Awareness and use of direct-to-consumer nutrigenomic tests, United States, 2006

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Purpose: Direct-to-consumer genetic tests are increasingly available and may improve confidentiality, convenience, and accessibility. Amid ethical concerns and an uncertain regulatory landscape, the future of this mode of delivery is unclear. One class of products, nutrigenomic tests, is used to analyze DNA and lifestyle habits to assess health risks. Little information is available regarding awareness or use of such tests among consumers or physicians. **Methods:** We assessed consumers' awareness and use of nutrigenomic tests in the 2006 HealthStyles national survey (5250 respondents) and awareness among physicians in the 2006 DocStyles national survey (1250 respondents). **Results:** In the HealthStyles survey, 14% of respondents were aware of nutrigenomic tests, and 0.6% overall had used these tests. Respondents who were aware of nutrigenomic tests tended to be young and educated with a high income. Many physicians (44%) were aware of nutrigenomic tests, although 41% of these physicians had never had a patient ask about such tests, and most (74%) had never discussed the results of a nutrigenomic test with a patient. **Conclusions:** These results provide insight into current trends in public demand and interest in nutrigenomic tests and will aid in assessing the impact of policies, efforts at public or provider education, and the evolution of the availability and demand for such tests. ***Genet Med*** **2007:9(8):510–517.**

Key Words: *HealthStyles survey, DocStyles survey, at-home, genetic tests, nutrigenomic*

Growing numbers of genetic testing products and services are being offered as direct-to-consumers (DTC) genetic tests over the Internet, in supermarkets, and elsewhere, providing individuals with the option of receiving a genetic test result without consulting a health care provider.[1,2] The purported advantages of this mode of delivery are to increase the availability, privacy, and convenience of genetic testing and to assist the public in realizing the benefits of publicly funded research, including the Human Genome Project and related efforts. Importantly, some genetic testing products are advertised but not sold DTC and are not the focus of this article because direct advertising does not include all the same purported advantages and disadvantages of DTC sale of genetic tests.

Genetic tests that can be ordered directly by consumers without the involvement of a health care provider have a variety of intended uses, including paternity testing, tests intended to reveal information on genealogy or ancestry, and health-related tests. This latter category increasingly includes tests previously ordered only by health care providers in clinical practice settings, such as testing for cystic fibrosis carriers or testing for hereditary hemochromatosis in individuals at risk based on symptoms or family history. One type of health-related genetic test that has received both scientific and media attention is nutrigenomic testing, generally involving genetic testing for multiple genes associated with more common disorders, such as heart disease, diabetes, or osteoporosis. In this case, results of the genetic testing are used, along with information provided by the tested individual on diet and lifestyle habits (e.g., smoking status, exercise) to assess potential health risks. Limited regulations or guidelines direct the type of pre- or posttest counseling that is provided, the credentials of the person who provides the counseling, and the accreditations and certifications of the laboratory that performs the genetic test; thus, companies offering DTC genetic tests are inconsistent in their practices in these areas. Furthermore, there is the potential for significant harm if consumers are interpreting test results and taking action based on health-related genetic tests without medical advice or counseling.

Amid ethical concerns[3–5] and an uncertain regulatory landscape, the future of this mode of delivery for genetic testing is

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The findings and conclusions in this report are those of the author(s) and do not necessarily represent the views of the funding agency.

Disclosure: The authors declare no conflict of interest.

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A supplementary Appendix is available via the ArticlePlus feature at www.geneticsinmedicine.org. Please go to the August issue and click on the ArticlePlus link posted with the article in the Table of Contents to view this material.

Submitted for publication March 9, 2007.

Accepted for publication May 15, 2007.

