

Eye on DNA | How will it change your life?

Direct-To-Consumer Genetic Tests - Good or Evil?

by [Dr. Hsien-Hsien Lei](#)

Posted April 4, 2008 in [DNA Testing](#)

[Email this](#) • [Stumble It!](#) • [Digg This!](#) • [Discuss on Newsvine](#)

Direct-to-consumer genetic testing companies will have a lot to mull over this weekend after the publication of a Genetics and Public Policy Center [case study of personalized medicine](#) in Science. The authors examined the use of CYP450 testing in the selection and dosage of SSRI drugs for depression and come up with some [general recommendations](#) for the regulation of direct-to-consumer genetic testing.

- Enhanced enforcement by the Federal Trade Commission against misleading claims. The agency has that authority, the researchers said, but it has “has not been a priority.”
- Development of a mandatory registry for those offering genetic tests. They would be required to submit data supporting the intended use of the tests to a publicly accessible database.
- FDA oversight of laboratory-developed tests, as opposed to those sold as a kit, which are already regulated by the agency.

[Genelex](#), one of the companies criticized for selling direct to consumers, has already responded on [their blog](#) (also a member of [The DNA Network](#)):

Genelex's Position:

- Individuals have a right to learn their genotype and control that information. If patients are denied direct access to this testing they may be reluctant to be tested because they are not confident that the confidentiality of the test results will be adequately protected.

- Excessive regulation, such as is advocated by the Genetics and Public Policy Center, will impede the already excessively slow rate of adoption of DNA testing for use in medication management. Were this testing adopted at a faster pace there are likely tens of thousands of adverse medical events that would have been prevented.

- There needs to be symmetry between the level of proof required for the adoption of a technology and the potential risk and cost benefit ratios.

- A peer developed rating system that describes where a given test lies on the continuum of scientific knowledge about the utility, acceptance and proof of that test. In this way individuals would be provided with the tools needed to help them make informed decisions.

The authors of the case study, however, point out that [genetic testing may actually backfire](#). Instead of improving a patient's health, it could cause damage instead.

...a patient informed of his or her CYP450 profile might independently change the dose of antidepressant medication with adverse health outcomes. ...the current situation also could lead both

providers and patients to lose trust in the value of genetic testing to improve drug-prescribing decisions.

Trust is the key. In an ideal world, patients would trust their physicians with all the information that's needed to maximize health. Unfortunately (or fortunately?), humans like being autonomous and don't want to lose control especially when it comes to their own bodies. Handing over all the decision making to their doctors is against what many patients are inclined to do. **It behooves physicians to gain the trust of their patients by demonstrating a solid knowledge of genetic testing and their strengths and limitations.** Even with greater federal regulation, the average family doctor is simply not qualified and may not even be any more qualified to give advice on genetic testing than the informed consumer. (I'm sure [Dr. Steve Murphy](#) would agree.)



Despite the warnings, co-author Kathy Hudson says in a [Newsweek interview](#) that there is an upside to genetic testing:

I think genetics has a huge amount to offer in making really important real-time health-care decisions. I think increasingly we're going to see genetic testing as being really important in both prescribing decisions and in treatment decisions. For example, will you respond to chemotherapy or not? Will you keel over and die if I prescribe this antiviral versus that antiviral?

Do you think direct-to-consumer genetic testing is good or evil? Take the poll in the [Eye on DNA](#) sidebar.

NB: The Genetics and Public Policy Center previously released an [American Society of Human Genetics \(ASHG\) Statement on Direct-to-Consumer Genetic Testing](#).

Update: [DNA Direct](#) (the company I work with) has also drafted [a letter to the editor](#) (pdf) in response to the Science article. An excerpt follows:

DNA Direct does not offer interpretation of CYP450 testing for SSRIs. DNA Direct is a web-enabled genetic consultation company staffed by board certified genetic counselors, with medical oversight provided by an M.D. medical geneticist. All medical genetic testing is provided according to standard medical guidelines developed under the oversight of our medical director. Secure, web-enabled interpretation and genetic consultation regarding test results is highly personalized to the patient. We advocate for consultation with a local provider if one is available for the patient – not always possible given the shortage of genetics professionals. Our patients may seek consultation directly or a physician may refer a patient for services. Of note, our most common healthcare provider referral is for consultation regarding CYP450 testing for tamoxifen. No patient receives testing through DNA Direct without the involvement of a healthcare provider.

Related Posts:

[Let's Talk About Direct-To-Consumer Genetic Testing...](#)

[The Next Generation's Perception of Genetic Testing...](#)

[Drug Companies Should Offer Free DNA Tests...](#)

[American Society of Human Genetics \(ASHG\) Statement on Direct-to-Consumer Genetic Testing...](#)

[Commercials for Myriad BRACAnalysis Genetic Test Under Scrutiny...](#)

[Intermediary Genetic Testing Companies Face Less Regulation...](#)

[Joining DNA Direct...](#)

Before Birth: Prenat... Biochemistry and Gen... Cancer-
 Related Genet... Genetic Technology a... Genetic Testing
 For ... Genetic Testing and ... Quality of Life
 and ... Trace Your Roots wit...

