

ORIGINAL ARTICLE

Evaluating the evidence: direct-to-consumer screening tests advertised online

Kimberly M Lovett, Timothy K Mackey and Bryan A Liang

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Objectives Unsupervised online direct-to-consumer (DTC) access to medical services has rapidly expanded to medical screening tests, which have not been critically evaluated for their evidence basis. The objective of this study is to identify the scope of online-advertised DTC screening tests, outline the evidence for use of available DTC testing and suggest regulatory reform to address the relevant issues.

Methods An observational study of website advertisements, testing services and counselling/follow-up services for DTC testing was conducted. Data were collected from websites between 4 April and 1 June 2011. Each website was assessed for tests offered, advertised indications and availability of counselling/follow-up services. Advertised testing indications were compared with US Preventive Services Task Force recommendations and/or specialty guidelines and categorized as Supported, Against, Insufficient Evidence or No Guidance.

Results Of 20 companies identified as offering DTC screening tests, 95% (19/20) do not clearly offer pretest counselling, post-test counselling and/or test follow-up. One hundred and twenty-seven different tests were identified. Only 19/127 (15%) could be *Supported* for screening in a target group selected for testing; 38/127 (30%) were given recommendations to avoid use in specific target group(s) selected for testing ('*Against* recommendations'); 29/127 (23%) had *Insufficient Evidence* of value, and for 64/127 (50%) *No Guidance* could be given. Only 4/127 (3%) tests were *Supported* for general screening use.

Conclusions Virtually all identified medical tests advertised and offered DTC are not recommended for use in screening by evidence-based guidelines. Limited oversight may lead to inaccurate self-diagnosis, treatment and wasted health resources.

See end of article for authors' affiliations

Correspondence to:
Kimberly Lovett, 1630 East
Main Street, El Cajon, CA
92021, USA;
klovett@ucsd.edu

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INTRODUCTION

Direct-to-consumer (DTC) availability of medical products is expanding rapidly. DTC marketing has broadened beyond traditional television, print and radio media onto the Internet. Consequently, DTC advertising potentially reaches millions of consumers searching online for health-care resources.¹ Whereas pharmaceutical advertising has traditionally dominated the DTC medical marketplace, online DTC advertising has now expanded to include medical tests of questionable efficacy, safety and utility for disease screening and diagnosis. Previous studies have highlighted the controversial marketing and sale of genetic susceptibility testing,² but little attention has been paid to the plethora of non-genetic medical tests available DTC that are being offered for 'screening' purposes.

The medical community defines disease screening as 'the systematic application of a test or inquiry, to identify individuals at sufficient risk of a specific disorder to benefit from further investigation or direct preventive action, among persons who have not sought medical attention on account of symptoms of that disorder'.³ This definition necessitates a pretest evaluation with screened individuals

to ensure the absence of symptoms as well as a quantification of each individual's risk of disease.

There are generally nine factors that contribute to the usefulness of a specific screening test: (1) the disease being screened for is well defined; (2) the incidence/prevalence of the disease being screened for is known; (3) the disease being screened for will lead to morbidity and/or mortality; (4) early management of asymptomatic individuals is more effective than management at clinical presentation of disease; (5) the screening test is simple and safe; (6) the test performs well with acceptable rates of false-positive and false-negatives; (7) the health benefit of screening justifies test costs; (8) there is access to resources for further diagnosis and treatment; (9) follow-up management after diagnosis is agreed upon and acceptable to both medical professionals and patients.⁴ To ensure safety, meeting these criteria requires screening outcomes evaluation and evidence-based support for screening test use before making testing widely available for screening purposes.

Companies advertising online and offering DTC medical tests for screening purposes are creating unique safety risks for any person, nationally and globally, with access to the

Internet. While aiming to empower consumers by providing private medical testing without professional consultation, these companies may be marketing unproven or harmful medical testing, resulting in poor health outcomes. By definition, where a pretest evaluation with consumers is absent, these DTC medical tests cannot be properly identified as 'screening' tests despite their advertised purpose and consumers are at risk for making ill informed decisions regarding medical care.⁵ Furthermore, similar to online DTC drug advertising, medical test risk and benefit information given to consumers may be misleading, inaccurate or incomplete. Several studies examining DTC medical tests for cardiovascular disease, genetic testing and imaging services have highlighted the potential risks involved in offering medical testing DTC without medical professional oversight.⁶⁻⁸

The DTC medical testing industry is fueling medical consumerism growth, unnecessary medical interventions and downstream resource waste. For example, a recent study reported 22 clinical cases of patients arriving self-referred or physician-referred to geneticists due to results of DTC genetic testing.⁹ The costs of initial genetic testing for each of these 22 patients was as high as US\$3120, while the cost of subsequent follow-up care (including visit to genetic counselor, referrals to specialists and referrals for additional diagnostic testing) ranged from \$40 to \$20,604 per patient.⁹ Not surprisingly, with the exception of BRCA 1/2 testing for breast cancer susceptibility, 64% of DTC genetic tests performed in these case reports were considered not clinically useful by genetic health-care professionals seeing these patients in follow-up.⁹

In response to powerful concerns related to DTC availability of genetic testing, the Food and Drug Administration (FDA) issued warning letters to companies offering DTC genetic testing.^{8,10} Further, recent recommendations for DTC genetic and cardiac testing have appropriately included requiring that testing be FDA approved before use/marketing, outcomes research be conducted before public availability, that testing be offered through health-care professionals and that counselling be offered pre-test and post-test to guide consumers toward appropriate care and follow-up.^{6,11} Despite these efforts, concerns remain regarding the ability of the FDA to regulate the DTC industry, given its limited mandate, inadequate funding and staff, and reluctance of US legislatures to infringe on commercial rights of free speech.¹²

It is important for global health, health-care cost containment and public safety that DTC medical testing be critically evaluated, the scope of the problem outlined and further policy pursued to regulate a currently unfettered industry that may be exploiting unproven medical testing at the expense of patient and consumer safety. In this study, we identify medical tests advertised online and available DTC, outline the evidence-base for use of available DTC testing, evaluate the availability of counselling and follow-up offered by DTC testing companies related to DTC testing services, and suggest regulatory reform and coordination among various stakeholders to address the relevant issues.

