# PERSPECTIVES

TRANSLATIONAL GENETICS — VIEWPOINT

## The future of direct-to-consumer clinical genetic tests

*Felix W. Frueh, Henry T. Greely, Robert C. Green, Stuart Hogarth and Sue Siegel*

Abstract | In light of the meeting of the US Food and Drug Administration (FDA) in March 2011 to discuss the regulation of clinical direct-to-consumer (DTC) genetic tests, we have invited five experts to consider the best means of overseeing the ordering and interpretation of these tests. Should these tests be regulated? If so, who, if anyone, should communicate results to consumers?

*What are the risks and benefits of offering clinical genetic tests to consumers directly, compared to more traditional means?*

**Felix W. Frueh.** We have to distinguish between tests that are used to make a potentially very critical clinical decision and tests that are used to assess more general genetic information such as lifetime disease risk. For the latter, recent reports (for example, the REVEAL study[1] and the Scripps/Navigenics study[2]) indicate that the risk of providing genetic information to consumers is significantly smaller than anticipated. While these early data may be limited and do not necessarily reflect all of the aspects around direct-to-consumer (DTC) genetic testing, I view these results as indicative of a very different risk: the risk of overprotecting. I argue that a consumer who is interested in these tests is also likely to be interested in understanding the results — be that by accessing the information portals provided with the tests, by doing research themselves or by engaging with an expert as the consumer sees necessary. Consumers act on their free will when purchasing such tests, and we trust consumers with direct access to many other tests that are of equal or higher relevance (for example, pregnancy testing). Consumers need appropriate and adequate information about what genetic information can and cannot reveal, but they do not need to be protected from being able to access their own genetic information if they would like to.

**Henry T. Greely.** Potential benefits come from the fact that people will not need a doctor's approval to get test results — and so do the harms.

More people will get genetic test results if they don't need a doctor's approval, especially when spurred by advertising by the for-profit DTC industry. That might improve their health.

But DTC testing also means people will not necessarily get a doctor's help in ordering the test or understanding its results. Most people — though perhaps not the genetics enthusiasts who currently support the DTC industry — know so little about genetics that, for them, genetic information without expert explanation may do more harm than good.

A woman learns that she is negative for *BRCA1* and *BRCA2* mutations and hence does not have the high genetic risks for breast cancer conferred by these variants. She might stop getting mammograms, but such an ill-informed action could be fatal. She is not at high genetic risk, but the results lower her overall risk only trivially below average. Requiring professional advice could limit that kind of mistake. It might also help prevent, or lessen, an epidemic of the 'worried well', who spend time and money and become overanxious about their health (at some risk) to follow up on weak genetic findings.

**Robert C. Green.** There is considerable speculation, but little data, about the benefits and harms of DTC testing. Most DTC genetic tests sample common variants and offer risk estimates that do not move individuals from one established risk category to another and, therefore, do not change recommended medical practices. In addition, estimates based upon genetic markers that ignore family history, environmental factors, lifestyle choices and ethnicity may be misleading. Thus, the potential harms of DTC testing include psychological distress and misunderstanding of actual risks, leading to either false reassurance or the possibility of unnecessary medical procedures. Potential benefits include the intrinsic value of self-knowledge and the possibility that this novel milieu for health education will motivate improved health behaviours.

A body of knowledge is slowly accruing about the benefits and harms of disclosing susceptibility genes for common complex disorders. Thus far, there is little evidence that health behaviours or health outcomes are improved[3,4]. Distress appears uncommon[1,2], but there is evidence that genetic risk information may be utilized to guide non-medical decisions[5–7]. Some false reassurance probably occurs[8], and self-perceived risk is strongly anchored and not-so-easily altered by genetic results[9]. As we begin to study actual DTC consumers, we must keep in mind that they are self-selected early adopters who may not fully reflect the behaviour of future consumers.