[Get Widget](#) Privacy



[RSS feed](#) | [Trackback URI](#)

Please note that comments left using the form below will be publicly displayed. If you'd like to correspond with me privately, please email me at hsien@eyeondna.com.

If your comment doesn't show up immediately, it's probably in moderation. I will approve it as soon as I can! Thanks for your patience.

39 Comments »

Comment by [SCG](#)

[2008-04-04 20:25:57](#)

If the family doctor doesn't feel confident in giving an advice, can't he refer the patient to a clinical geneticist for counseling? My idea is that everyone should have a TALK (not just read some infos online) with an expert before any kind of genetic test. A 30-60 min discussion to have the opportunity to ask questions and be completely conscious of the choice. A genetic test can indeed change one's life, so I think "the consumer" should be well informed before making his choice.

[Reply to this comment](#)

Pingback by [DNA Direct Talk » Blog Archive » DNA Direct Replies to Science: A Case Study of](#)

[Personalized Medicine](#)

[2008-04-04 21:21:30](#)

[...] about genetic testing for drug metabolism, which was the target of this article in Science, see Eye on DNA's post and the Personalized Medicine Blog's [...]

[Reply to this comment](#)

Comment by [StevenMurphy MD](#)

[2008-04-05 00:36:16](#)

Hsien,

You are absolutely correct. Over regulation is something that I have seen coming from a mile away. I wish someone would have asked my opinion....especially 23 and Me and deCode. I could have solved all of their issues prior to them launching. When your "boss" met with my old partner she moved in the completely right direction. These other "rush" jobs did not. Unfortunately now they have awoken the giant and the US will absolutely over-regulate this field.

As for the "provider" I am here to say they stand woefully unprepared to deliver this type of care. It will take 10-20 years to get them up to speed and that is only because the it will take that long for all of the ignorant ones to retire. That being said....trained professionals should be involved in the provision of these services....

-Steve

<http://www.helixhealth.org>

[Reply to this comment](#)

Comment by NA

[2008-04-07 02:23:07](#)

Over regulation is needed to protect the consumer. I don't want to see a lot of personalized medicine companies going into business just because they can screen certain genes for certain health conditions. Personally, I think these type of companies should never be allowed to do non-clinical genetic testing. A genetic test should only be offered through a health professional and tested by a lab that is all of the legalities straight and then send the results back to the healthcare professional.....not directly to the consumer.

[Reply to this comment](#)

Comment by Dirk

[2008-04-07 04:07:08](#)

"A genetic test should only be offered through a health professional and tested by a lab that is all of the legalities straight and then send the results back to the healthcare professional.....not directly to the consumer."

!!!!!!!!!!!!!!

Are you denying people the right to learn about their own DNA?! The problem with most new inventions, and I sincerely hope the ability to sequence/test specific DNA segments which are of ancestral and medical importance will be one of the few exemption, is that once these inventions become popular the government steps in and makes rules to regulate them!!! There is no logical justification for having a gate-keeper, i.e., the "trained professional", between a person and the knowledge about him/herself! Why do you think people are too stupid to understand their own DNA? Do you think people are not intelligent enough to read a paper themselves?

[Reply to this comment](#)

Comment by NA

[2008-04-07 04:32:33](#)

The point I'm getting is not the consumer not being able to understand their DNA, it's keeping people who should not be having a direct-to-consumer business from having it. A person needs to be counseled when going over genetic test results. We shouldn't be throwing a bunch of test results to a consumer showing a mutation in this gene and that gene because the mutation in that gene or this gene may not even affect the person's health.

The results need to be talked over in a controled envrionment.

(Comments wont nest below this level)

[Reply here](#)

Pingback by [Genetic Testing Under the Microscope » The Genetic Genealogist](#)

[2008-04-07 08:04:05](#)

[...] Eye on DNA - Direct-To-Consumer Genetic Tests - Good or Evil? [...]

[Reply to this comment](#)

Pingback by [DNA tests: Indexed « ScienceRoll](#)

[2008-04-07 20:39:38](#)

[...] Direct and Hsien-Hsien Lei posted their [...]

[Reply to this comment](#)

Comment by DMW

[2008-04-15 02:33:33](#)

To "NA," who posted on 4/7/2008:

"Over regulation is needed to help the consumer."

Since when has extra government bureaucracy in health care ever actually helped a patient? Since when has filling out surplus forms and jumping through unnecessary bureaucratic loops actually helped a health care provider?

I'd submit that over regulation is precisely what will cause the development of this useful technology to take upwards of 20 years if it doesn't deteriorate all together in the first place.

Further, I'd say that if a consumer buys a product, the consumer has every right to directly receive that product. He/she should certainly seek medical counsel at his/her own discretion but it should not be mandated.

If the all-knowing government, however, require that the tests be made available through health care providers only, a complete copy of the results should be made to the patient and physician alike.