METHODS

Google searches were performed to identify medical tests advertised online via DTC medical testing company websites.

'DTC Medical Testing Company' was defined as a company offering medical testing direct-to-consumer without prior physician consultation/prescription. 'Medical tests' were defined as any imaging test or any tests advertised as measuring any serum, saliva or urine analyte. The company websites were evaluated for information including: whether the companies offer pre-/post-test counselling or follow-up for abnormal results. Where the companies did not explicitly address these issues on their websites, they were coded 'unclear from website'.

Google searches were run using US Department of Health and Human Services-focused health categories beyond 'general health',¹³ i.e. heart health, diabetes, prostate health, reproductive health, colorectal health, eye and ear health, breast health, and oral health. Terms were searched with the term 'screening' added (for example, 'heart health screening'). To provide a general sense of the scope of offered DTC medical testing while limiting the number of identified medical tests to a manageable data-set, organic and sponsored search results of pages 1 and 2 were evaluated to identify DTC Medical Testing Companies, medical tests offered, availability of pre-/post-test counselling and follow-up care provisions. 'Organic search results' are listings on search engine results pages that appear because of their relevance to the search terms, as opposed to appearing as advertisements. In contrast, 'sponsored search results' are paid-for listings that appear on the results page for a fee to the search engine company. Indeed, consumers may be confused regarding the difference in these search results, with studies indicating that only 38% of US users could make a distinction between organic and sponsored results.¹⁴ Searches were completed between 4 April and 1 June 2011.

After identifying medical tests, we evaluated the evidence-base for medical test use via US Preventive Services Task Force ('USPSTF') guidelines or relevant specialty society guidelines where USPSTF guidance was unavailable. We chose this method primarily because all identified DTC medical tests were advertised specifically for 'screening' purposes. We chose to evaluate the usefulness of each identified medical test according to the evidence-base relating to the advertised testing purpose. Medical tests were stratified according to whether evidence-based guidelines support screening (Supported); advise against screening (Against), do not offer definitive recommendations because of conflicting, poor, or incomplete data (Insufficient Evidence), or do not address the medical test for screening purposes (No Guidance). The 'Insufficient Evidence' category is based on USPSTF 'I Statements', which signify 'current evidence is insufficient, ... of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.'¹⁵ Because screening guidelines generally provide recommendations for specific populations, any given medical test may have ≥ 1 recommendation, coded 'multiple recommendations.'

RESULTS

Twenty DTC Medical Testing Companies were identified (Table 1); 19 (95%) websites either do not offer or do not indicate whether they offer pre-/post-test counselling, or follow-up (Table 1).

Table 1 Identified direct-to-consumer testing companies and parameters of offered services

Company Name	URL (Archived URL)	Pre-test counselling available	Post-test counselling available	Follow-up with physician for abnormal tests available
Advanced Body Scan of Newport	http://www.newportbodyscan.com/PricingandIncentivePrograms.htm (Archived at http://www.webcitation.org/6180EAbZh)	Unclear from website	Unclear from website	Unclear from website
Affordable Wellness	http://www.labscreening.com/ (Archived at http://www.webcitation.org/6180LhVw)	No	No	No
Ann Arbor Thermography	http://aathermography.com/FAQ/FAQ.htm (Archived at http://www.webcitation.org/6180TqGTz)	No	No	No
Bone Health Montana	http://www.bonehealthmontana.com/CompanyInformation/BoneDensityTestingFAQ.html (Archived at http://www.webcitation.org/6180mAcB7)	No	Yes (non-physician)	Unclear from website
Carlsbad Imaging Center	http://www.carlsbadimaging.com/cash_pricelist.html (Archived at http://www.webcitation.org/618P02dm9)	Unclear from website	No	No
Dr Mercola's Natural Health Center	http://naturalhealthcenter.mercola.com/services/thermography.aspx (Archived at http://www.webcitation.org/618P6zGk)	Unclear from website	No	No
Health Check USA	http://www.healthcheckusa.com/Find-a-test/46823/ (Archived at http://www.webcitation.org/618PNlc9J)	No	Unclear from website	Unclear from website
Health Testing Centers	http://www.healthtestingcenters.com/blood-test-list.aspx (Archived at http://www.webcitation.org/618PUm85r)	No	No	No
Health Watch	http://www.healthwatch.cc/Testing_services.html (Archived at http://www.webcitation.org/618Pdwtlc)	No	Unclear from website	No
Heart Health Screening	http://www.dean-wellness.com/fe/13007-hhscreen (Archived at http://www.webcitation.org/618QR4z5v)	Available at extra cost	Available at extra cost	Available at extra cost
Home Health Screening	http://www.homehealthscreening.com (Archived at http://www.webcitation.org/618QdqSFo)	No	No	No
Home Health Testing	http://www.homehealthtesting.com (Archived at http://www.webcitation.org/618QjM5TD)	No	No	No
Lifeline Screening	http://www.lifelinescreening.com/health-screening-services/default.aspx (Archived at http://www.webcitation.org/618QdTxk)	No	No	No
Optimum Health Center	http://www.optimumhealthclinic.info/och_ebook_events.html (Archived at http://www.webcitation.org/618R7jeGV)	Yes (with non-physician)	Yes (with non-physician)	Unclear from website
Safe Heart Health Screens	http://www.safehearthealthscreens.com/html/faq.html (Archived at http://www.webcitation.org/618RD0ix)	No	No	No
Superior Body Scan	www.superiorbodyscan.com (Archived at http://www.webcitation.org/618Rl9KGN)	Yes	Available at extra cost	Unclear from website
Testicountry.com	http://www.testicountry.com (Archived at http://www.webcitation.org/618RNB6WVb)	No	No	No
Testimyhormones.com	http://www.testimyhormones.com/test_information.htm (Archived at http://www.webcitation.org/618RSReYg)	No	No	No
US Wellness	http://www.uswellness.com/dt/pl/uv/screening.asp (Archived at http://www.webcitation.org/618Rbl46s)	Unclear from website	Unclear from website	Unclear from website
9Health Fair	http://www.9healthfair.org/find/screenings.aspx (Archived at http://www.webcitation.org/618Rh5Utm)	Unclear from website	Variable	Variable