As consumer genetics companies expand into monogenic disease testing, the potential benefits and harms could be amplified. The opportunity for consumers to discover highly penetrant mutations could transform pre-conception screening and allow life-saving surveillance for syndromes such as cancer or cardiomyopathy. Yet errors or misunderstandings in these cases would have higher costs. Such offerings presage an impending future when genome sequencing will be readily available, and the variable penetrance and expressivity of established mutations — along with the even greater uncertainty associated with novel variants — will require nuanced interpretation and clinical guidance. Careful interpretation and guidance is the hallmark of traditional genetics practitioners, but is harder to imagine in a DTC model.

**Stuart Hogarth.** The risks and benefits of DTC genetic testing vary depending on the type of test on offer.

Most consumer genetics companies offer tests for susceptibility to common diseases. Many scientists and clinicians believe these tests are a waste of time and money; however, their lack of utility is independent of whether a doctor is involved in the offer and delivery of the test.

A small proportion of DTC companies offer more traditional clinical genetic tests for a range of monogenic disorders, such as cystic fibrosis. These tests are extremely valuable, but there is widespread international support for the view that they should be offered only in the context of medical supervision and with appropriate genetic counselling. This principle is central to the guidelines developed by the Organisation for Economic Co-operation and Development (OECD) and the Protocol on Genetic Testing produced by the Council of Europe.

**The contributors***

Felix W. Frueh is President of the Medco Research Institute in Bethedsa, Maryland, USA. He leads Medco's peer-reviewed research initiatives and collaborations, examining how new developments in science can improve the safety and efficacy of prescription drug care. He joined Medco in 2008 as vice president of Medco's personalized medicine research and development organization. Prior to joining Medco, he was Associate Director for Genomics at the US Food and Drug Administration (FDA) and held senior positions at Stepoutside Consulting, Transgenomic and Protogene Laboratories. He is a Member of the Board of the Personalized Medicine Coalition and holds an Adjunct Faculty position at the Institute for Pharmacogenomics and Individualized Therapy (IPIT) at the University of North Carolina (UNC), USA.

Henry T. Greely is the Deane F. and Kate Edelman Johnson Professor of Law, Professor, by courtesy, of Genetics and Director of the Center for Law and the Biosciences at Stanford University, California, USA. His work focuses on ethical, legal and social implications of biosciences, especially human genetics, neuroscience and stem-cell research. He chairs the California Advisory Committee on Human Stem Cell Research and, from 2007 to 2010, he was a co-director of the Law and Neuroscience Project. In genetics, he currently works on issues around non-invasive prenatal genetic diagnosis, the clinical use of whole-genome sequencing and the ethics of genomic biobanks.

Robert C. Green is a physician–scientist whose research interests are in translational genomics and health outcomes. He is Associate Director for Research of the Partners Center for Personalized Genetic Medicine, Clinical Research Director in the Division of Genetics at the Department of Medicine at Brigham and Women's Hospital, and Associate Professor of Medicine at the Harvard Medical School, all based in Boston, Massachusetts, USA. He directs the REVEAL (Risk Evaluation and Education for Alzheimer's Disease) Study (HG02213), a multi-centre project in which over 1,000 individuals have been collectively enrolled in randomized clinical trials to explore emerging themes in translational genomics. Along with joint-principal investigator Scott Roberts, he is directing the first US National Institutes of Health study (HG005092) to prospectively examine the impact of consumer-based personal genomics services.

Stuart Hogarth is a member of the Global Biopolitics Research Group in the Department of Political Economy at King's College London, UK. Stuart has a long-standing interest in the regulation of genetic testing and has produced policy reports on this topic for Health Canada, the UK Human Genetics Commission (HGC) and the European Commission. He participated in the drafting of the Organisation for Economic Co-operation and Development's guidelines on quality assurance for molecular genetic testing and the HGC's Common Framework of Principles for DTC genetic testing. He is continuing his work in this area as a member of the FP7 EuroGentest network.

