberts, 2019; Blue, 2014; Henniger, 2018; Kim, 2019; Madison, 2015; McIntyre, Bagley, Frakt, & Carroll, 2017; Roberts & Fowler, 2017; Rothstein et al., 2015; Sarata et al., 2011; Terry, 2018; Wolfe, 2018).

Much ink has been spilled regarding whether the statutory constraints imposed by the ACA, GINA, and the Americans with Disabilities Act (42 U.S.C§, 2000ff-1; Americans with Disabilities Act, 1990) are complementary or conflicting. This has been the subject of ongoing policy debates as well, including consideration of HR.1313 (American Society of Human Genetics, 2017; Condiles, 2019; Hudson & Pollitz, 2017; Maintaining Protections for Patients with Preexisting Conditions Act of, 2019, 2019; New York Times, 2017; NSGC Position Statement, 2017; Oliphant & Terry, 2016; Protect Act, 2019; Ray, 2017; The Preserving Employee Wellness Programs Act, 2017). Operationalizing these three

statutes (ADA, GINA, and ACA) necessitates a balancing or reconciliation of the nondiscrimination rights (and informational privacy rights) afforded under GINA and ADA with the promotion of health via wellness programs under ACA, and the Equal Employment Opportunity Commission (EEOC) is charged with this responsibility. When the EEOC issued its regulations, they were immediately and fiercely challenged. While voluntariness is a prerequisite to lawfulness of any wellness program as per GINA or ADA, what is "voluntary" is not defined by the statutes, calling into question whether financial incentives under ACA could be permissible when wellness programs implicate GINA or ADA (such as incorporating genetic information or testing). Initially, the EEOC had taken the position that incentives could not be tied to an employee's disclosure of GINA- or ADA-protected information, but the EEOC reversed this position with issuance of its final rules in 2016 (EEOC, 2016a; EEOC, 2016b; EEOC, 2018a; EEOC, 2018b). Litigation ultimately led to the EEOC's regulatory provisions on wellness programs being vacated (AARP v. EEOC & 292 F, 2017; AARP v. EEOC & 226 F, 2017; Equal Employment & Fed. Reg.65296-01, 2018; Equal Employment & Fed. Reg.65296-02, 2018; EEOC, 2019). While during litigation the EEOC had assured the D.C. District Court that replacement rules would be issued by October 2019 and while this item was on the EEOC's regulatory agenda for fall 2019 with explicit expectation of proposed rules issuing by January 2020, no proposed text for interim or final rules has yet (as of 20 May 2020) been issued. While the statutory provisions and bulk of implementing regulatory provisions remain in place, regulatory uncertainty persists with regard to wellness programs integrating genetic information or testing components and contemplating incentives.

Thus, despite any potential health benefits that the integration of genetic services into employer-sponsored wellness programs might have, there is ample reason to examine the policies and practices of genetic testing products offered by vendors to employers. To better understand genetic services offered by corporate wellness program vendors, we undertook a landscape analysis of current vendor products and practices using information available publicly online.

2 | MATERIALS AND METHODS

To identify vendors offering corporate wellness programs with genetic services, asystematic search of vendors offering business-to-business (BTB) genetic testing as part of a corporate wellness program was conducted using the Google search engine. BTB corporate wellness vendors were defined as companies (i.e., vendors) that sell products (i.e., corporate wellness programs) directly to other businesses (i.e., employers). Search strings were identified from keywords listed in relevant academic research articles and news coverage that addressed topics on and related to genetic testing as a corporate wellness strategy. Sixteen (16) unique search strings were identified (Table 1). Webpages in the United States, written in English, and last updated no earlier than 1 January 2000 were automatically included in the search results using Google's advanced search feature and filter tool. The first 30 uniform record locators (URLs) results were recorded for each search string and a total of 480 results were recorded for all 16 search strings used. These methods (use of Google and focusing the analysis on the first 30 URLs in the results) were selected based on a preliminary set of searches that were performed to determine a reasonable approach. The preliminary searches was performed using three search engines (Bing.com, Yahoo.com, and Google.com) and a single search string ("Corporate wellness program genetic testing"). The first 100 URLs from each search engine's results were compared. Google outperformed the other two search engines in identifying the most vendors, and saturation was reached within 30 URLs of the results (i.e., reviewing URLs after the

TABLE 1 Search strings used in the Google.com systematic search

	Unique search strings	Number of vendors identified
1	Workplace wellness program genetic testing	1
2	Organizational wellness genetic testing	6
3	Corporate wellness genetic testing	8
4	Workplace health promotion genetics	1
5	Employee Wellness genetic screening	4
6	Corporate wellness program genetic testing	6
7	Employee precision health genetics	3
8	Employee clinical genomics	2
9	Employer-sponsored wellness genetic testing	3
10	Worksite wellness program genetic testing	3
11	Worksite health promotion programs genetic testing	1
12	Employer-based wellness genetic testing	3
13	Wellness vendors genetic testing	1
14	Genetic test & employee	2
15	Employer genetic testing	2
16	Weight loss corporate wellness genetic testing	6

The "unique search strings" column shows the search strings that were used for the Google search. The "number of vendors identified" column demonstrates the number of vendors that were identified in the Google results page with each search string.

30th search result was unlikely to yield any additional unique vendors). Each URL was reviewed to first identify vendors that appear to sell (not merely promote or advertise) a corporate wellness program to employers. Most of the URLs directed to news articles and commentary about corporate wellness programs, direct to consumer genetic testing, and direct to consumer wellness programs. The resulting vendors were further refined by only including those that offer genetic testing as a component of their corporate wellness program (which is some cases was the sole wellness offering). The systematic Google search was performed November 27 to 1 December 2019 (Figure 1).

Like methods used for landscape analyses of various sectors of the DTC industry (Wagner, Cooper, Sterling, & Royal, 2012), content analysis of the websites for each of the vendors identified in the systematic search was performed, and data collection for each vendor was started and completed on a single day (Table S1). Data were collected between 1 December 2019 and 9 December 2019, and each vendor's website was analyzed independently. The data gathered about each vendor included the following variables: vendor characteristics (vendor name, unique search strings used to identify the vendor in the systematic Google.com search [Table 1], URL to the vendor corporate wellness page, foundation date, headquarter address, scientific advisory board, and number of genetic testing products listed on their website) (Table 2). Data collected on vendor policies included the privacy policy, the policies on sharing data with employers, third parties, employee users, and primary care physician (PCP), the Health Insurance Portability and Accountability Act (HIPAA; Health Information Portability & Accountability Act, 1996), mention of GINA, the terms and conditions, jurisdictional areas excluded, stated limitations, and stated risks of the corporate wellness program and the genetic testing products. Vendor marketing points of emphasis (such as improved employee job performance, employee health outcomes, and employer financial outcomes) were assessed from the language used on the vendors' corporate wellness page. Finally, the characteristics of the genetic testing products on the vendors' websites were also examined, including the DNA collection method, the type of insight the test provides, the number of variants detected, the method at which results are delivered, the availability and type of posttesting counseling, the type of results available to the end user, and identification of the product as a component of the corporate wellness package (Table 2). When there were no explicit links to genetic tests from the corporate wellness program landing page, the entire vendor website was assessed and direct-to-consumer tests were included in the analysis. Investigators WSM, JKW, PAD, and MSW contributed to the development of the codebook of variables to measure. For coding consistency, only one researcher (WSM) performed the coding and content analysis of each website, as consistency of approach was prioritized over the risk of introducing bias. The data were collected and analyzed in Microsoft Excel version 16 in Microsoft Office 365.