A total of 127 DTC medical tests were identified (Table 2). In several cases, medical test components were not decipherable from website descriptions and therefore listed by panel name (e.g. 'antioxidants', 'female hormones', 'male hormones' and 'heavy metals'). Medical tests include a host of body fluid and imaging studies. Importantly, our searches did not reveal many types of DTC genetic testing that have been highly publicized in recent years.

Of 127 medical tests, 63 (50%) have USPSTF or relevant specialty society screening guidance, 19/127 (15%) have ≥ 1 Supported recommendation for screening use; double this number (38/127, 30%) were given recommendations to avoid use in specific target group(s) selected for testing ('Against recommendations'); and 27/127 (21%) carry ≥ 1 statement of Insufficient Evidence of value.

A detailed review revealed that only 4/127 (3%) are Supported without any Against or Insufficient Evidence recommendations (Table 2). The remainder ($N = 123$, 97%) had only recommendations Against ($N = 23$, 18%), statements of Insufficient Evidence ($N = 15$, 12%), multiple recommendations ($N = 21$, 17%), or No Guidance ($N = 64$, 50%). Virtually all DTC medical tests are not clearly supported for screening in the general population.

Tests are further categorized in Tables 3–5 by published guidance. Table 3 lists the 19 DTC medical tests carrying any Support recommendation. Most (15/19, 79%) of these also carry recommendations Against use and/or statements of Insufficient Evidence. For example, USPSTF recommends colon cancer screening in individuals aged 50–75 but recommends against screening for individuals over age 76. Moreover, even for the 4 Supported tests without Against or Insufficient Evidence recommendations, guidelines clearly limit Support recommendations to specific target populations. For example, breast cancer screening is USPSTF Supported, but only for average risk women over 49 and younger high-risk women. Therefore, we count these tests as Supported, but the guideline clearly excludes many other target populations (e.g. low-risk women aged 35).

Table 4 lists the 38 medical tests with ≥ 1 recommendation Against use in screening; 19/38 tests (32%) carry specific recommendations Against use in all target population groups, while another 10/38 tests (37%) are advised Against for all low-risk patients. For example, guidelines recommend Against carotid artery stenosis screening for all persons, while AAA screening is Supported for men age >65 who have smoked but recommended Against for all women. Within this group of tests, most ($N = 29$, 69%) are recommended Against for either all individuals or all low-risk individuals.

Of the 127 medical tests, 29 (23%) medical tests carry ≥ 1 recommendation of Insufficient Evidence to inform use in screening (Table 5). Some may have arguable clinical utility but evidence-based guidance suggests that the available data are insufficient to determine whether screening benefits outweigh risks (e.g. osteoporosis screening in men, hyperlipidaemia screening in young persons and diabetes screening in persons without hypertension).

Finally, 64 (50%) identified DTC medical tests have no published guidance from USPSTF or specialty societies (Table 6). These also involve body fluid testing and imaging studies, spanning the scope from melatonin levels

and antioxidant screening through virtual bronchoscopy and thermography.

DISCUSSION

Though recent commentary has focused on the implications of DTC cardiac and genetic tests, the patient safety threat posed by the breadth of available DTC medical tests has not been adequately addressed. Furthermore, probably due to recent FDA warnings targeting DTC genetic testing companies, access to DTC genetic tests has become much less appreciable. In fact, most companies we identified did not specifically advertise or offer the range of DTC genetic susceptibility tests previously reported in the literature. However, we have identified a large scope of non-genetic DTC medical testing and, as such, regulatory oversight in combination with non-governmental and professional society intervention is critical in future efforts.

Principal results and implications

Of the 127 identified DTC medical tests advertised online, virtually all (97%) have clear guidance advising against use, insufficient or conflicting evidence to inform use, or no guidance at all regarding use for screening purposes.

The relative lack of evidence-based support is alarming, but in addition the 3% of tests with unopposed recommendations of Support were all limited to very specific target populations. In fact, where tests are Supported, they are supported for a narrow range of individuals, and where tests are advised Against, they are advised against for target populations. This means that not a single identified DTC screening test has evidence-based guidance to support general population screening. Ultimately, traditional medical care uses evidence-based guidelines based on outcome data to restrict screening test recommendations to narrow target populations in order to improve the risk/benefit ratio of testing. However, DTC medical testing companies do not limit their testing according to evidence-based guidelines, and are therefore exposing the general population to tests that likely pose more risk than benefit to many of these consumers. In general, no screening tests are recommended for broad use in the general population, yet these tests are offered to the public without any mechanism to filter consumers who may benefit and those who may not. Indeed, medical testing offered to the general public without adequate pretest evaluation cannot even be properly identified as a 'screening' test. Consumers searching online are therefore confronted with a quagmire of medical tests that are generally not evidence-based and in all probability not applicable to their specific circumstance.