Sue Siegel is a General Partner at Mohr Davidow, a top-tier Silicon Valley venture firm in California, USA, leading investments in companies involved in personalized medicine, life sciences and health care. Prior to her venture-capital career, she spent over 20 years growing biomedical companies (including Bio-Rad, DuPont and Amersham (now GE Healthcare)) through technology leadership as a corporate professional. Until 2005, as President and board member of Affymetrix, Inc., a company recognized for pioneering GeneChip technology, she focused on accelerating the advent of personalized medicine. Currently, she serves as a board member at Crescendo Biosciences, Corventis, Inc., Navigenics, On-Q-ity, Pacific Biosciences and RainDance Technologies. She completed her masters degree in biochemistry at Boston University Medical School, Massachusetts, USA.

*Listed in alphabetical order.

**Sue Siegel.** Early research suggests that genetic knowledge may motivate and improve consumer compliance with recommended health screening, without generating anxiety from revealing predisposition to disease. The Scripps Genomic Health Initiative, an ongoing 20-year study to assess the behavioural impact of personal genetic testing, has found a positive correlation between disease susceptibility risk as revealed by the tests and consumers' intent to be screened with medical tests, such as mammograms and colonoscopies[2]. Furthermore, the vast majority of study participants have not experienced any heightened state of anxiety as a result of receiving genetic information, regardless of their measured genetic risk.

Additionally, we know that some genetic associations carry similar, if not greater, relative risk indications than other more traditional clinical risk factors. For example, 9p21 — a SNP correlated with myocardial infarction — carries a 1.68 risk factor as compared with a family medical history of myocardial infarction (1.52)[10–13] (for more information, see the Navigenics white paper). Such risk indications may provide further personal motivation to engage in behaviour change and increase prevention-oriented health and wellness practices on a regular basis.

Given that this field is still evolving, there is a need to further investigate the effectiveness of these tests as compared with traditional clinical methodologies. Early findings, however, are promising and substantiate the widely held belief that consumers have a right to understand the impact of their personal genomes on their health.

**Q** *What would be the fairest and safest way to regulate DTC genetic tests?*

**F.W.F.** DTC genetic tests are a medical device or tool and should be regulated. We have experience with other DTC tests (I mentioned pregnancy testing above) and we have experience with over-the-counter drugs. In all of these cases, a risk-based approach is used to determine how to regulate the product. The question, of course, is how risk is being defined, which goes back to your first question. The risk for DTC genetic tests is in information that could have tremendous significance in choosing a clinical path (for example, information about *BRCA1* and *BRCA2* mutation status). While I believe that consumers should have direct access to this information if they wish, the information should be provided in context and with background for adequate

interpretation of the result. The specific use of a test or test result to guide a medical decision (for example, a mastectomy in the case of the *BRCA* example) should be initiated by a health professional and be based on results from a validated and appropriately regulated test performed for this purpose. This is not unusual: a second, more rigorous test is often performed before a significant medical intervention is undertaken, hence the DTC genetic test could be viewed as a general screening tool. If the results are intended to be used for a clinical decision, they may have to be verified in a second test that was validated for this specific purpose.

**H.T.G.** First, we should make health-related genetic tests 'restricted devices' available only on order by a health professional. This would eliminate DTC tests, but would allow conventional genetic tests — the ones that currently help patients.

The US Food and Drug Administration (FDA) should then create a process to require proof that specific genetic tests, even when ordered by physicians, are 'safe and effective'. The statute sets this standard for all medical devices, including diagnostic tests. In the past, the FDA exempted so-called 'laboratory-developed tests', but those tests were almost always ordered through doctors. I would not require clinical trials, though that would be within the FDA's power. Instead, I would require proof that each genetic test has both analytical and clinical validity — that it correctly detects the genetic variation of interest and that there is good reason to believe that the genetic variation is associated with a particular health condition. Analytic validity requires both approving the testing method as a medical device and regulating the test site under the Clinical Laboratory Improvement Amendments (CLIA). The FDA could assess clinical validity from the submission of adequate and replicated peer-reviewed findings or from conclusions by professional groups or consensus conferences.

The FDA should then consider whether some DTC genetic tests should be allowed, because, like other over-the-counter devices (such as home pregnancy tests), they can be used safely and effectively without professional help.