DOI: 10.1097/GIM.0b013e31812e6ac3

unclear. Critics of DTC genetic tests have compared the tests with "modern day snake oil"[6] that provides consumers with little or no real health-related information. Up to this point, there has been little regulation of genetic tests in the United States, including those sold DTC. Although laboratories that provide testing on human specimens must be certified under the Clinical Laboratory Improvement Amendments (CLIA),[7] which provide regulatory guidance to laboratories on issues such as quality control and assurance, and personnel qualifications, no specialty area for molecular or biochemical genetic tests has been created under CLIA. The U.S. Food and Drug Administration has recently issued two guidance documents[8,9] that may lead to additional regulation of genetic tests in the future. In the meantime, a recent fact sheet released jointly by the U.S. Food and Drug Administration, the Federal Trade Commission, and the Centers for Disease Control and Prevention (CDC)[10] perhaps provides the most revealing summary of the current situation, that of "buyer beware." Other issues that must be clarified are privacy concerns regarding disposal of the sample provided for analysis or the genetic information generated from the test and the potential for this mode of delivery to increase health disparities.

A recent report by the Government Accountability Office[11] highlighted a few of the concerns with four examples of DTC nutrigenomic tests (hereafter referred to as DTCngts). The Government Accountability Office report raised concerns that the tests may mislead consumers by making unsound and ambiguous predictions about health risks. In addition, the test results frequently include recommendations for the consumer to purchase dietary supplements that may be significantly overpriced compared with similar products available through a supermarket or pharmacy and that may, in fact, be harmful for some individuals. Although the recommendations are intended to be "tailored" to the individual based on his or her unique genomic profile, the examples given in the report appear to indicate little or no influence of the genetic test result in determining the recommendations compared with the lifestyle information. Finally, although many manufacturers recommend that consumers discuss the test results with their physicians, it is uncertain how frequently consumers follow this advice.

Critical information is lacking regarding an important stakeholder—the consumer—in the ongoing policy debate surrounding these tests. Until now, no baseline information has been available regarding public awareness, interest in, or use of DTCngts. Likewise, information is scarce on health care providers' knowledge, attitudes, and experiences with DTCngts. This information will provide insight into the public demand for such tests and the potential for harm and, as additional information is collected over time, will provide a historical reference of trends in awareness and use. In addition, baseline information can be tracked longitudinally to assess the impact of policies, efforts at public and provider education, and the evolution of the availability and demand for such tests.

To inform this debate, we present data from two national surveys conducted in 2006 to assess U.S. consumers' awareness and use of DTCngts (HealthStyles) and to assess knowledge of and experiences with these tests among U.S. physicians (DocStyles).

MATERIALS AND METHODS

Study design

Sampling and data collection for the 2006 HealthStyles survey were conducted by Synovate, Inc. as part of a marketing survey. A total of 20,000 potential respondents were selected through stratified random sampling to create a nationally representative sample from a consumer mail panel of approximately 450,000 potential respondents. A total of 13,260 people completed the initial recruitment survey. The incentive was entry into a sweepstakes, and the response rate was 66%. HealthStyles surveys were sent to 6600 of the households that returned the initial survey, and 5250 participants responded to the HealthStyles survey, for a response rate of 80%.

For the DocStyles Web-based survey of primary care physicians and pediatricians, respondents were drawn from the Epocrates Honors Panel, an opt-in, verified panel of 142,000 physicians. A random sample of 2382 eligible physicians were invited to participate in the survey; this sample was drawn to match the American Medical Association's master file proportions for age, sex, and region. Physicians were eligible to participate in the survey if they practiced in the United States; actively saw patients; worked in an individual, group, or hospital practice; and had been practicing medicine for at least 3 years. An honorarium of $30 was paid to physicians for completing the survey. Of those invited, 1455 (61%) completed the entire survey. Because of a data storage error, however, 205 completed surveys were lost, resulting in a total of 1250 respondents. Additional responses that were not part of the final study included 19 respondents who did not complete the entire survey, 25 who logged in to take the survey but were terminated because of filled quotas (of 1250 respondents), and 30 who were disqualified because they did not meet the eligibility criteria.

The CDC licenses the results of the HealthStyles and DocStyles surveys from Porter Novelli (Washington, DC), and analysis of these results was exempt from institutional review board approval because personal identifiers were not included in the data provided to the CDC.