3 | RESULTS

A total of fifteen (15) BTB corporate wellness vendors that offer genetic services were identified and analyzed in December 2019 (Table 3). The mode for year of founding was 2015 (26.7%, n = 4, range 1993–2017), and 47% (n = 7) have corporate headquarters in the state of California (Table 3). The genetic tests listed on each vendor's website were categorized by the type of insight the results provide for the end user; Dynamic DNA labs and Silverberry Genomix had the most diverse offering of genetic tests on their website (Table 3). The number of vendor-branded genetic tests offered was also variable; however, Pathway genomics, Dynamic DNA labs, and Silverberry Genomix appeared to sell the highest number of individual genetic tests (n = 14, 13, and 12, respectively). At the time, data collection was completed (9 December 2019), no vendor listed the BTB prices for the corporate wellness program, or clearly disclosed the specific genetic tests included in their corporate wellness program. All prices for genetic tests listed on the vendors websites were

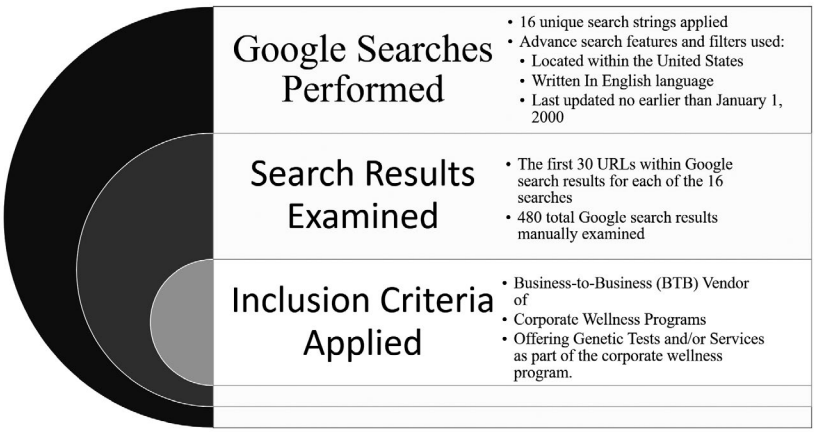

FIGURE 1 Systematic search methodology is a funnel plot of the systematic search strategy used to identify (1) business-to-business vendors of, (2) corporate wellness programs, (3) offering genetic tests and/or services as part of the corporate wellness program.

TABLE 2 Content Analysis Codebook displays the content analysis codebook that identifies and defines the variables used to collect data on each vendor

Category	Variable	Definition	Data structure
Vendor organizational characteristics	Vendor name	Name of the vendor.	Verbatim text
	URL	Uniform Record Locator to the vendor's corporate wellness page.	Website address
	Foundation date	Date the vendor founded the company.	Date
	Headquarter address	Location of the primary offices.	Physical address
	Executive leadership	Name of Founder, President or Executive officer(s).	Name(s)
	Leadership contact information	E-mail address of executive leadership.	E-mail address
	Marketing slogan	Large or bold stand-alone text on the top 30% of the vendors landing page.	Verbatim text
	Laboratory accreditation	Laboratory accreditation acronyms listed anywhere on vendor website.	Verbatim text
	Affiliate companies	Companies with products that integrate with or are a supplement to the genetic products apparently sold by the vendor.	Company name
	Endorsements	Does the vendor mention other organizations that use their products or service?	Yes/No
	Stated market size	The vendor reported market size or products offered.	Verbatim text
	Scientific advisory board	Did the vendor have a group of independent scientists that advise on the scientific and technical aspects of the vendors business?	Yes/No
	Vendor-authored white paper	Did the vendor publish an authoritative report that informs the reader of an issue within their industry and presents their philosophy on the issue at hand?	Yes/No
	Number of genetic testing products	Summation of the genetic testing products apparently sold by the vendor.	Number
Vendor policies	Privacy policy	Did the vendor have a statement disclosing the methods at which the vendor gathers, uses, discloses, and manages the employee user's data?	Yes/No
	Data sharing with employers verbatim	Text addressing the vendors policies on sharing employee user's data with employers.	Verbatim text
	Data sharing with employers (Y/N/na)	Evaluation of vendor policy language on the issue of sharing employee user data with employers to determine if data is (Yes) or is not (No) shared with employers. If the vendor policy language is vague the data is coded as not available (na).	Yes/No/Not available (na)
	Data sharing with 3rd-party (verbatim)	Text addressing the vendors policies on sharing the employee user's data with third parties.	Verbatim text
	Data sharing with 3rd-party (Y/N/na)	Evaluation of vendor policy language on the issue of sharing employee user data with third parties to determine if data is (Yes) or is not (No) shared with third parties. If the vendor policy language is vague, the data is coded as not available (na).	Yes/No/Not available (na)
	Data sharing with employee user PCP (verbatim)	Text addressing the vendors policies on sharing the employee user's data with the employee users primary care physician.	Verbatim text
	Data sharing with employee user PCP (Y/N/na)	Evaluation of vendor policy language on the issue of sharing employee user data with the employee users primary care physician (PCP) to determine if data is (Yes) or is not (No) shared with the PCP. If the vendor policy language is vague, the data is coded as not available (na).	Yes/No/Not available (na)
	HIPAA mentioned	Did the vendor mention the Health Insurance Portability and Accountability Act (HIPAA) on their website?	Yes/No
	GINA mentioned	Did the vendor mention the Genetic Information Nondiscrimination Act (GINA) on their website?	Yes/No