**R.C.G.** All forms of genetic testing — medical or non-medical, traditional or DTC — should be regulated to ensure analytic validity, to maintain appropriate safeguards for sample handling and to avoid exaggerated and false marketing. CLIA should be modernized to consider the special circumstances involved in genetic testing[14,15]. The calculation of risk estimates should be transparent and, as suggested in recent discussions of a US National Institutes of Health Genetic Testing Registry, test developers should provide more complete and easily accessible information[16]. Genetic tests for traits unrelated to health need not be further regulated.

The question of whether health-care professionals should be required for the ordering and interpretation of genetic tests related to reproductive planning, pharmacogenetics or disease risk is more complex. The safest scenario would seem to require clinician involvement but, since empirical data on benefits and harm are unavailable, such broad regulation might stifle technical innovation and alienate individuals who favour proactive information-seeking, either out of curiosity or in pursuit of health and wellness.

DTC genetic testing has arisen at a historical moment when multiplex testing technologies are becoming affordable but are not yet fully integrated into clinical medicine, and when genetic information is still largely misunderstood as overly deterministic. As the limits and benefits of genetic tests become better understood, we can expect a subset of genetic tests to join other medical tests in being routinely reported by laboratories to clinicians. The clinicians will, in turn, utilize that information in conjunction with the symptoms, family history and physical examination of the individual being tested. At that point, DTC testing may be less relevant. In the meantime, this transitional era demands respect for authentic innovators, in conjunction with judicious collection of empirical data on benefits and harms and, of course, an open mind.

**S.H.** We need a risk-based approach to regulation of genetic tests but there should be some minimum common requirements that all tests must meet. Many of these are set out in the Guiding Principles document developed by the UK Human Genetics Commission (HGC). For instance, laboratory quality assurance should be mandatory, and there should be clear standards regarding the type of information that is provided to consumers.

However, while I have long advocated the use of information-disclosure mechanisms to encourage transparency, I think we need independent control to verify the quality of companies' information in order to ensure that consumers are not being misled. Like the HGC (and both its US counterpart, the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) and SACGHS's predecessor body, the Secretary's Advisory Committee on Genetic Testing (SACGT)), I believe that this is most easily achieved through the regulatory frameworks for *in vitro* diagnostic (IVD) devices. Commercial genetic tests, whether offered DTC or not, should be treated as medical devices and be subject to independent pre-market evaluation to ensure that they meet basic standards for analytical and clinical validity. This latter point is important in terms of fairness — the IVD industry needs a level playing field. It is wrong that, in the United States, companies making test kits have to gain FDA approval, but companies commercializing their products as laboratory-developed tests do not. Industry exploitation of this loophole has grown over time, not least in the consumer genetics space. The FDA has now clearly signalled its intent to address this issue.

However, these basic standards will not always be sufficient; some tests pose greater risks and should be subject to stricter regulation. The question of which tests should be available DTC and which should only be available via a medical consultation is one on which opinions vary widely (not least among consumer genetics companies, many of whom only offer susceptibility or nutrigenetic testing). I believe that pharmacogenetic testing and clinical genetic testing for monogenic disorders and high-risk familial subsets of common diseases (for example, *BRCA1* and *BRCA2* testing for breast cancer) should only be available via a medical consultation and with appropriate genetic counselling. In many cases, susceptibility testing could be offered DTC, but we need to look carefully at serious or potentially fatal diseases.

Some argue that such an approach is paternalistic and infringes individuals' rights to unfettered access to their genomes. However, the fact is that consumer-genetics companies themselves act as gatekeepers. They control access to our genomic data by setting standards on what they report, how they report it, who they report it to, how much their service costs and through efforts to keep competitors out of the market. We can argue the merits of who is best placed to act as genomic gatekeeper, but let's not pretend that the choice we face is between gatekeepers or unmediated access.

**S.S.** The FDA has considered how to regulate genetic tests since the Human Genome Project began over 30 years ago. At that time, genetic tests were available for approximately

one hundred monogenic diseases, such as Tay–Sachs disease and cystic fibrosis. As genomic technologies have advanced, tests are now available for a wider range of multigenic, common diseases.