Online advertisements for DTC medical tests generally fail to offer evidence-based screening information, informed consent and potential risks of testing. This information is necessary for informed acceptance or refusal of test risks and benefits. Informed consent provides a mode of evidence-based patient selection and accountability for advising use of various medical tests for screening purposes and direct questioning with a qualified health professional allows determination of whether a consumer is truly seeking screening for asymptomatic disease or if he/she has symptoms requiring diagnostic testing and follow-up.

Table 2 Identified direct-to-consumer medical tests

	Test identified	Mode identified	Support	Against	Insufficient evidence	No guidance
1	Abdominal aortic aneurysm	Ultrasound	X	X		
2	ABO/RH blood types	Blood				X
3	Alcohol use	Blood				X
4	Alcohol use	Urine				X
5	Alcohol use	Home testing kit				X
6	Alkaline phosphatase	Blood				X
7	Allergy IgE testing	Blood		X		
8	Alphafetoprotein	Blood				X
9	ALT	Blood				X
10	Amylase	Blood				X
11	ANA	Blood				X
12	Anti-SM antibodies	Blood				X
13	Antioxidants	Blood				X
14	AST	Blood				X
15	Atrial fibrillation	Electrocardiogram				X
16	Atrial fibrillation	Echocardiogram				X
17	Bacteruria	Urine	X	X		
18	Bacteruria	Home testing kit				X
19	Beta carotene	Blood				X
20	Beta naturetic peptide	Blood		X		
21	BRCA	Blood		X		
22	Breast cancer	Self breast exam pads		X		
23	Breast cancer	Digital mammogram			X	
24	Breast cancer	MRI			X	
25	Breast cancer	Thermography				X
26	Breast cancer	Mammogram	X			
27	CA 27-29 tumour marker	Blood		X		
28	CA-125 tumour marker	Blood		X		
29	CA-19-9 tumour marker	Blood		X		
30	Cardiac disease	Electrocardiogram		X	X	
31	Cardiac disease	Non-contrast CT		X	X	
32	Cardiac disease	Electron beam CT		X	X	
33	Cardiac disease	Echocardiogram	X	X		
34	Cardiac disease	Non-contrast MRI		X		
35	Cardiac disease	CT angiography		X		
36	Carotid artery stenosis	Ultrasound		X		
37	Carotid intima media thickness	Ultrasound			X	
38	Complete blood count	Blood	X		X	
39	CEA tumour marker	Blood		X		
40	Celiac disease	Blood	X	X		
41	Chlamydia/GC	Blood	X	X	X	
42	Co-Q10	Blood				X
43	Cocaine use	Blood				X
44	Cocaine use	Urine				X
45	Cocaine use	Home testing kit				X
46	Colon cancer	Feces	X	X		
47	Colon cancer	Virtual colonoscopy			X	
48	Colon cancer	Home testing kit				X
49	Cortisol	Blood				X
50	Dental disease	Non-contrast CT				X
51	Diabetes mellitus	Fasting glucose, blood	X		X	
52	Diabetes mellitus	Random glucose, blood	X		X	
53	Diabetes mellitus	Hg A1c, blood	X		X	
54	Diabetes mellitus	Fasting glucose, finger stick (FS)				X
55	Diabetes mellitus	Random glucose, FS				X
56	Diabetes mellitus	Hg A1C, FS				X
57	Diabetes mellitus	Home testing kit				X
58	Diabetes mellitus	Urine				X
59	Ecstasy use	Blood				X
60	Ecstasy use	Urine				X
61	Ecstasy use	Home testing kit				X
62	Electrolytes	Blood				X
63	Female hormones	Saliva				X
64	Female hormones	Blood				X
65	Folate	Blood				X
66	Full body imaging	Non-contrast CT		X		
67	Full body imaging	Non-contrast MRI		X		
68	Full body imaging	Electron beam CT		X		

Table 2 (Continued.)