Category	Variable	Definition	Data structure
	Terms and Conditions	Did the vendor have a statement disclosing the rights and responsibilities of any individual using the site?	Yes/No
	Jurisdictional areas excluded	Identifies the physical locations that each vendor cannot conduct business.	Physical location
	Law enforcement coordination	Did the vendor mention that they would use and/or disclose personal health information in order to comply with federal, state or local law enforcement or public health activities?	Yes/No
	Governing law provision	The location in which rules and laws will govern in the event of a legal issue.	Physical location
	Scientific peer-reviewed articles cited	Did the vendor cite scientific peer reviewed articles about corporate wellness programs or the genetic test?	Yes/No
	Stated limitations	Text addressing risks associated with the use of the website or products. No text addressing limitations were listed as "na."	Verbatim text
	Stated risks	Text addressing limitations associated with the use of the website or products. No text addressing risks were listed as "na."	Verbatim text
Vendor marketing points of emphasis	Employee participation	Did the vendors mention phrases such as "increased participation in wellness program" on their corporate wellness page?	Yes/No
	Employee morale improvement	Did vendors mention phrases such as "stress levels," "emotional health," and/or "happiness" on their corporate wellness page?	Yes/No
	Employee talent retention	Did vendors mention phrases such as "keep top talent" and "company loyalty" on their corporate wellness page?	Yes/No
	Employee job performance	Did the vendors mention phrases such as "employee productivity" on their corporate wellness page?	Yes/No
	Disease prevention	Did vendors mention phrases such as "disease prevention" on their corporate wellness page?	Yes/No
	Employee behavior change	Did vendors mention phrases such as "employees exercise regularly" and "employees make healthier diet choices"on their corporate wellness page?	Yes/No
	Employee health outcomes	Did vendors mention phrases such as mention phrases "improve overall health" and "improved medical outcomes" on their corporate wellness page?	Yes/No
	Employer financial outcomes	Did vendors mention phrases such as "positive return on investment," "reduce healthcare costs" and "improved bottom-line" on their corporate wellness page?	Yes/No
	Benefit of corporate wellness program	Text of the business case for employers to purchase the corporate wellness program.	Verbatim text
Genetic testing product characteristics	Product name	Name of the genetic test advertised or appearing to be sold on the vendor website.	Verbatim text
	DNA collection method	Method at which user's DNA is collected for each test: Saliva (1), Cheek swab (2), Blood draw (3), Variable (4), Inquiry required (na).	1,2,3,4, na
	Individual ordering test	The individual that is able to order the genetic test from the vendor: Employee user (1), Employee User PCP (2), or medical professional affiliated with vendor (3), Inquiry required (na).	1,2,3, na
	Individual collecting the DNA	The individual that is able to collect the DNA that will be tested: Employee user (1), Employee Users PCP (2), or health professional affiliated with vendor (3), Inquiry required (na).	1,2,3, na
	Insight	Categories that define each genetic test: Ancestry & Familial (1), Traits & Conditions (2), Nutrigenetics (3), Fitness (4), Pharmacogenomics (5), Pathogenic Variants (6).	1,2,3,4,5,6,

Category	Variable	Definition	Data structure
	Number of traits tested	The number of specific characteristics within an individual that will be evaluated in a given genetic test, if this information is not available, the data is coded as "na."	Number
	Number of variants tested	The number of genetic variations from the reference genome that will be evaluated in an individual's unique DNA sequence. If the information is not available, the data is coded as "na."	Number
	Number of genes	The number of genes that will be evaluated in a given genetic test. If the information is not available, the data is coded as "na."	Number
	Health conditions evaluated	The specific health conditions mentioned on the product page that the genetic test will detect. If no health condition is applicable for the genetic test in question, the data is coded as "none," if the information on the specific health condition is not available, the data is coded as "na."	Verbatim text
	Results delivery	The methods at which results from each genetic testing product are delivered to the user: paper report (1), mobile app (2), website interface (3), one-on-one consultation (4), email (5), and Inquiry required (na).	1,2,3,4,5, na
	Counseling	The method at which the user receives a consult with a learned health or genetic professional to discuss the results of the genetic test: Genetic counselor (1), Health coach/dietitian (2), pharmacogenomics consultant (3), Physician (4), no consultation (none), and inquiry required (na).	1,2,3,4, none, na
	Stated benefits of the test	Text addressing the benefits of the genetic test in question.	Verbatim text
	Stated limitations of the test	Text addressing the limitation(s) of the genetic test in question. If no limitation is listed, the data is coded as "na."	Verbatim text
	Stated risks of the test	Text addressing the risk(s) of the genetic test in question. If no risk is listed, the data is coded as "na."	Verbatim text
	Listed price of the genetic test.	Price (USD) of the genetic test listed on the website. International currencies were converted to USD using the Google Finance Morningstar currency converter. Genetic tests without price information are listed as "na."	($)
	Type of data accessible to the end user	The type of genetic result that the individual providing the DNA will have access to be categorized as raw genetic data files (1), summary data (2), no data (3), or inquiry required (na).	1,2,3, na
	Product promoted as part of a wellness package	Evaluate the individual product page and corporate wellness page to determine of the product in question is clearly stated as part of the corporate wellness program.	Yes/No/na

Note: The data structure column identifies the type of data that was collected for each variable and the type of code that will be included in the raw table (see Table S2).

DTC prices (see Table S2). Data regarding all genetic tests that each vendor offers were collected to understand the full range of tests that had the potential to be part of the corporate wellness program. A subsequent check of the vendors' websites on 30 January 2020 revealed that, while many websites updated content, only three vendors updated their content to specify the genetic tests and services involved in their corporate wellness program (footnotes Table 3 and Table S2). The vendor websites were searched to identify their policies on sharing individual or aggregated identified or de-identified data with employers, third parties, and employee user's PCP; vague policy language was also identified and is defined as language used by the vendor that is inconclusive with regard to their policy on sharing employee user data with employers, third-parties, or employee user PCPs. Most of the vendors were vague about their stance on sharing employee data with employers (60%, n = 9), only two vendors (13%) explicitly stated that they would share employee data with employers and four vendors (27%) stated that employee data would not be shared with employers (Table 4). An example statement that employee data are shared with employers and third parties found on the Color website is "if your employer has provided or paid for (in whole or in part) the Test, you acknowledge and agree that your de-identified Results and [Personal and

Family Health Information] PFHI may be anonymized and/or aggregated and returned to your employer or its designee (e.g., plan administrator or pharmacy benefits manager) as a data analytics resource…We may disclose your [personally identifiable information] PII and PHI to others involved in your care, including healthcare providers…". The results

TABLE 3 Business-to-business corporate wellness vendors offering genetic tests as a component or the entirety of the corporate wellness program displays data about each business-to-business corporate wellness vendor, identified in the systematic google search, appearing to offer genetic test, and services in their corporate wellness program

Vendor name	URL	Foundation date	Headquarter city, state, country	Genetic test insight(s)	No. of genetic tests
AGS Health[a]	https://www.ags-health.com/corporate-wellness-genetic-testing-program	2012	Scottsdale, AZ, USA	Traits & Conditions Nutrigenetics Pharmacogenomics	4
ArcPoint Labs	https://www.arcpointlabs.com/	2005	Greenville, SC, USA	Ancestry & Familial Nutrigenetics Fitness	5
BDS Admin[b]	https://bdsadmin.com/employer/wellness-programs/	1993	Mechanicsburg, PA, USA	Nutrigenetics Fitness	1
Caligenix	https://www.caligenix.com/corporate-wellness	2015	Los Angeles, CA, USA	Traits & Conditions Nutrigenetics Fitness	3
Cambiati	https://www.cambiati.com/corporate-wellness-programs/	2009	Lafayette, CA, USA	Nutrigenetics	1
Color[c]	https://www.color.com/benefits-2	2015	Burlingame, CA, USA	Traits & Conditions Nutrigenetics Pharmacogenomics Pathogenic Variants	3
Dexafit	https://www.dexafit.com/how-it-works/corporate-wellness	2011	Dallas, TX, USA	Fitness	3
DNA Fit-Prenetics	https://www.dnafit.com/us/enterprise/	2013	Orpington, Kent, England, United Kingdom	Traits & Conditions Nutrigenetics Fitness Pathogenic Variants	4
Dynamic DNA Labs	https://dynamicdnalabs.com/pages/corporate-partners	2015	Springfield, MO, USA	Ancestry & Familial Traits & Conditions Nutrigenetics Fitness Pharmacogenomics	13
GenoMaxx Fitness	https://www.genomaxxfitness.com/corporate-wellness/	2016	San Diego, CA, USA	Traits & Conditions Nutrigenetics Fitness	3
Genome Medical[d]	https://www.genomemedical.com/employers/	2016	South San Francisco, CA, USA	Pathogenic Variants	3
GenoVive	https://www.genoviveusa.com/corporate-wellness-programs/	2008	New Orleans, LA, USA	Nutrigenetics Fitness	1
Pathway Genomics	https://www.pathway.com/corporate-wellness/	2009	San Diego, CA, USA	Traits & Conditions Nutrigenetics Fitness Pharmacogenomics	14
Precision Genetics	https://precisiongenetics.com/our-solutions/	2015	Greenville, SC, USA	Pharmacogenomics	1
Silverberry Genomix	https://silverberrygenomix.com/corporate-wellness-program/	2017	San Francisco, CA, USA	Traits & Conditions Nutrigenetics Fitness Pharmacogenomics Pathogenic Variants	12