The FDA is now developing a specific framework to ensure validity for the genetic technologies used in supporting such multigenic genetic testing. In support of the FDA framework, I submit a set of at least five standard practice guidelines for the personal genomics industry, including criteria for performance, service and quality:

- Validity, accuracy and quality. Tests must be run in a CLIA-certified laboratory and in accordance with state and federal regulations. All genetic associations and predispositions must be statistically validated and peer-reviewed.
- Clinical relevance. Information provided to the consumer should be vetted by a team of clinically trained reviewers, with content screened by leading medical institutions.
- Actionability. There must be valid clinical or scientific information available to demonstrate an ability to prevent, delay or enhance treatment options for an included health condition.
- Genetic counselling. Any service that provides genetic testing to individuals must provide access to genetic counsellors to facilitate understanding of the implications of their particular profile.
- Security and privacy. Genetic-testing services must ensure that only the individual member has access to their profile and has complete control over granting access to others. These services must operate in a manner consistent with the Health Insurance Portability and Accountability Act (HIPAA) regulations.

**Q** *What should be the role of health professionals?*

**F.W.F.** The most important role for the health professional will be to ensure that the consumer understands that the genetic information he or she has just received must be viewed in the context of many other factors. Pointing to these factors and providing the context for the genetic information should be the focus of this discussion. A health professional in this context can be a doctor, a nurse, a pharmacist or anyone who is familiar with and can explain the meaning of a DTC test or test result to a layperson. Their support and engagement can be crucial for these tests to be used appropriately and responsibly. I expect, however, that there will be many consumers who will not seek the advice of a health professional — current experience from DTC genetic testing companies indicates that a large portion of consumers does not engage with a health professional and no adverse impact of this non-engagement has been seen. We should make it as easy as possible for consumers to seek the advice of a health professional, but should not force them to.

**H.T.G.** In the short run, almost all health-related genetic tests should require an order from a doctor (or other appropriate professional) in a legitimate professional relationship with the tested person. I say "almost all" because there are a few circumstances where a doctor–patient relationship does not exist: as in mandatory neonatal testing, where there is no relationship, or prenatal testing, where the tested fetus is not the patient. In the longer run, the FDA might approve selected tests for DTC use with no required professional involvement.

Ultimately, even a doctor–patient relationship will not be enough. For most genetic testing, particularly with the rise of multiplex methods such as whole-genome sequencing, we will need to come up with better ways than 'a talk with their doctor' to help patients understand the massive amounts of complicated information that genomics will give them. There just won't be enough knowledgeable doctors, clinical geneticists, genetic counsellors, time or money to provide full, individual discussion of all meaningful results. These methods will have to incorporate video and web technologies but should still require some degree of personal — preferably face-to-face — counselling from health professionals.

**R.C.G.** Health professionals and their representative organizations should acknowledge that the traditional clinical relationship between patient and health-care provider is now only one of many ways in which individuals obtain personal health-related information. This is particularly true for risk information that could be used predictively and preventively. Health-care professionals will remain the major licensed avenue for accessing prescription medications, medical surveillance and medical interventions and so are likely to act as sensible gatekeepers for these services even if individuals obtain risk information from other sources. While some have expressed concern that consumers armed with DTC risk profiles could cause clinicians to unnecessarily increase health-care costs[17], this issue transcends DTC testing and will increasingly apply in the near future when predictive biochemical or imaging biomarkers, as well as extensive genomic sequence information, become integrated into future models of clinical medicine.

In the meantime, health professionals should communicate and form constructive partnerships with bodies that seek to educate the lay public about genetics and health, including professional medical genetic organizations and DTC genetic testing companies[18]. One of the societal benefits of providing genetic testing directly to consumers may be the accelerated transformation of the medical model towards increasingly more personalized, preventative and evidence-based care.

**S.H.** Health professionals should support patient access to high-quality, useful genetic tests through our established health-care systems, encourage scepticism about tests of dubious utility and advocate for responsible regulation. Professional bodies should take a lead in providing high-quality, independent information for consumers.