	Test identified	Mode identified	Support	Against	Insufficient evidence	No guidance
69	Heavy metals	Blood				X
70	<i>Helicobacter pylori</i>	Blood			X	
71	Hepatitis B	Blood	X	X		
72	Hepatitis C	Blood		X	X	
73	Heroin use	Blood				X
74	Heroin use	Urine				X
75	Heroin use	Home testing kit				X
76	HIV	Blood	X	X		
77	Homocysteine	Blood			X	
78	HS-CRP	Blood			X	
79	Iron	Blood				X
80	Lead	Blood		X	X	
81	Lipase	Blood				X
82	Lipids	Blood	X	X	X	
83	Lipids	Blood, FS				X
84	Lung disease	Non-contrast CT			X	
85	Lung disease	Electron beam CT			X	
86	Lung disease	X-ray			X	
87	Lyme disease	Blood		X		
88	Magnesium	Blood				X
89	Male hormones	Saliva				X
90	Male hormones	Blood				X
91	Marijuana use	Home testing kit				X
92	Marijuana use	Blood				X
93	Marijuana use	Urine				X
94	Melatonin	Blood				X
95	Nicotine use	Blood				X
96	Nicotine use	Urine				X
97	Nicotine use	Hair				X
98	Nicotine use	Home testing kit				X
99	Nuclear magnetic resonance (NMR) lipoprofile	Blood		X		
100	Orthopaedic imaging	3D CT		X		
101	Osteoporosis	Heel Ultrasound	X		X	
102	Osteoporosis	DXA	X		X	
103	Osteoporosis	Quantitative CT	X			
104	Parathyroid function	Blood				X
105	Peripheral arterial disease	Ultrasound		X		
106	Prostate specific antigen	Blood		X	X	
107	Pulmonary function tests	Spirometry		X		
108	Rheumatoid factor	Blood				X
109	Selenium	Blood				X
110	Skin cancer	Dermoscopy			X	
111	Spinal disease	Non-contrast MRI		X		
112	Syphilis	Blood	X			
113	Thyroid function	TSH, blood			X	
114	Thyroid function	T4, blood			X	
115	Thyroid function	T3, blood			X	
116	Thyroid function	T7, blood			X	
117	Vertical autoprofile (VAP) lipoprofile	Blood		X		
118	Viral herpes	Blood		X		
119	Virtual arteriography	3D CT				X
120	Virtual bronchoscopy	3D CT				X
121	Vitamin A	Blood				X
122	Vitamin B ₆	Blood				X
123	Vitamin B ₁₂	Blood		X		
124	Vitamin C	Blood				X
125	Vitamin D	Blood	X			
126	Vitamin E	Blood				X
127	Vitamin K	Blood				X
Totals	19	38	29	64		

CT, computed tomography; ALT, alanine transaminase; ANA, antinuclear antibody; AST, aspartate transaminase; BRCA, breast cancer; MRI, magnetic resonance imaging; HS-CRP, high sensitivity C-reactive protein; DXA, dual-energy X-ray absorptiometry; CA, Cancer Antigen; CEA, Carcinoembryonic Antigen

In addition to a lack of informed consent and pretest counselling, consumers are generally not offered post-test counselling or follow-up. On the basis of misused testing and/or misinterpreted results, patients may choose to

self-diagnose and self-treat, including purchasing pharmaceuticals online.²⁶ Inappropriate self-interpretation may prompt patients to seek unnecessary care, or worse, erroneously preclude them from seeking needed care because

Table 3 Direct-to-consumer medical tests with guideline support for use in screening

Identified screening test	Identified testing modality	Guidelines recommendation
Bone health		
Osteoporosis	Imaging	USPSTF supports for women >64 yo and younger women with significant risk factors with heel ultrasound and DXA ¹⁶
<ul style="list-style-type: none"> ● Heel ultrasound ● Dual-energy X-ray absorptiometry (DXA) ● Quantitative computed tomography (qCT) of spine 		American College of Radiology supports Heel ultrasound, DXA, and qCT of the spine ¹⁷
Breast health		
Breast cancer	Imaging	USPSTF supports for average risk women >50 yo and younger high-risk women ¹⁶
<ul style="list-style-type: none"> ● Mammography 		
Colorectal health		
Colon cancer	Faeces	USPSTF supports for adults 50–75 yo ¹⁶
<ul style="list-style-type: none"> ● Faecal occult blood testing 		
Diabetes health		
Diabetes	Blood	USPSTF supports for adults with hypertension ¹⁶
<ul style="list-style-type: none"> ● Fasting glucose ● Random glucose ● Haemoglobin A1C 		
General health		
Anaemia screening (complete blood count)	Blood	USPSTF supports for anaemia screening in pregnant women ¹⁶
Bacteruria	Urinalysis	USPSTF supports for pregnant women only ¹⁶
Celiac disease	Blood	American Gastroenterological Association ¹⁸ and American Dietetic Association ¹⁹ recommend screening for individuals with positive diagnosis in first-degree relative
Sexually transmitted diseases	Blood	USPSTF supports for syphilis screening in high risk and pregnant women, HIV screening for high-risk adults, Hepatitis B screening in pregnant women, Chlamydia/GC screening in high-risk women ¹⁶
<ul style="list-style-type: none"> ● Chlamydia/GC ● Hepatitis B ● HIV ● Syphilis 	Urine	
Vitamin D deficiency	Blood	National Guidelines Clearinghouse lists one recommendation supporting screening in distinct high-risk groups of patients. There are otherwise no official guidelines on this screening test ²⁰
Heart and lung health		
Abdominal aortic aneurysm	Ultrasound	USPSTF supports for men 65–75 yo who ever smoked ¹⁶
Cardiac disease	Echocardiogram	American College of Cardiologists and American Heart Association suggest that the benefits might slightly outweigh the risks for patients with known hypertension ²¹
Lipids	Blood	USPSTF supports for high-risk men 20–35 yo, average risk men >34 yo, high-risk women >20 yo ¹⁶

USPSTF, US Preventive Services Task Force; yo, years old; GC, Gonococcal

they believe a single test has precluded a positive result. Pre- and post-test counselling, even if offered, has its own limitations, and may not promote patient safety without adequate referral services to a medical professional. The vast majority of identified sites offered no pre- post-test counselling and consequently also did not offer any referral services following a test result. This lack of adequate patient follow-up and continuity of care could have significant adverse impact.

In general, abnormal results from DTC medical testing lead to further care for repeat testing, treatment or further investigation. Consequently, medical testing that is promoted in a fashion inconsistent with evidence-based

medicine is highly likely to lead to unnecessary resource waste, iatrogenic harm from downstream treatments or management, premature labelling of patients and excessive anxiety over testing results, while not improving health outcomes.