Variables considered

Respondents to the HealthStyles survey were asked about their awareness and use of a variety of genetic tests, including DTC testing. To assess their knowledge of DTCngts, respondents were asked "Genetic tests that analyze your DNA, diet, and lifestyle for potential health risks are currently being marketed by companies directly to consumers. Have you heard or read about these genetic tests?" If they answered yes, they were then asked "Have you ever had a genetic test that analyzes your DNA, diet, and lifestyle for potential health risks?" In addition, respondents were asked about their sources of information for DTCngts. For comparison, respondents were asked about their

awareness and use of more conventional genetic products and services, including genetic tests for "genetic screening in pregnancy" (pregnancy), "screening newborn babies" (newborn), "diagnosis of a genetic disease" (diagnosis), "testing to predict the likelihood you will develop a disease in the future" (prediction), "carrier testing for a genetic disease" (carrier testing), and "genetic testing to prescribe the correct medication or adjust the dose of medication" (pharmacogenetics). The survey asked for demographic information including age, sex, race/ethnicity, income level, education, and geographic region; self-reported health status; and family history of heart disease, diabetes, stroke, breast cancer, ovarian cancer, and colorectal cancer.

To assess awareness of DTCngts among physicians, respondents to the DocStyles survey were asked "Genetic tests that analyze a person's DNA, diet, and lifestyle for potential health risks are currently being marketed by companies directly to consumers. Have you heard or read about these genetic tests?" If the respondents answered yes, they were asked to identify the source(s) of information from a list of potential sources. Regardless of the answer to the previous question, respondents were asked, "Over the past year, what proportion of your patients (or their parents) have asked questions about having this type of genetic test?" and "Over the past year, what proportion of your patients (or their parents) brought results from this type of genetic testing to you for discussion?" Demographic data including age, sex, and race were also included in the survey as well as characteristics of the physician's practice such as the specialty, the work setting, the average number of patients per week, the number of years of practice, and the financial situation of the majority of the patients. Respondents were also asked about their general sources of information on patient health–related topics. The specific wording of the questions regarding genetic testing for both the HealthStyles and DocStyles surveys is included in the supplemental online materials (see Table S1 available online).

Statistical methods

For the HealthStyles survey, weights were provided to adjust the observations to a nationally representative distribution. Analyses were conducted with and without weights, but because no differences were observed in the conclusions of the analysis, only the unweighted analysis is reported here. We used S-PLUS (Version 14, Insightful Corporation, Seattle, WA) for all statistical analyses, including χ^2 and t tests for univariate analyses of discrete and quantitative variables, respectively. In addition, we performed multivariate logistic regression and used an analysis of deviance for the sequential addition of each variable to identify predictors of DTCngt awareness and use that were significant at the 0.05 level. All reported P values are uncorrected for multiple testing.

RESULTS

HealthStyles survey

A total of 5250 consumers responded to the HealthStyles survey. Overall, 715 respondents (14%) were aware of DTCngts, similar to the proportion of respondents who were aware of pharmacogenetic tests (15%). In contrast, respondents were more likely to be aware of conventional forms of genetic testing, including screening in pregnancy (50%), screening of newborns (43%), diagnosis of disease (38%), testing for carrier status (37%), and prediction of disease risk (30%). Demographic characteristics were similar between respondents who were aware of DTCngts and those not aware of DTCngts, except that the former tended to have the highest income (48% vs. 39%; $P = 0.0001$), more than a high school education (76% vs. 65%; $P < 0.0001$), and age younger than 55 years (71% vs. 64%; $P = 0.0001$) (Table 1). In multivariate logistic regression, only education ($P < 0.0001$) and age ($P = 0.0002$) remained in the model as independent predictors of DTCngt awareness. The odds ratio (95% confidence interval) was 1.43 (1.23–1.66) for those with a graduate or professional degree and 1.07 (0.95–1.19) for those with at least some college education compared with those with a high school education or less. For the age variable, the odds ratios and 95% confidence intervals were as follows: 1.28 (0.87–1.84) for those 18 to 24 years old, 1.24 (1.02–1.51) for those 25 to 34 years old, 1.02 (0.86–1.70) for those 35 to 44 years old, 1.04 (0.88–1.22) for those 45 to 54 years old, and 0.96 (0.79–1.16) for those 55 to 64 years old compared with those aged 65 years and older. Income was no longer significant after adjusting for the other variables.