**S.S.** Physicians play an essential role in health, wellness and patient care. Personal genomics, however, is a new and evolving field that many physicians have yet to incorporate into their practices. Most health professionals understandably have difficulty keeping pace with today's rapid advances in genomics. Given this gap, I believe that the best model focuses on board-certified genetic counsellors. Genetic-counselling sessions made available during all phases of the testing experience — both to physicians and to patients — are a critical part of any personalized genetic-testing service.

Genetic counsellors are highly trained professionals who help patients and clinicians understand genotypic information and make it relevant to individual health and prevention decisions. They are the point of translation of genetic information and understand the intersection of genetic science, clinical medicine and personal understanding. Their involvement is essential to any high-quality, useful and ethical genetic-services offering.

*Felix W. Frueh is at the Medco Research Institute, Medco Health Solutions, Inc., 7315 Wisconsin Ave. Ste 1050E, Bethesda, Maryland 20814, USA.*
*e-mail: felix_frueh@medco.com*

*Henry T. Greely is at the Stanford Law School, Crown Quadrangle, 559 Nathan Abbott Way, Stanford, California 94305-8610, USA.*
*e-mail: hgreely@stanford.edu*

*Robert C. Green is at the Partners Center for Personalized Genetic Medicine, Division of Genetics, Department of Medicine, Brigham and Women's Hospital and Harvard Medical School, 41 Avenue Louis Pasteur, Suite 301, Boston, Massachusetts 02115, USA.*
*e-mail: rcgreen@genetics.med.harvard.edu*

*Stuart Hogarth is at the Global Biopolitics Research Group, Department of Political Economy, King's College London, Strand Campus, London WC2R 2LS, UK.*
*e-mail: stuart.hogarth@kcl.ac.uk*

*Sue Siegel is at Mohr Davidow, 3000 Sand Hill Road, 3-290 Menlo Park, California 94025, USA.*
*e-mail: ssiegel@mdv.com*

doi:10.1038/nrg3026
Published online 1 June 2011

1. Green, R. C. *et al.* Disclosure of *APOE* genotype for risk of Alzheimer's disease. *N. Engl. J. Med.* **361**, 245–254 (2009).
2. Bloss, C. S., Schork, N. J. & Topol, E. J. Effect of direct-to-consumer genomewide profiling to assess disease risk. *N. Engl. J. Med.* **364**, 524–534 (2011).
3. McBride, C. M., Koehly, L. M., Sanderson, S. C. & Kaphingst, K. A. The behavioral response to personalized genetic information: will genetic risk profiles motivate individuals and families to choose more healthful behaviors? *Annu. Rev. Public Health* **31**, 89–103 (2010).
4. Marteau, T. M. *et al.* Effects of communicating DNA-based disease risk estimates on risk-reducing behaviours. *Cochrane Database Syst. Rev.* **2010**, CD007275 (2010).
5. Zick, C. *et al.* Genetic testing for Alzheimer's disease and its impact on insurance purchasing behavior. *Health Aff. (Millwood)* **24**, 483–490 (2005).
6. Taylor, D. Jr *et al.* Genetic testing for Alzheimer's and long-term care insurance. *Health Aff. (Millwood)* **29**, 102–108 (2010).
7. Vernarelli, J. A. *et al.* Effect of Alzheimer's disease genetic risk disclosure on dietary supplement use. *Am. J. Clin. Nutr.* **91**, 1402–1407 (2010).
8. LaRusse, S. *et al.* Genetic susceptibility testing versus family history-based risk assessment: impact on perceived risk of Alzheimer disease. *Genet. Med.* **7**, 48–53 (2005).
9. Linnenbringer, E., Roberts, J., Hiraki, S., Cupples, L. & Green, R. "I know what you told me, but this is what I think:" perceived risk of Alzheimer disease among individuals who accurately recall their genetics-based risk estimate. *Genet. Med.* **12**, 219–227 (2010).
10. Helgadottir, A. *et al.* A common variant on chromosome 9p21 affects the risk of myocardial infarction. *Science* **316**, 1491–1493 (2007).
11. Samani, N. J. *et al.* Genomewide association analysis of coronary artery disease. *N. Engl. J. Med.* **357**, 443–453 (2007).
12. Mainous, A. G. *et al.* A coronary heart disease risk score based on patient-reported information. *Am. J. Cardiol.* **99**, 1236–1241 (2007).
13. Wilson, P. W. *et al.* Prediction of coronary heart disease using risk factor categories. *Circulation* **97**, 1837–1847 (1998).
14. Hudson, K. L. Genetic testing oversight. *Science* **313**, 1853 (2006).
15. Javitt, G. & Hudson, K. Federal neglect: regulation of genetic testing. *Issues Sci. Technol.* **22**, 59–66 (2006).
16. Javitt, G., Katsanis, S., Scott, J. & Hudson, K. Developing the blueprint for a genetic testing registry. *Public Health Genomics* **13**, 95–105 (2010).
17. McGuire, A. & Burke, W. Raiding the medical commons: an unwelcome side effect of direct-to-consumer personal genome testing. *JAMA* **300**, 2669–2671 (2008).
18. Evans, J. P. & Green, R. C. Direct to consumer genetic testing: avoiding a culture war. *Genet. Med.* **11**, 1–2 (2009).