Legally, given that nearly all identified medical tests lack evidence to support use in the general population, online DTC advertising and/or sale of this testing as 'screening' or otherwise may be construed as false or misleading where it does not adequately reflect the risk versus benefit of use. This may represent violation of FDA regulations regarding advertisement and sale of DTC medical products.²⁷ Moreover, advertisements for DTC medical tests that

Table 4 Direct-to-consumer medical tests with guidelines against use in screening

Identified screening tests	Testing modality	Guidelines recommendation
Breast health Breast cancer ● Self breast examination (SBE) pads	Physical exam	USPSTF recommends against SBE ¹⁶
Colorectal health ● Faecal occult blood testing	Faeces	USPSTF recommends against colon cancer screening for adults >76 yo ¹⁶
General health Allergy screening ● IgE levels for various foods and allergens	Blood	American Academy of Allergy, Asthma, and Immunology recommends against the use of random or indiscriminate screening for allergies using serum testing, especially without correlation to history and physical examination ²²
Bacteruria	Urinalysis	USPSTF recommends against bacteruria screening in non-pregnant women and men ¹⁶
BRCA screening for breast/ovarian cancer	Blood	USPSTF recommends against BRCA screening in low-risk patients ¹⁶
CA-125 screening for ovarian cancer	Blood	USPSTF recommends against ovarian cancer screening with CA-125 ¹⁶
GI cancer ● CEA ● CA-19-9 ● CA-27-29	Blood	USPSTF recommends against pancreatic cancer screening with the use of serological markers: CEA, CA-19-9, CA-27-29 ¹⁶
Celiac disease	Blood	American Gastroenterological Association ¹⁸ and American Dietetic Association ¹⁹ recommend against population screening in asymptomatic and low risk patients
Full body imaging ● Non-contrast computed tomography (CT) ● Non-contrast magnetic resonance imaging (MRI) ● Electron beam CT (EBT)	Imaging	USPSTF recommends against pancreatic cancer screening, ovarian cancer screening, heart scan in low-risk patients ¹⁶ American College of Radiology (ACR) recommends against use of CT/MRI/EBT for screening purposes ¹⁷
Joint disease with orthopaedic imaging ● 3D CT arthrography	Imaging	ACR recommends against use of CT arthrography for screening or first-line diagnosis of most types of suspected joint pathology ¹⁷
Lead screening	Blood	USPSTF recommends against lead screening ¹⁶ in low-risk children and pregnant women
Lyme disease screening	Blood	Centers for Disease Control and Infectious Diseases Society of America recommends against lyme disease screening for the general population ²³
Sexually transmitted diseases ● Chlamydia/GC ● Hepatitis B ● Hepatitis C ● HIV ● Viral herpes	Blood Urine	USPSTF recommends against syphilis screening in patients at low risk for infection, HIV screening in low-risk patients, hepatitis B screening in low-risk patients, hepatitis C screening in low-risk patients, viral herpes screening for any patients, chlamydia/GC screening in low-risk women ¹⁶
Spinal disease ● Non-contrast MRI	Imaging	ACR recommends against use of this modality of spinal imaging in the absence of neurological signs or symptoms ¹⁷
Vitamin B ₁₂ deficiency screening	Blood	Centers for Disease Control recommends against B ₁₂ deficiency screening in the general population ²³
Heart and lung health Abdominal aortic aneurysm	Ultrasound	USPSTF recommends against screening in men 65–75 who never smoked and all women ¹⁶
Beta natriuretic peptide (BNP)	Blood	ACC/AHA recommend against the use of BNP to evaluate asymptomatic adults for heart disease ²¹
● Cardiac disease ● Non-contrast CT ● Electron beam CT ● Echocardiogram ● Electrocardiogram ● Non-contrast MRI ● CT angiography	Imaging	USPSTF recommends against screening in low-risk patients for EKG, non-contrast CT and electron beam CT ¹⁶ American College of Cardiology (ACC) and American Heart Association (AHA) recommend against use of CT or MRI for screening purposes and recommend against use of echocardiogram to screen in patients without known hypertension ²¹

Table 4 (Continued.)

Identified screening tests	Testing modality	Guidelines recommendation
Carotid artery stenosis Lipids	Ultrasound Blood	USPSTF recommends against ¹⁶ USPSTF recommends against screening in low-risk men <35 yo and all low-risk women ¹⁶
Nuclear magnetic resonance (NMR) lipoprofile	Blood	ACC/AHA recommend against the use of any lipoprofile beyond standard lipid screening for screening of cardiovascular disease ²¹
Peripheral arterial disease Pulmonary function tests Vertical auto profile (VAP) lipoprofile	Ankle Brachial Index Spirometry Blood	USPSTF recommends against ¹⁶ USPSTF recommends against ¹⁶ ACC/AHA recommend against the use of any lipoprofile beyond standard lipid screening for screening of cardiovascular disease ²¹
Prostate health Prostate cancer (PSA)	Blood	USPSTF recommends against screening in men >74 yo ¹⁶

USPSTF, US Preventive Services Task Force; BRCA, breast cancer; CEA, Carcinoembryonic antigen

Table 5 Direct-to-consumer medical tests with insufficient evidence for use in screening