The "genetic test insight(s)" column represents the six insight categories that each genetic test are defined by; (1) "nutrigenetics," (2) "fitness," (3) "traits & conditions," (4) "Pharmacogenomics," (5) "ancestry & familial," and (6) "pathogenic variants."

[a]The corporate wellness page was updated as of 19 January 2020 to include a product named "Health and Wellness" (see Table S2 [cell S41]).

[b]BDS Admin does not have a separate product page detailing the genetic test that is offered as part of their wellness program. The corporate wellness page does provide a brief description of the genetic test offered and from this description, the test was given the insight categories of a Nutrigenetics and fitness genetic test. See Table S2 [cell AM13] for the product description.

[c]Since completing the data collection for this study December 2019, the corporate wellness page was updated as of 14 January 2020 to include three products now listed on their corporate wellness page named "Cancer," "Heart," and "Medication" none of which were identified during data collection. See Table S2 [cell S80].

[d]This vendor did not appear to sell genetic tests but offered genetic counseling services direct to consumers and employers. In December 2019, the business model was to provide genetic counseling based on three services groups listed on their website (Proactive Genetic exploration, Advanced Genetic Care and Family Variant Insight Program). The descriptions on the website indicated the insight category to be pathogenic variant testing. See Table S2 [cell M38-M40] for descriptions of the three types of genetic services. The corporate wellness page was updated as of 19 January 2020 to include the names of the three genetic services (see Table S2 [cells S38:S40]).

TABLE 4 Data sharing policies of vendors of B2B corporate wellness programs represents the data sharing policies mentioned on each of the vendor websites.

	Data shared with employers			Data shared with 3rd-party			Data shared with employee user PCP			HIPAA mentioned	
	Explicit Yes	Explicit No	Vague language	Explicit Yes	Explicit No	Vague language	Explicit Yes	Explicit No	Vague language	Yes	No
% of vendors	13%	27%	60%	40%	27%	33%	27%	6.7%	66.7%	60%	40%
No. of vendors	2	4	9	6	4	5	4	1	10	9	6

Each page on the vendor website was searched to identify language that addressed policies on sharing individual or aggregated identified or de-identified employee data with employers, third parties, and employee primary care physicians. Each vendor webpage was also searched to identify if HIPAA is mentioned. The language used by vendors on each policy was placed into three categories (1) "explicit Yes" meaning the vendors language used clearly states that the employee data will be shared with employers, third-parties or employee PCP; (2) "explicit No" meaning the vendors language used clearly states that the employee data will not be shared with employers, third-parties or employee user PCPs; and (3) "vague language" means the language used by the vendor is inconclusive with regard to their policy on sharing employee user data with employers, third-parties, or employee user PCPs.

on vendor policies about sharing employee data with third parties show that six vendors (40%) explicitly stated that employee data will be shared, four (27%) explicitly stated that employee data would not be shared, and five (33%) vendors are vague about their policies on sharing employee data with third parties (Table 4). An example statement affirming employee user data will be shared with third parties found on the GenoMaxx website is "GenoMaxx Fitness™ may disclose your PHI to other companies or individuals who need your PHI in order to provide specific services to us. These other entities, known as "business associates" must comply with the terms of a contract designed to ensure that they will maintain the privacy and security of the PHI we provide to them or which they create on our behalf…". Most vendor policies on sharing employee data with the employee user's PCP are vague about this policy (66.7%, n = 10), although 27% (n = 4) explicitly stated they share employee data with the employee's PCP and 6.7% (n = 1) explicitly stated they do not share employee data with the employee user's PCP. An example policy, found on the Caligenix website, about sharing employee user data with the employee user's PCP is "Only your healthcare professional will be able to access your genetic test results through the Caligenix Portal… All genetic data is sent through a secure 256-bit encryption server…". The vendor websites were also searched to identify whether they mentioned HIPAA, and only nine vendors (60%) did so on any of their website's pages (Table 4).

The vendor websites were further examined to identify stated risks and limitations involved in activities such as using their website, ordering products, using products, sharing data, and understanding results. Less than half (46.7%, n = 7) of all vendors stated any limitations on their website. An example limitation found on GenoVive's website was "the information provided by GenoVive and contained in this website, including an individual's results of the GenoVive Nutrition and Fitness Genetic Test, is not intended to prevent, diagnose or treat any medical condition and should not replace the advice of a physician". Only six vendors (40%) mentioned risks on their website; an example risk found on the Pathway Genomics website was "despite the reasonable and appropriate efforts of you and Pathway, there is always some risk that an unauthorized third party will access without permission our systems or intercept transmissions of your information" (Table 5). Most limitation and risk statements were found on the vendor terms and conditions, privacy policy, or consent pages (data not shown).

The marketing points of emphasis on each vendor corporate wellness page was searched to identify trends in the advertised benefits of corporate wellness program with genetic testing. The majority (86.67%, n = 13) of vendors mentioned

TABLE 5 Variability in risks and limitations mentioned on vendor websites displays examples of risks and limitations listed on the vendor website.