Among the 715 respondents who were aware of DTCngts, only 29 (4%) had used a DTCngt (0.6% of the whole sample). Of those respondents who had used a DTCngt, only 10% (3 of 29) had discussed the test result with their physician. It is not known whether the respondents had also discussed the DTCngt with their physician before ordering it or who initiated the discussion of the test result. The demographic characteristics of the respondents who had used DTCngts were strikingly different from the characteristics of both those nonusers who were aware and those who were not aware of DTCngts. Most of these differences were not statistically significant and are likely to reflect chance variation given the small sample size. For example, compared with those who were not aware of DTCngts, the respondents who had used a DTCngt were more likely to be female (66% vs. 55%; $P = 0.33$), Hispanic (38% vs. 14%; $P = 0.0023$), young (10% vs. 3% were 18–24 years; $P = 0.054$), from the South (48% vs. 36%; $P = 0.59$), and more educated (71% vs. 65% had more than a high school education; $P = 0.22$). In addition, test users were more likely to have a positive family history for most of the diseases that were investigated, including heart disease (59% vs. 39%; $P = 0.05$), diabetes (48% vs. 37%; $P = 0.29$), stroke (31% vs. 17%; $P = 0.08$), and ovarian cancer (17% vs. 5%; $P = 0.013$) (Table 1). In multivariate logistic regression, only race/ethnicity remained in the model. In general, individuals who were aware of or used DTCngts were two to three times more likely to be aware of more conventional genetic testing services and products than were those individuals who were not aware of DTCngts (Fig. 1).

Among the respondents who were aware of DTCngts, 73% had heard or read about them through three media sources of information: television (46%), magazines (35%), or newspa-

Table 1
Characteristics of consumer respondents to the HealthStyles survey by awareness and use of DTCngts

	Not aware of DTCngts		Aware of DTCngts			Used DTCngts			
Characteristic	No.	%	No.	%	P^a	No.	%	P^a	Total
Total	4392	84	715	14		29	0.6		5250
Sex					0.056			0.33	
Male	1990	84	296	13		10	0.4		2358
Female	2402	83	419	14		19	0.7		2892
Race/Ethnicity					0.066			0.0023	
White	2980	84	487	14		13	0.4		3562
Black	530	84	72	11		3	0.5		628
Hispanic	603	84	94	13		11	1.5		714
Other	279	81	62	18		2	0.6		346
Age, yr					0.0001			0.054	
18–24	133	82	25	15		3	1.8		163
25–34	547	82	113	17		6	0.9		668
35–44	1111	84	189	14		9	0.7		1322
45–54	1067	83	190	15		6	0.5		1278
55–64	696	84	113	14		4	0.5		832
65+	838	85	85	9		1	0.1		987
Household income					0.0001			0.24	
<$25k	1252	84	160	11		12	0.8		1483
$25k–$59.9k	1401	85	214	13		6	0.4		1655
$60k+	1739	82	341	16		11	0.5		2112
Region					0.97			0.59	
East	835	84	132	13		4	0.4		996
Midwest	1013	84	164	14		6	0.5		1205
South	1590	83	265	14		14	0.7		1911
West	954	84	154	14		5	0.4		1138
Education level					<.0001			0.22	
High school or less	1521	87	165	9		8	0.5		1757
At least some college	2330	83	428	15		14	0.5		2819
Graduate/professional	485	80	114	19		6	1.0		609
Family history									
Heart disease	1714	83	294	14	0.31	17	0.8	0.05	2056
Diabetes	1624	84	258	13	0.68	14	0.7	0.29	1934
Stroke	751	83	144	16	0.054	9	1.0	0.08	909
Breast cancer	501	83	88	15	0.52	3	0.5	0.91	601
Ovarian cancer	226	83	43	16	0.38	5	1.8	0.013	273
Colorectal cancer	249	82	46	15	0.47	2	0.7	0.91	302
Health					0.059			0.48	
Excellent	400	80	81	16		4	0.8		497
Very good	1552	83	280	15		8	0.4		1873
Good	1660	85	241	12		13	0.7		1957
Fair	639	85	90	12		2	0.3		751
Poor	124	82	19	13		2	1.3		151

DTCngts, direct-to-consumer nutrigenomic tests.
Row totals may vary because of missing data; rows may not add to 100% because of rounding error.
[a]Unadjusted χ^2 test for categorical variables using all categories listed in the table compared with respondents who were not aware of DTCngts.