Identified screening tests	Testing modality	Guidelines recommendation
Bone health Osteoporosis ● Heel ultrasound ● Dual-energy X-ray sbsorptiometry (DXA)	Imaging	USPSTF makes I Statement for all men ¹⁶
Breast health Breast cancer ● Digital mammography ● Magnetic resonance imaging	Imaging	USPSTF makes I Statement for both digital mammography and magnetic resonance imaging ¹⁶
Colorectal health Colon cancer ● Virtual colonoscopy with non-contrast computed tomography	Imaging	USPSTF makes I Statement ¹⁶
Diabetes health Diabetes ● Fasting glucose ● Random glucose ● Haemoglobin A1C	Blood	USPSTF makes I Statement for adults without hypertension ¹⁶
General health Anaemia screening (complete blood count) Drugs of abuse (nicotine, heroin, cocaine, marijuana, ecstasy, alcohol) <i>Helicobacter pylori</i> screening	Blood Blood Urine Hair Saliva Blood	USPSTF makes I Statement for children ¹⁶ USPSTF makes I Statement about screening with questionnaires. However, there is no guidance to direct the use of body fluid screening in patients ¹⁶ American Gastroenterological Association makes the statement that there is not enough data to support or advise against use ²⁴
Lead screening	Blood	USPSTF makes I Statement for lead screening in high-risk children ¹⁶
Lung disease ● Non-contrast computed tomography (CT) ● Electron beam CT ● X-ray	Imaging	USPSTF makes I Statement for high-risk patients ¹⁶
Sexually transmitted diseases ● Chlamydia/GC ● Hepatitis C	Blood Urine	USPSTF makes I Statement for hepatitis C screening in high-risk individuals and chlamydia/GC screening in high-risk men and low-risk pregnant women ¹⁶
Skin cancer screening	Dermoscopy	USPSTF makes I Statement for skin cancer screening by patient or by primary care physicians ¹⁶
Thyroid screening ● TSH ● T3 ● T4 ● T7	Blood	USPSTF makes I Statement ¹⁶

Table 5 (Continued.)

Identified screening tests	Testing modality	Guidelines recommendation
Heart health		
Cardiac disease	Imaging	USPSTF makes I Statement for high-risk patients ¹⁶
<ul style="list-style-type: none"> ● Non-contrast computed tomography (CT) ● Electron beam CT ● Electrocardiogram 		
Carotid intima media thickness	Ultrasound	USPSTF makes I Statement for high-risk patients ¹⁶
Coronary calcium score	Imaging	USPSTF makes I Statement for high-risk patients ¹⁶
<ul style="list-style-type: none"> ● Non-contrast computed tomography (CT) ● Electron Beam CT 		
Lipids	Blood	USPSTF makes I Statement for patients <20 yo with high risk for cardiovascular disease ¹⁶
Non-traditional cardiac risk factors	Blood	USPSTF makes I Statement for both HS-CRP and homocysteine ¹⁶
<ul style="list-style-type: none"> ● HS-CRP ● homocysteine 		
Prostate health		
Prostate cancer (PSA)	Blood	USPSTF makes I Statement for men <75 yo ¹⁶

US Preventive Services Task Force; TSH, thyroid-stimulating hormone; HS-CRP, high-sensitivity C-reactive protein

Table 6 Direct-to-consumer medical tests with no guidance for use in screening

Screening test identified	Testing modality	Guidelines searched
Atrial fibrillation	Imaging	USPSTF National Guideline Clearinghouse American College of Cardiology American Heart Association
<ul style="list-style-type: none"> ● Electrocardiogram ● Echocardiogram 		
Breast cancer screening	Imaging	USPSTF National Guidelines Clearinghouse American College of Radiology American Cancer Society (ACS) <i>ACS states on their website that thermography should not be used as a substitute for mammography</i> ²⁵
<ul style="list-style-type: none"> ● Thermography 		
Co-Q10	Blood	USPSTF American College of Cardiology American Heart Association
Dental screening	Imaging	USPSTF National Guideline Clearinghouse American Dental Association
<ul style="list-style-type: none"> ● Non-contrast computed tomography 		
Diabetes screening	Urine	USPSTF National Guidelines Clearinghouse American Endocrinologic Association American Diabetes Association None of the guidelines making recommendations on screening for diabetes consider urine testing for screening purposes
<ul style="list-style-type: none"> ● Glucose 		
Female hormones	Saliva	USPSTF National Guidelines Clearinghouse American College of Obstetrics and Gynecology
Finger stick testing	Blood	Finger stick blood testing has not been discussed in any guidelines as an effective modality of screening patients for disease
Various including lipids, Hg A1c, random glucose, fasting glucose, HS-CRP		
Home testing kits	Varying	Home testing kits have not been discussed in any guidelines as an effective modality of screening patients for disease
Various including bacteruria, diabetes, drugs of abuse, colon cancer, male hormones, female hormones, sexually transmitted diseases		

Table 6 (Continued.)

Screening test identified	Testing modality	Guidelines searched
Drugs of abuse Body fluid testing for: alcohol, cocaine, ecstasy, heroin, nicotine	Varying	USPSTF National Guidelines Clearinghouse USPSTF does give recommendations for screening for drugs of abuse with questionnaires but does not discuss body fluid testing as a screening modality for drugs of abuse.
Male hormones	Saliva	USPSTF National Guidelines Clearinghouse
Virtual arteriography ● 3D computed tomography	Imaging	USPSTF National Guidelines Clearinghouse American College of Cardiology American Heart Association American College of Radiology
Virtual bronchoscopy ● 3D computed tomography	Imaging	USPSTF National Guidelines Clearinghouse American College of Chest Physicians American College of Radiology
Various blood testing includes ABO/Rh blood type, Alpha fetoprotein, alkaline phosphatase, ALT, amylase, ANA, anti-SM antibodies, antioxidants, AST, beta carotene, cortisol, electrolytes, female hormones, folate, heavy metals, iron, lipase, magnesium, male hormones, parathyroid hormone, RF, selenium, vitamin A, vitamin B ₆ , vitamin C, vitamin E, vitamin K	Blood	USPSTF National Guidelines Clearinghouse