Vendor name	Example of limitation	URL to limitation	Example of risk	URL to risk
AGS Health	"Newborn screening is another problem that arises with EHRs (Electronic Health Records)—and genetic data. Tests done at birth vary from state to state, but all states must screen for at least 21 disorders by law, and some states test for 30 or more. Currently, tests are limited to conditions for which childhood medical intervention is possible and may be beneficial."	https://www.ags-health.com/privacy-statement-2017	na	na
ArcPoint Labs	"The contents of our website, including any risk estimates or other reports generated by the services (collectively, "Your Report") and any other information, data, analyses, editorial content, images, audio and video clips, hyperlinks and references (collectively, "Content"), are for informational purposes only and are not intended to substitute for professional medical advice, diagnosis, or treatment nor are they intended to be interpreted as a recommendation for a particular treatment plan."	https://www.arcpointlabs.com/home-kits/terms-conditions/	na	na
BDS Admin	na	na	na	na
Caligenix	na	na	na	na
Cambiati	na	na	na	na
Color	"Limitations of the test: … However, this test may not detect every variant associated with disease risk, or every variant or allele that may impact how a person processes or responds to medications… Color implements several safeguards to avoid technical errors, but as with all medical tests, there is a chance of a false positive or a false negative result…. In addition, if you have certain rare biological conditions or have had certain bone marrow, kidney, liver or heart transplants, transfusions, or hematologic malignancies, these conditions may limit the accuracy or relevance of the results or prevent the Test from being completed."	https://www.color.com/informed-consent	"The Test is a genetic test that may cause you to discover sensitive information about your health or disease risks, including risk for hereditary disorders other than the one for which you are testing, or for disorders that currently have no treatment. The US Genetic Information Nondiscrimination Act of 2008 (GINA) prohibits discrimination on the basis of genetic information with respect to health insurance and employment. However, certain exceptions apply, and we encourage you to review GINA and related laws and regulations. There are currently no US federal laws that prohibit discrimination in life insurance, disability insurance or long-term care insurance, which may be governed by state law. If you live outside of the US, depending on your country of residence, there may be significant differences in the laws and regulations governing the use and disclosure of genetic information…",	https://www.color.com/informed-consent

Vendor name	Example of limitation	URL to limitation	Example of risk	URL to risk
Dexafit	"DexaFit Disclaimer DexaFit technicians do not provide diagnosis or treatment at DexaFit facilities. They only answer basic questions based on the data from your testing, then suggest you follow up with your referring physician or one of DexaFit's licensed medical practitioners for further interpretation and consultations."	https://www.dexafit.com/plans-and-pricing-1	na	na
DNA Fit-Prenetics	na	na	"Sharing Self-Reported Information through surveys, or other features on Our Site, is voluntary and done at your sole risk. DNAfit cannot take responsibility for Information that you release or that you request us to release publicly."	https://www.dnafit.com/us/legals/privacy.asp
DynamicDNA Labs	na	na	"We are not responsible if information made available on this site is not accurate, complete or current. The material on this site is provided for general information only and should not be relied upon or used as the sole basis for making decisions without consulting primary, more accurate, more complete or more timely sources of information. Any reliance on the material on this site is at your own risk….Any use by you of optional tools offered through the site is entirely at your own risk and discretion and you should ensure that you are familiar with and approve of the terms on which tools are provided by the relevant third-party provider(s)."	https://dynamicdnalabs.com/pages/legal
GenoMaxx Fitness	"4.2) Genetic research is not comprehensive…4.3) The laboratory may not be able to process your sample… 4.4) The laboratory process may result in errors… 4.5) We may not be able to present you with a full complement of results. In rare cases, despite our best efforts, it may not be possible to obtain an unambiguous result for some DNA variations (SNPs) due to biological or technical complications. This means that a result cannot be called clearly… 4.8) The GenoMaxx Fitness™ product range is intended for informational and educational use only and is not intended to be used for medical advice or diagnosis or treatment."	https://www.genomaxxfitness.com/terms-and-conditions/	"4.6) Your Personal Information may be anonymised and used for research and development (R&D) purposes to contribute knowledge to the field and further improve our Products…4.7) Genetic Data you share with others could have social, legal or economic implications. Use of genetic test results by employers in pre-employment medical checks is restricted in the UK by the Equality Act 2010, and in the US by the 2008 Genetic Information Nondiscrimination Act (GINA), which makes genetic discrimination illegal and addresses discrimination in health insurance and employment practices. However, as of yet, this protection does not explicitly cover life or disability insurance providers as these products are considered as more discretionary than health insurance."	https://www.genomaxxfitness.com/terms-and-conditions/

Vendor name	Example of limitation	URL to limitation	Example of risk	URL to risk
Genome Medical	na	na	na	na
GenoVive	"The information provided by GenoVive and contained in this website, including an individual's results of the GenoVive Nutrition and Fitness Genetic Test, is not intended to prevent, diagnose or treat any medical condition and should not replace the advice of a physician."	https://www.genoviveusa.com/1126-2/	na	na
Pathway Genomics	na	na	"Despite the reasonable and appropriate efforts of you and Pathway, there is always some risk that an unauthorized third party will access without permission our systems or intercept transmissions of your information."	https://www.pathway.com/privacy-statement/
Precision Genetics	na	na	Na	na
Silverberry Genomix	"Silverberry Statement of Limitations…DNA-based predisposition is NOT a diagnosis of a disease or condition. Predisposition risk or likelihood is a statistical measure based on the latest advances in genomics science and is provided as an additional layer of information for wellness decision-making. Silverberry recommendations fall within established non-medical guidelines for wellbeing and do not constitute medical advice. Consult with your Physician before making any major changes to your wellness or health choices."	https://silverberrygenomix.com/our-science/	"Potential Issues and Risks Keep in mind that the results may change how you feel, and there is a chance that some questions will make you uncomfortable. You can choose to not answer…Depending on the package you select, your results can reflect your health risks, fitness potentials, or predisposed personality traits. These could lead to many different emotions. We recommend that you discuss your results with a physician or other certified healthcare professionals before making any major changes to your routines.	https://silverberrygenomix.com/consent
Percent with stated limitations or risks	46.7%	–	40%	–
Number of vendors	7	–	6	–

Note: The columns titled "example of limitation" and "example of risks" contains verbatim text from the vendor website containing vendor disclosed risks and limitations. The column titled "URL to limitation" and "URL to risks" contains the web address where the example limitation or risk statement was first identified. The "na" indicates that the data is not available.