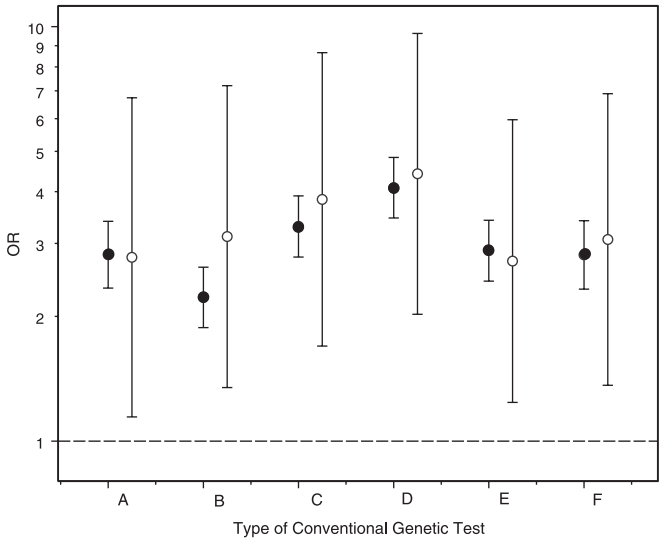

Fig. 1. Point estimates of odds ratios and confidence intervals for awareness of conventional genetic testing products and services adjusted for age, sex, income, and education. Data are presented for respondents who were aware of direct-to-consumer nutrigenomic tests (DTCngts) (solid circles) and for respondents who had used DTCngts (open circles) compared with respondents who were not aware of DTCngts. The conventional genetic testing products and services are as follows: (A) pregnancy screening, (B) newborn screening, (C) diagnosis, (D) prediction, (E) carrier testing, and (F) pharmacogenetics.

pers (29%) (Fig. 2). Health professionals were a source of information for 13% of respondents who were aware of DTCngts, but it is not clear who initiated the discussion of DTCngts. In contrast, among the respondents who had used a DTCngt, the media were a source of information for only 58% of respondents, whereas health professionals were a source of information for 63% of respondents. Although the sample size of DTCngt users is small, these results suggest that health professionals are an influential source of information when consumers make decisions regarding DTCngts. An alternative explanation for these observations might be that the respondents who used a DTCngt may have confused DTCngts with other,

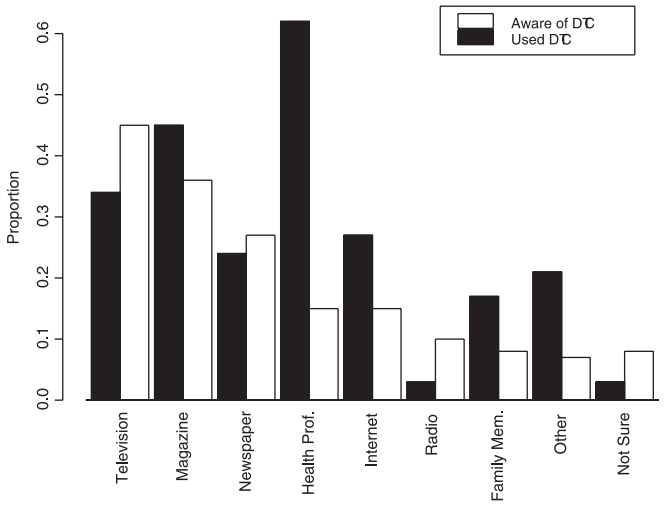

Fig. 2. Sources of consumers' information about DTCngts. The proportion of consumers who had heard about (white bars) or used (black bars) DTCngts and who obtained information about them from each source.

more conventional genetic services and products that are usually obtained clinically. However, the fact that only 10% of respondents discussed their test results with a health care provider provides some reassurance that this was not the case.