USPSTF, US Preventive Services Task Force; ALT, alanine transaminase; ANA, antinuclear antibody; AST, aspartate transaminase; SM, Smooth muscle; HS-CRP, high-sensitivity C-reactive protein

include potentially fraudulent or misleading statements regarding efficacy and/or utility⁶ also implicate US state and federal consumer protection laws.^{28,29}

Recommendations for reform

Collectively, the limited scientific support, lack of patient/consumer safety protections and legal concerns necessitate multistakeholder actions to address this burgeoning industry. Like illicit online pharmacies, unregulated online advertisement, sale and administration of DTC medical testing poses a threat to public health and inappropriately fuels health expenditures.^{1,6–8} Yet medical screening tests, if evidence-based and used appropriately with patient safety safeguards, can promote and inform health and education. Hence, efforts to collect outcomes data, create public awareness, highlight best practices for the DTC medical testing industry and implement a robust regulatory regimen to promote responsible access to DTC medical screening tests should be explored.

Collecting outcomes data are an essential first step in addressing the DTC medical testing industry. As seen via evidence-based guidelines based on outcome data, unnecessary screening with many of these medical tests will lead to downstream harms within traditional medical practice. In addition to known harms from false-positive/negative results and iatrogenic harms from widespread testing, it is probably that there are additional harms related to a lack of informed consent and follow-up in the DTC medical testing industry. While there are few case reports detailing severe anxiety and hopelessness of consumers after being given results of DTC genetic screening tests,³⁰ larger outcome based studies evaluating DTC testing harms, downstream intervention harms and costs are needed.

Secondly, DTC medical testing companies should be limited to offering medical screening as a public health service, in an organized manner, according to a specified protocol, requiring medical professional oversight, appropriate pre-test evaluation, post-test counselling for people with positive testing results, availability of diagnostic services and diagnostic support and treatment, and service monitoring.⁴ Indeed, where medical testing is being advertised and offered DTC without appropriate medical professional oversight, it should be prosecuted by US state Attorney Generals and organized medical associations as the unauthorized practice of medicine. DTC medical testing companies should be limited to offering only outcomes proven medical screening tests endorsed by professional screening bodies. In addition, where online advertisements could be construed as fraudulent, misleading or lacking appropriate evidence-based risk/benefit information, companies should be sanctioned.

Because of the national scope of this DTC medical testing industry, the FDA should be a primary driver for regulation and oversight in the US FDA involvement here is consistent with draft guidance indicating oversight of tests that: ‘might use measured or observed values of multiple variables, such as a patient’s age, weight, metabolite level, and gene expression levels.’³¹ FDA oversight could include guidance and surveillance of websites advertising and selling DTC screening tests,¹² including requiring DTC testing companies be FDA-registered under a programme verifying federal certification for engagement in medical testing sale and administration.

The combination of these safeguards would ensure companies selling DTC screening tests in the US are legitimate, tests are evidence-based, patients are informed, counselling is available, and that marketing is responsible, monitored by regulators, and appropriately reflects screening test risks

and benefits. Importantly as well, providing accessible consultation by a medical professional would alleviate the burden on patients in interpreting confusing (especially abnormal) results, and would allow patients to make more informed decisions regarding health care and screening test purchase and follow-up care. DTC medical testing in combination with the unprecedented increase in Internet access and illicit pharmaceutical activity has now moved the health-care arena into uniquely troubling waters. Society now faces unfettered diagnosis and treatment completely peripheral to professional guidance, creating the potential for a medical delivery system promoting patient self-diagnosis and self-treatment that may be inaccurate, ineffective, potentially harmful and resource wasteful. This safety risk is growing as DTC sale and online advertisement of medical resources expands and regulation lags.

Study limitations

There are several limitations to this study. First, our study methodology did not capture various previously identified DTC tests such as genetic testing and fetal ultrasound imaging.^{7,32} This implies, however, that there are probably more suspect DTC tests available than those identified here. In addition, our methodology did not address actual utilization of online DTC screening test services, making it difficult to quantify the public health and patient safety impact; however, the continued existence of these companies offering such a spectrum of medical tests implies that there is a lucrative market keeping companies financially viable and tests available. Finally, the Internet is a rapidly changing, dynamic environment, and our assessment was limited to data from the specific time periods when we performed searches.

CONCLUSION

Online advertising and access to DTC medical products has made screening tests readily available to consumers without the need of a prescription or medical consultation and without adequate clinical follow-up. The scope of DTC medical testing advertised online is broad and most available medical tests have limited evidentiary support. Companies offering DTC medical tests fail to provide for informed consent, pre-/post-test counselling or follow-up care, creating substantial risks to patient safety and legal concerns. Reform is needed to address this growing public health risk.

Authors' affiliations

Kimberly M Lovett, Kaiser Permanente; Department of Family and Preventive Medicine, University of California, San Diego School of Medicine; Institute of Health Law Studies, California Western School of Law; San Diego Center for Patient Safety, University of California, San Diego School of Medicine, San Diego, CA, USA

Timothy K Mackey, Institute of Health Law Studies, California Western School of Law; Joint Doctoral Program in Global Health, University of California, San Diego-San Diego State University; San Diego Center for Patient Safety, University of California, San Diego School of Medicine, San Diego, CA, USA

Bryan A Liang, Institute of Health Law Studies, California Western School of Law; Department of Anesthesiology, University of

California, San Diego School of Medicine; San Diego Center for Patient Safety, University of California, San Diego School of Medicine, San Diego, CA, USA

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