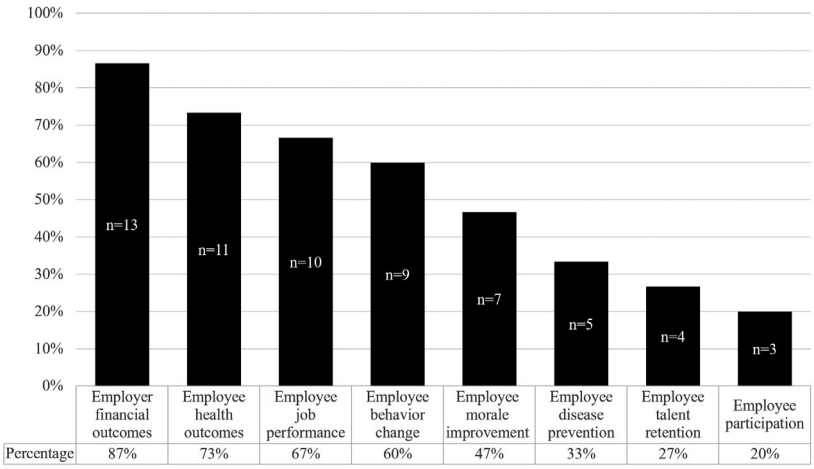

FIGURE 2 Vendor marketing points of emphasis represents the marketing emphasis made on each of the vendors corporate wellness webpage. The "employer financial outcomes" bar represents the percentage of vendors that mentioned phrases such as "positive return on investment," "reduce healthcare costs," and "improved bottom-line" on their corporate wellness page. The "employee health outcomes" bar represents the percentage of vendors that mentioned phrases alluding to overall health improvement for employees on the corporate wellness page such as "improve overall health" and "improved medical outcomes. The "employee job performance" bar represents the percentage of vendors that mentioned phrases like "improve employee productivity" on their corporate wellness page. The "employee behavior change" bar represents the percentage of vendors that stated phrases such as "employees exercise regularly" and "employees make healthier diet choices." The "employee morale improvement" bar represents the percentage of vendors that alluded to changes in employee "stress levels," "emotional health," and "happiness" on their corporate wellness page. The "employee disease prevention" bar represents the percentage of vendors that alluded to their corporate wellness programs ability to "prevent disease," to "identify high-risk patients," or to "decrease rates of illnesses" on their corporate wellness page. The "employee talent retention" bar represents the percentage of vendors that mentioned phrases such as "keep top talent" and "company loyalty" on their corporate wellness page. The "employee participation" bar represents the percentage of vendors that mentioned phrases such as "increased participation in wellness program" on the corporate wellness page. The values (n = x) within each bar represent the number of vendors that made each marketing point on their corporate wellness page. All the categories were coded independently; the percentages are calculated as the number of vendors that mention each marketing point (n = x)/total number of vendors identified (n = 15) × 100.

employer financial outcomes as a benefit to purchasing their corporate wellness program. Employee health outcomes, employee job performance, and employee behavior change were frequently referenced by vendors (73.33% (n = 11), 66.67% (n = 10), and 60% (n = 9), respectively) as benefits to purchasing their corporate wellness program. Vendors also promoted their corporate wellness programs' ability to improve employee morale (46.67%, n = 7), prevent disease among employees (33.33%, n = 5), and to retain employee talent (26.67%, n = 4). The least number of vendors (20%, n = 3) mentioned employee participation in the corporate wellness program as a reason for employers to purchase their corporate wellness program (Figure 2).

To determine the types of genetic tests that appear to be sold in the corporate wellness market, all genetic tests on the vendor websites were categorized by six insights: Nutrigenetics, fitness, traits & conditions, Pharmacogenomics, ancestry & familial, and pathogenic variant testing. A total of 71 genetic tests were identified across the 15 BTB corporate wellness vendors. Nutrigenetic testing category that identifies genetic variants associated with an individual's differential responses to nutrition represented 28% (n = 20) of all genetic tests on the vendors websites and fitness genetic tests that identifies genetic variants in genes associated with body weight, differential responses to exercise, and variants associated with muscle mass and recovery also represented 28% (n = 20) of genetic tests on the vendors websites (Figure 3). The traits & conditions tests which identifies genetic variants implicated in an individual's skin health, personality, food aversions, and allergies represented 24% (n = 17) of all genetic tests on the vendors websites. Pharmacogenomic tests which identifies an individual's differential responses to pharmaceutical drugs and drug doses represented 21% (n = 15) of tests that appear to be sold by corporate wellness vendors. Pathogenic variant testing that detects genetic variants associated with the predisposition to inherited or sporadic diseases such as cancers (i.e., uterine, breast, ovarian, melanoma, pancreatic, stomach, and prostate), inherited heart disease (i.e., cardiomyopathy, arrhythmia, arteriopathy, and familial hypercholesterolemia), the American College of Obstetricians and Gynecologists (ACOG) recommended conditions (i.e., sickle cell disease, cystic fibrosis, and beta-thalassemia), and the Ashkenazi Jewish conditions (i.e., Bloom syndrome, mucolipidosis IV, and factor XI deficiency) represented 15.5% (n = 11) of all genetic tests that appeared to be sold on the corporate wellness vendors websites. The ancestry & familial tests that

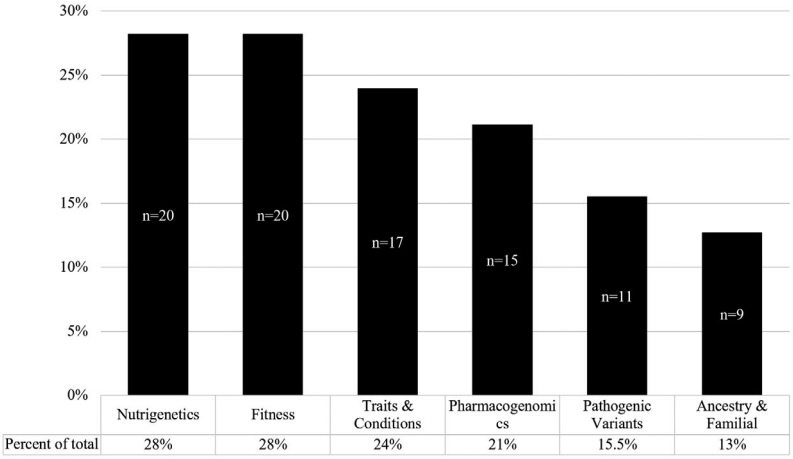

FIGURE 3 Variability in the type of genetic tests offered by vendors who also offer B2B corporate wellness programs illustrates the percentage of each type of genetic test across the vendors identified within the BTB corporate wellness market. A total of 71 genetic tests for all 15 vendors were identified. There are six insight categories: Nutrigenetics, fitness, traits & conditions, Pharmacogenomics, ancestry & familial, and pathogenic variants were determined. The values (n = x) within each bar represent the number of genetic testing products identified for each insight category. The percent of total row below the bar graph is calculated from n = x/the total number of tests identified in the market (n = 71) × 100.

(a)

	Vendors	Health or Genetic consultation (Yes/No)
1	AGS Health	Y
2	ArcPoint Labs	N
3	BDS Admin	N
4	Caligenix	Y
5	Cambiati	Y
6	Color	Y
7	Dexafit	N
8	DNA Fit-Prenetics	Y
9	DynamicDNA Labs	Y
10	GenoMaxx Fitness	N
11	Genome Medical	Y
12	GenoVive	N
13	Pathway Genomics	Y
14	Precision Genetics	N
15	Silverberry Genomix	N
	% of vendors providing professional health/ genetic consultations.	**53 %**

(b)

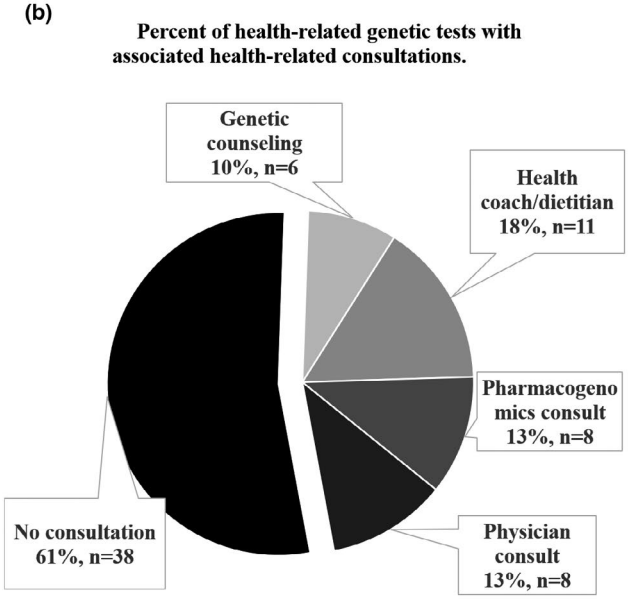

FIGURE 4 Posttesting health and genetic consultations among vendors of B2B corporate wellness programs and their health-related genetic testing products. (A) displays the relative percentage of all vendors that provide consultations with their genetic tests. The percentage of vendors providing professional health or genetic testing consultation was calculated from the total count of "Y" (n = 8)/total number of vendors identified (n = 15) × 100. (B) pie chart shows the percentage of all health-related genetic testing products (n = 62) offered by BTB corporate wellness vendors that contained posttesting health or genetic consultation with a learned professional as a part of the product. The "pharmacogenomics consult" category represents the percentage of products that offered a consult with a health professional to discuss drug sensitivities and medication changes, and the "no consultation" category represents the number of products that did not mention any consultation with a health or genetic professional. The percentage values accompanying each category is calculated from the total number of tests for each category/the total number of health-related genetic tests identified (62) *100. Data for each category of consultation were gathered independently.

detects familial relationships represented 13% (n = 9) of all genetic test offered among the BTB corporate wellness vendors (Figure 3).