DocStyles survey

A total of 1250 physicians responded to the DocStyles survey. Overall, 44% (555/1250) of physicians reported that they were aware of DTCngts. However, this estimate may be inaccurate because an additional 11% (138/1250) of physicians reported that their patients had asked about DTCngts or that their patients had discussed the results of DTCngts with them. To avoid misclassification, we excluded those respondents who said they had patients who asked about DTCngts or who had discussed the result of a DTCngt with their patient, but who said they had not heard of DTCngts. Demographic characteristics were similar between the physicians who were aware of DTCngts and the physicians who were not aware of DTCngts, except that the former group was more likely to be male (71% vs. 63%; $P = 0.008$) (Table 2).

Of those physicians who were aware of DTCngts, most (76%) reported that <1% of their patients had asked about such tests (Table 2), and 93% reported that <1% of their patients had discussed results of a DTCngt with them. These results are consistent with the low frequency of respondents to the HealthStyles survey who reported discussing the results of DTCngts with their health care providers.

As part of the DocStyles survey, physicians were asked to identify as many as five sources of patient health–related information that they considered to be the most trusted from a list of 16 options. Physicians were fairly consistent in their responses, which included journal articles (96%), government agencies (83%), other physicians (80%), professional organizations (74%), and medical Web sites (62%) as among the most trusted sources (Fig. 3). In addition, physicians were asked how often they used each of these sources to obtain patient health–related information. In general, a strong correlation was found between physicians' level of trust in the source and frequency of use (Fig. 3). In contrast, when physicians were asked to identify their sources of information about DTCngts, the media (television, newspaper, or radio), one of the least trusted sources for patient health–related information, were the most frequently reported source (62%). This finding suggests either that limited information is available on DTCngts from trusted sources or that physicians are not easily able to access the available information from trusted sources. An opportunity therefore exists for provider education on this topic.

DISCUSSION

The results of the national HealthStyles survey indicate that a small percentage of the US population is aware of the availability of DTCngts (14%; 95% confidence interval, 12.7%–14.6%), and only a fraction of the overall population has used a DTCngt (0.6%; 95% confidence interval: 0.4%–

Table 2
Characteristics of physician respondents to the DocStyles survey by awareness of DTCngts

	Unaware[a] of DTCngts		Aware of DTCngts							
Characteristic	Total	%	Total	%	P^b	& Pts have asked[c]	%	& Pts have not asked[c]	%	P^c	Total
Total	557	45	555	44		330	26	225	18		1250
Specialty					0.042					0.001	
Family/general practitioner	62	39	73	46		46	29	27	17		157
Internist	359	43	380	45		240	28	140	17		843
Pediatrician	136	54	102	41		44	18	58	23		250
Work setting					0.098					0.891	
Individual practice	99	45	97	44		57	26	40	18		221
Group practice	380	46	354	43		209	25	145	17		830
Hospital/clinic	78	39	104	52		64	32	40	20		199
Sex					0.008					0.117	
Male	353	42	394	47		243	29	151	18		843
Female	204	50	161	40		87	21	74	18		407
Race					0.813					0.061	
Hispanic	27	44	31	50		17	27	14	23		62
White	379	45	381	45		217	26	164	19		843
Black	115	44	104	40		74	28	30	11		262
Other	36	44	39	48		22	27	18	22		82
Age[d]	44.7 (8.3)	44.1 (8.4)	0.676	43 (8.2)		46 (8.5)		0.896			
No. of patients per wk[d]	120 (69)	121 (69)	0.837	125 (73)		116 (64)		0.751			
No. of yr of practice[d]	14 (7.6)	14 (7.5)	0.441	13 (7.1)		15 (7.8)		0.887			
Financial situation of patients					0.047					0.016	
Very poor–poor	13	45	14	48		5	17	9	31		29
Poor–lower middle class	60	42	68	48		36	25	32	23		142
Lower middle class–middle class	222	46	220	45		128	26	92	19		486
Middle class–upper middle class	220	42	234	45		144	28	90	17		520
Upper middle class–affluent	42	58	19	26		17	23	2	3		73
% Patients asking about DTC											
None	557	71	225	29		0	0	225	29		787
<1	0	0	192	65		192	65	0	0		294
1–10	0	0	118	81		118	81	0	0		145
>10	0	0	20	83		20	83	0	0		24
% Patients discussing DTC results											
None	557	53	409	39		187	18	222	21		1056
<1	0	0	105	74		102	72	3	2		142
1–10	0	0	30	79		30	79	0	0		38
>10	0	0	11	79		11	79	0	0		14