**Acknowledgements**
R.C.G. would like to acknowledge funding from the National Human Genome Research Institute of the National Institutes of Health.

**Competing interests statement**
S.S. declares competing financial interests: see Web version for details.

## FURTHER INFORMATION

**Felix W. Frueh's homepage:** www.medcoresearchinstitute.com
**Henry T. Greely's homepage:** http://www.law.stanford.edu/directory/profile/27/
**Robert C. Green's homepage:** http://www.brighamandwomens.org/Research/depts/Medicine/genetics/Pls/green/default.aspx
**Stuart Hogarth's homepage:** http://www.kcl.ac.uk/schools/sspp/politicaleconomy/people/hogarth.html
**Sue Siegel's homepage:** http://www.mdv.com/who-we-are/sue-siegel
**A Common Framework of Principles for Direct-to-Consumer Genetic Testing Services (Human Genetics Commission document):** http://www.hgc.gov.uk/UploadDocs/DocPub/Document/Principles%20consultation%20final.pdf
**Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Genetic Testing for Health Purposes:** http://conventions.coe.int/Treaty/en/Treaties/html/203.htm
**Applying Preventive Genomic Medicine in Clinical Practice (Navigenics white paper):** http://www.navigenics.com/static/pdf/physician/physician-whitepaper.pdf
**Clinical Laboratory Improvement Amendments (CLIA):** http://wwwn.cdc.gov/clia/default.aspx
**Human Genetics Commission:** http://www.hgc.gov.uk
***Nature Reviews Genetics* series on Translational Genetics:** http://www.nature.com/nrg/series/translation/index.html
**Organisation for Economic Co-operation and Development:** http://www.oecd.org
**Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS):** http://oba.od.nih.gov/SACGHS/sacghs_home.html
**Secretary's Advisory Committee on Genetic Testing (SACGT):** http://oba.od.nih.gov/SACGHS/sacgt_info.html

**ALL LINKS ARE ACTIVE IN THE ONLINE PDF**

ONLINE ONLY

**Subject categories**
Disease genetics, Technology, Ethics, Nucleic acid sequencing

**ToC blurb**

000 **The future of direct-to-consumer clinical genetic tests**

*Felix W. Frueh, Henry T. Greely, Robert C. Green, Stuart Hogarth and Sue Siegel*

Direct-to-consumer (DTC) genetic tests allow individuals to learn about their health or that of their future offspring. Should we protect individuals from potentially misleading genetic information about themselves or should we assume that adults who seek DTC services can interpret the genetic findings even without the intervention of a health professional? We present five different perspectives on whether DTC genetic tests should be regulated and, if so, how.

**Competing interests statement**
Sue Siegel is a member of Mohr Davidow, a Silicon Valley venture-capital firm, who are shareholders in Navigenics, Inc.