The product page for each genetic test was evaluated to determine if a consultation with a physician, medical geneticist, genetic counselor, or health coach was available for individuals to discuss their test results and any recommended changes to their diet, exercise, medications, or health care. AGS Health, Caligenix, Cambiati, Color, DNA Fit, Dynamic DNA Labs, Genome Medical, and Pathway Genomics were

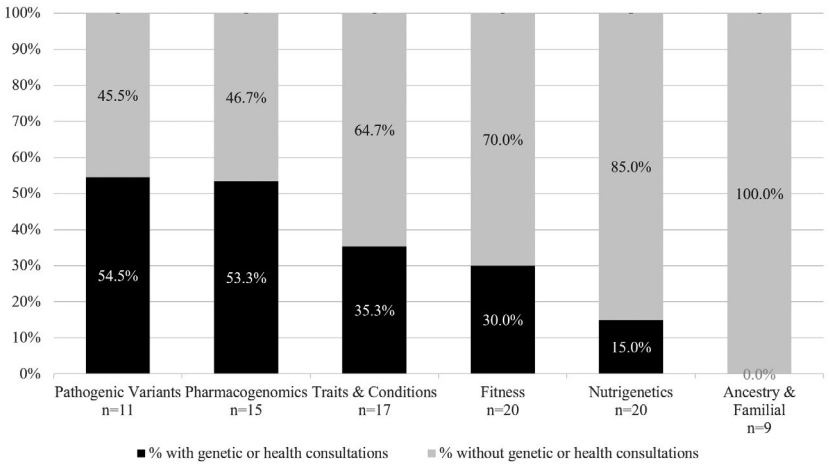

FIGURE 5 Variability in posttesting health and genetic consultations offered by type of genetic test. The percentage of insights providing consultations with a learned professional was calculated independently for each insight. For example, if a single genetic test provides both Fitness and Nutrigenetics insight and offers a genetic or health consult a percentage point is added to both the Fitness and Nutrigenetics insights in the row titled "percent with genetic or health consultations." N = x is total number of tests in each category. Each category was coded independently.

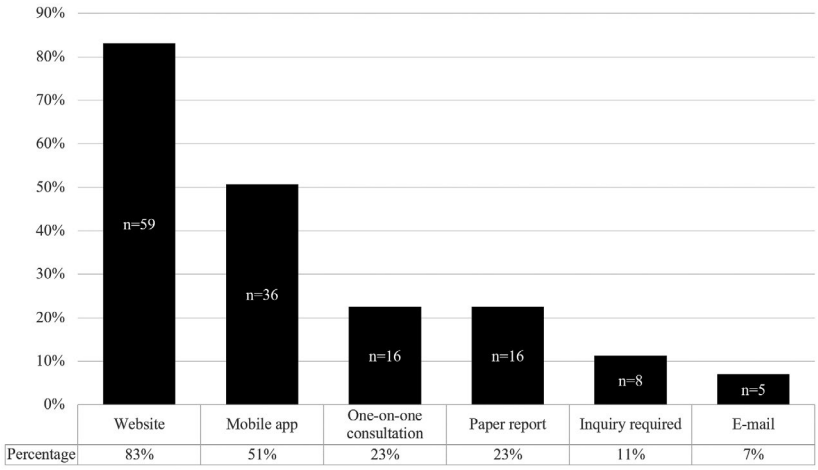

FIGURE 6 Variability in how genetic results are reported by vendors of B2B corporate wellness programs represents the method at which the genetic test results are reported to the user (either a consumer if as part of a DTC service or an employee or participating dependent if the test is provided as part of a corporate wellness program). All genetic tests (n = 71) offered by the BTB corporate wellness vendors were assessed to determine the method at which the user would receive their results. Five reporting categories were identified. The "paper report" category represents the percentage of all products that had the ability to mail results to the user and that mentioned the words "paper report" within the description. The "inquiry-required" category represents the percentage of products that had no information about results reporting within their product description. The values (n = x) within each bar represent the number of genetic testing products identified for each reporting method. The percentages were calculated using n = x/total genetic testing products identified (n = 71) × 100.

the only 8 vendors (53%) out of the 15 vendors identified that included health or genetic consultations as part of any genetic test or genetic service offered on their websites (Figure 4a). To identify health-related genetic testing products that include consultations, we excluded ancestry and familial testing from the analysis because we do not expect consultation to be offered with these tests; therefore, the denominator was reduced from 71 total tests to 62 health-related tests. Notably, 61% (n = 38) of all 62 health-related genetic tests in the BTB corporate wellness market did not offer any associated health-related consultation (Figure 4b). A consult with a health coach was included in 18% (n = 11) of the 62 tests, a pharmacogenomics consult was included in only 13% (n = 8) of the 62 tests, and a consultation with a physician was included in 13% (n = 8) of the 62 tests offered among the BTB corporate wellness vendors identified. Finally, products that offered genetic counseling represented only 10% (n = 6) of the 62 health-related genetic tests in the BTB corporate wellness market (Figure 4b). A total of 11 pathogenic variant tests were identified, and only 54.5% (n = 6) offered health or

genetic consultations. Fifteen pharmacogenomics tests were identified, and only 53% (n = 8) offered posttesting health consultations (Figure 5). The traits & conditions, fitness, and Nutrigenetics test insight categories have a total of 17, 20 and 20 tests identified, respectively; however, only 35% (n = 6), 30% (n = 6), and 15% (n = 3), respectively, offered health and genetic consultations. As expected, none of the nine (9) tests in the ancestry & familial insight category offered health or genetic consultations (Figure 5).

The product page for each genetic test was evaluated to determine the method by which individuals received their genetic test results. Five categories of result reporting were identified among all 71 products apparently sold by the BTB corporate wellness vendors: (a) genetic results accessible through the vendor website or a third-party website contracted with the vendors; (b) genetic test results available through a mobile device like a phone or tablet; (c) genetic results available through a one-on-one consultation with a health professional; (d) genetic results available to print; or (e) genetic results available through email (Table 2). Products that are not clear about the method at which results are reported are indicated as "inquiry required." Most of the product pages mention results are reported through a website 83% (n = 59) or through a mobile app 51% (n = 36). Select products delivered results through a one-on-one consultation 22.5% (n = 16), a paper report 22.5% (n = 16), and/or e-mail 7% (n = 5). Many of the product pages (11%, n = 8) were not clear about the method at which results were reported to the individual (Figure 6).