DTCngts, direct-to-consumer nutrigenomic tests; Pts, patients.
Row totals may vary because of missing data and because physicians who reported they were not aware of DTCngts but who had patients ask about these tests were excluded; rows may not add to 100% because of rounding error and because of the excluded physicians.
[a]Physicians who reported that they were not aware of DTCngts when asked "Genetic tests that analyze a person's DNA, diet, and lifestyle for potential health risks are currently being marketed by companies DTC. Have you heard or read about these genetic tests?" and who also reported that none of their patients had asked questions about DTCngts or brought results from a DTCngt for discussion.
[b]Unadjusted χ^2 test or t test comparing physicians who were aware versus not aware ($n = 557$) of DTCngts.
[c]Unadjusted χ^2 test or t test comparing physicians who were aware of DTCngts and who had patients that asked about DTCngts versus physicians who were aware of DTCngts and who did not have patients that asked about DTCngts.
[d]Quantitative covariates are reported as mean (SD). All other results are number (%).

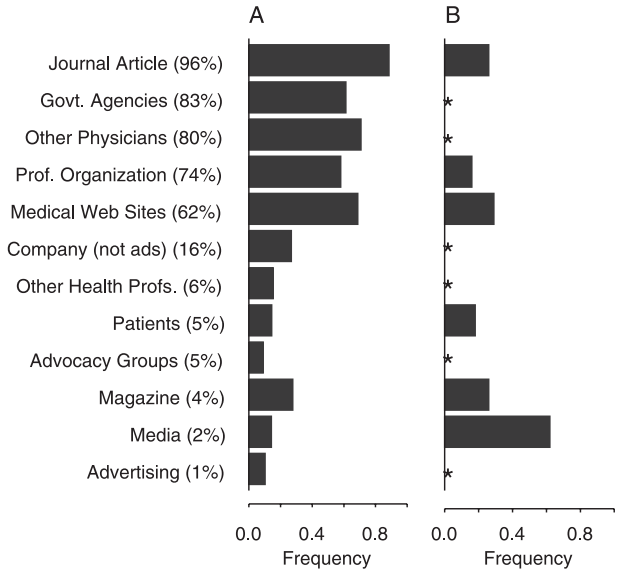

Fig. 3. Sources of information are ranked from highest to lowest based on the proportion of physicians who considered each source to be one of the most trusted sources of patient health–related information, which is indicated in parentheses next to each source (as many as five responses were allowed). Other health professionals include nurses, nurse practitioners, and physician assistants. Media include radio, television, and newspaper articles. Company includes information provided by the manufacturer other than advertisements. The Medical Web sites source was listed as a generic Internet category in part B and could include trusted sources such as medical Web sites or journal articles or less trusted sources such as the manufacturer's Web site, advertisements, and media reports. The information in this figure only includes the responses for physicians who were aware of DTCngts. (A) Proportion of physicians who reported that they "often" or "regularly" used each source for patient health–related information in general. (B) Proportion of physicians who reported that they did hear or read about DTCngts from each source (multiple responses were allowed). Categories with an asterisk were not part of the question in B.

0.8%). This estimate may be inaccurate if consumers were uncertain about interpretation of the questions. However, if these results are accurate, the observed proportion would correspond to 1.8 million users of DTCngts nationwide. Although 44% of physicians in the DocStyles survey were aware of DTCngts, the apparent lack of trusted sources of professional information on DTCngts is a concern because physicians may be influential in consumers' decisions regarding the use of DTCngts.

This study provides valuable data from the consumers' perspective on the national policy debate surrounding DTCngts. The vast majority of individuals who are aware of DTCngts have not used them. It is also notable that the media are the primary sources of information on DTCngts for both consumers and physicians. Thus, educational efforts geared to consumers or health care providers from alternative sources such as professional organizations or government agencies are not being heard or are not yet sufficiently developed. The lack of professional information sources may be related to the scarcity of studies and data gaps that exist for many of the products that are currently available. Until this deficiency is rectified, there is a need and an opportunity for professional organizations, individual scientists, and government agencies to inform the professional community that these knowledge gaps exist. Educating the professional community is especially important because the majority of respondents who used a DTCngt reported that the information about these tests came from a health care provider. Finally, the differences in demographic characteristics between those who are aware of DTCngts and those who are not raise legitimate concerns regarding the potential for increased health disparities from this mode of delivery, such as inconsistent access to these tests (because of cost) or awareness of these tests (because of targeted marketing). Any DTCngts that are demonstrated to have a health benefit should be marketed to everyone so that the benefits are shared across society.

Several limitations of the present study can be addressed in future surveys on this topic. First, the sampling methodology that was used for both surveys may not have produced a truly random national sample. For instance, previous studies that asked about awareness of conventional genetic tests reported a higher percentage of respondents who were aware of specific types of genetic tests,[12–14] although in some instances the sample sizes were smaller than in this study, and the study questions may have referred to specific genetic tests (e.g., genetic testing for breast cancer susceptibility) rather than types of genetic testing (e.g., predictive genetic testing) as in this study. Thus, the findings from these studies may not be representative of the entire U.S. population. Although we are not aware of any other national surveys collecting the same information at this time, the results of this study will be compared with similar questions from the Behavioral Risk Factor Surveillance System, contributed by CDC-funded genomics programs in three state departments of health (Utah, Oregon, and Michigan), when these data become available late in 2007. Second, the small number of respondents who had used a DTCngt naturally limits the precision and generalizability of the study findings. Third, the nested format of the questions could have led to an underestimate of the number of respondents who had used a DTCngt because individuals were not asked whether they had used a DTCngt unless they answered that they were aware of these tests. However, for more conventional genetic tests or services that did not have this nested format, only a small percentage of respondents (between 0.7% and 1.6%) indicated that they had used a genetic test or service when they indicated that they were not aware of that type of test or service. Thus, we anticipate that this bias would be small. In a related issue, the validity of the questions has not been fully assessed, and some residual confusion over the survey questions may exist. Some questions were not evaluated because the meaning of the responses was unclear. For example, some male respondents reported that they had used a genetic test during pregnancy (this could refer to carrier testing of the father, carrier testing of the mother, or genetic testing of the fetus), and some elderly respondents reported that they had undergone newborn screening even though such testing was not available at the time they were infants. Finally, the survey questions were restricted only to nutrigenomic tests, although other types of genetic tests are sold DTC. It is possible that awareness and use of other types of DTC genetic tests may be higher than for nutrigenomic tests, particularly those that are more medical in

nature (e.g., cystic fibrosis carrier testing or testing for hereditary hemochromatosis). Despite these concerns, this study represents an initial effort to assess public awareness of this issue, and we anticipate that future versions of these questions will clarify these remaining problems.

Alternative sources of information on consumers' awareness and use of DTCngts could include marketing surveys or records of sales from the genetic test distributors. However, companies are not always willing to share such information and are rarely required to provide such information, except in New York State, which does not disclose the information. Furthermore, information on providers' awareness and experiences with DTCngts should be extended beyond physicians because consumers could be learning about these tests from nutritionists, chiropractors, or other health care providers. A related limitation of the present study is that the term *health care providers* was never explicitly defined and could have a different meaning for different respondents.

Despite these limitations, this report provides valuable initial baseline data that are important for public health surveillance and for tracking trends within the population. We anticipate that these trends will change over the next few years as these tests are applied, used, and advertised more frequently. In addition, these studies are unique in providing a national picture of awareness and use of DTCngts and may influence policy and educational efforts concerning the appropriate use of genetic tests.

ACKNOWLEDGMENTS

This work was supported, in part, by a fellowship (to K.G.) jointly sponsored by the Centers for Disease Control and Prevention and the American Society of Human Genetics in Public Health Genomics Research and Practice.

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