4 | DISCUSSION

The RAND Corporation identified five attributes for successful corporate wellness programs: (a) develop effective communication strategies about the wellness program to employees, (b) provide opportunities for employees to engage in the wellness program, (c) engage leadership and promote a culture of wellness, (d) use existing resources, and (e) continue to evaluate and improve the wellness program (Mattke, 2013). These five attributes were not readily apparent from the websites of the 15 BTB corporate wellness vendors appearing to incorporate genetic testing into their wellness program that we systematically identified. While broad generalizations should be avoided (as what these vendors are doing could be distinct from what their online information suggests) and while further research is needed to understand vendor and employer behavior when initiating an employer-sponsored wellness program involving genetic testing and services, a few observations are appropriate.

Effective communication and outreach strategies in the form of genetic and health counseling is apparent among only 53% of corporate wellness vendors analyzed. Learned professionals are needed to communicate the limitations and risks of specific genetic tests and the implications of any identified pathogenic variants. It is a noteworthy gap that some vendors do not offer the critical benefit of health and genetic counseling to employee-participants.

Most wellness vendors identified in the systematic search allow for the individuals to provide DNA samples at home which is a significant convenience compared with a mandatory doctor's visit. A major accessibility concern emergent from our observations was that individuals' access to genetic test results was biased toward users of website and mobile applications, leaving few opportunities for individuals with no access to or limited proficiencies with computers or advanced mobile technologies to participate fully in the program. Known age, race, and economic disparities in the distribution of technologies and information is especially concerning when it comes to genetic information because of the potentially life-changing impact of a pathogenic variant and a pharmacogenomic result. Further efforts are needed to understand and close the "digital divide" and its impacts on uptake of genetic testing services.

Understanding GINA and HIPAA compliance is important for corporate decision-making when selecting vendors for wellness programs. Corporate leadership might be inclined to implement wellness programs with genetic testing into their organization's benefits package if wellness program vendors were transparent about their efforts to ensure compliance with GINA and HIPAA. Given the regulatory uncertainty surrounding, the use of financial incentives for employer-sponsored wellness programs involving genetics and the continued confusion and limited awareness regarding what employer obligations under GINA and related state laws are in this area, it is incumbent on vendors of corporate wellness programs involving genetics to be aware and able to guide their prospective business customers. Our review of online information provided by vendors revealed very few even mentioning HIPAA and GINA among their online materials, which is a potential red flag that the legal and policy issues are not given adequate attention. Furthermore, in the vendor-stated risks and limitations of the corporate wellness program, standard disclaimer language was used to absolve vendors from both regulatory oversight and liability. Best practices for this industry should include, at a minimum, disclosures by the vendors detailing how their program aligns with GINA and relevant state laws protecting employee privacy and nondiscrimination rights. Transparency regarding what (if any) data access is provided by the vendors to employers and what (if any) data sharing with third parties is occurring are particularly important details given a variety of intertwined legal requirements (e.g., GINA's mandate that employers not have access to anything more than aggregated, de-identified information; the ADA's prohibition against

employers compelling employees to agree to data transfers to third parties; but HIPAA's allowance for data sharing with "business associates") and growing public discontent over data privacy and governance.

Well-established corporate wellness program vendors, such as Wellness Corporate Solutions, Virgin Pulse, and Provant Health Solutions (Aditi, 2019) were not among those vendors identified as offering genetic testing services, highlighting genetic testing in wellness as a niche business proposition. That mainstream wellness programs have yet to incorporate genetic testing could be due to several factors, including but not limited to the lack of empirical evidence of positive return on investment and the actual or perceived regulatory constraints. Vendors did not report their own programmatic successes or provide evidence to substantiate their claims that genetic testing in corporate wellness improves health or reduces health-care costs. The omission of this information further frustrates attempts by employee-rights advocates to evaluate whether vendors are offering products and services that are adequately supported by scientific evidence, or alternatively, offering nothing more than a test with unproven benefits and the potential for clinical harms. If the observed trends persist, those vendors eager to push genetic testing in corporate wellness may undermine broader efforts to promote evidence-based, medically actionable genetic testing for unselected individuals in the U.S. workforce.

Another profoundly troubling finding is that at the time data collection was completed (9 December 2019), none of the vendors described the details of the genetic tests and services offered *specifically* as part of their corporate wellness program. All understanding about options available to employers is entirely speculative because the vendors' DTC offerings might or might not align with the BTB wellness program offerings. As of 30 January 2020, only 3 of the 15 vendor websites have specified the genetic tests that are offered in their corporate wellness program. Although a small number with substantial room for improvement, this indicates a positive shift toward improved transparency among corporate wellness program vendors. Further research is needed to understand vendor and employer behavior when initiating and participating in an employer-sponsored wellness program involving genetic testing and services.

As scholars such as Anya Prince (Prince, 2015) have rightly noted, the provision of genetic information is not itself prevention but is dependent upon subsequent actions based on that information that are themselves influenced by contextual conditions (such as financial opportunity). If genetic testing and services are to offer opportunities for wellness programs to demonstrate effectiveness in improved health and well-being for participants and reduced health care costs, we must encourage vendors of employer-sponsored wellness programs to consistently contribute standardized performance data so that we can collectively evaluate if genetic testing in corporate wellness adds value or if, as scholars have already commented (Manolio et al., 2019, at 80) "[i]t is time…to rethink [this] enthusiasm for the wellness movement."

ACKNOWLEDGMENTS

This research was funded by the National Human Genome Research Institute (NHGRI) Award No. R01HG009694-03S1 to Vanderbilt University (as prime) and Geisinger Clinic as a subaward. The content of this article is solely the authors' responsibility and might not represent the views of the authors' funding sources, employers, or any other person or entity. The protocol for this research was submitted to the Geisinger Institutional Review Board and determined not to be human subjects research (IRB #2019-1117) on November 26, 2019.

CONFLICT OF INTERESTS

This research was funded by the National Human Genome Research Institute (NHGRI) Award No. R01HG009694-03S1. Dr. Peterson is a consultant for Color Genomics (http://www.color.com). The authors declare no other potential conflicts of interest with the information presented in this manuscript and specifically declare no interests with any of the vendors identified in this manuscript.

AUTHORS' CONTRIBUTION

W.M. conceived the idea, W.M., J.W., M.W., and P.D. developed and designed the study methodology, W.M collected, and analyzed the data, W.M., J.W., M.W., and P.D. interpreted the data., W.M and J.W drafted the manuscript, W.M, J.W., P.D., M.W., L.W., and J.P. provided editorial assistance and approved the final version of the manuscript.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

How to cite this article: McDonald WS, Wagner JK, Deverka PA, Woods LA, Peterson JF, Williams MS. Genetic testing and employer-sponsored wellness programs: An overview of current vendors, products, and practices. *Mol Genet Genomic Med*. 2020;8:e1414. https://doi.org/10.1002/mgg3.1414