[Reply to this comment](#)

Comment by Ashton Haney

[2008-04-15 04:01:49](#)

The idea of Direct to Consumer genetic testing is a beautiful one in that it provides genetic information to the consumer on a more time and cost effective manner than alternative methods; however, its consequences go far beyond the benefits of its improved accessibility. I am well aware of the overall aim to provide patients with more genetic information to help them modify their lifestyles, prepare them for their futures in the case of testing for adult onset conditions or common malignancies, etc. However, DTC does not guarantee the validity of test results, and there are no preventative measures to insure appropriate test ordering and test interpretation procedures are followed in most states. I can only begin to imagine the shock and emotional turmoil of discovering that you may indeed have the BRAC gene for breast cancer and then finding out later on that your test results were misread. With the use of DTC, professional counseling and consultation with physicians and specialists are not immediately available resources which are highly recommended by professionals in genetic testing facilities. How would a patient know whether or not to change medications, choose an alternative lifestyle, live with knowing of a future with cancer lurking close behind, etc? DTC's accessibility may be seen as a convenient way to find out answers to the unknown of one's genetic makeup, but consumers of today may jump at this opportunity without planning or preparing to deal with the outcomes of the test, and whether or not the consumer chooses to trust the test results is ultimately up to him/her.

Another reason why DTC raises my suspicions is not knowing who has access to DTC? Is there an age requirement, and if so, what is it and how do you determine the age at which you can have a genetic test? If genetic tests are not available to peoples under eighteen, can parents sign for their children to have the tests? What if parents decide to force their children to take the genetic tests without their consent? On the other hand, let's say you can get a DTC at any age. Does a child, anyone under the age of eighteen, have the ability to decide what to do with the information gained from the test? My questions regarding the applications of DTC are currently endless, and I remain skeptical of DTC genetic testing in its current and new developmental state. I expect that more research and concern to further understand and regulate DTC will provide more sound knowledge of how it proves to be beneficial to its consumers and grants a means of answering genetic questions that will improve our overall health and wellbeing.

[Reply to this comment](#)

Comment by Niki

[2008-04-15 04:42:03](#)

I wholeheartedly believe that there should be a healthy dose of regulation regarding DTC genetic testing. We're not talking about a pregnancy test with a plus meaning pregnant and a minus, not. Last time I checked, genetics can be pretty complicated. I agree that we have a right to learn about our own DNA if that's what we want. However, I also can say that the majority of people are really not educated enough to understand DNA and even at that read and/or interpret the results of a genetic test. This interpretation should be left to the professionals who have had years of education in the sciences and are better able to understand and interpret these results. I'm not saying that it's not possible for John Doe to learn and understand genetic tests, but I really feel that there is very little motivation to do so. So many people want it now and don't want to put the effort into learning the why and how behind it all. Genetic testing should be regulated to be available through health care providers only. It's like a blood test; we don't draw our own blood, send it off, and then interpret our own results...let the doctors do that. That's what their trained to do.

[Reply to this comment](#)

Pingback by [Let's Talk About Direct-To-Consumer Genetic Testing](#)

[2008-04-15 10:36:53](#)

[...] Direct-To-Consumer Genetic Tests - Good or Evil? [...]

[Reply to this comment](#)

Comment by Bronwyn 

[2008-04-15 14:20:14](#)

DTC genetic testing should be heavily regulated because of the potential problems that could come from it. Consumers should have direct access to their results, if they so choose to have the test done, but what if the results end up in the wrong hands (insurance companies, for example)? How can anyone ensure the confidentiality of the test results, and that they stay between the patient (consumer) and doctor? The privacy of the consumer should be one of the main concerns, whenever the government does decide to start looking at regulating DTC genetic testing. Consumers need to be protected from any potential abuse of DTC testing. DTC genetic testing is a very new concept that requires much more research, by everyone considering having the test done or actually doing the testing. Because it is a new technology, companies in this field have the potential to capitalize on it at the expense of those wanting the test done. Someone needs to protect the consumer from those out to make money off of this, and they are out there.

[Reply to this comment](#)

Comment by KM

[2008-04-15 14:43:22](#)

I think selling DTC genetic testing is an awful idea. Honestly, what is the average person going to do with those results? Those kits are just a money making scheme that can backfire terribly when uneducated people take health care into their own hands. DTC should not even be an option in my opinion. It is unnecessary when genetic testing via a trained physician is readily available. This way, the patient is able to get the information they desire along with specific directions from their doctor on how to deal with their results. Regarding government regulations...the more the government stays out of health care the better. Without the option of DTC, there should be no need for tight regulations regarding genetic testing when a trained physician is involved.

[Reply to this comment](#)

Comment by VT

[2008-04-15 15:00:07](#)

I think DTC will be a good genetic testing for mankind to further enhance our understanding of various factors in diseases. With that being said, there's should be some regulations in both companies that perform the genetic testing and the federal government to the ethics issues that held in the DTC genetic-testing matters. Companies should disclose the predictive value of the test and the purpose of the testing in an understandable and accessible fashion even a person who never approaches science will understand. They should tell the patients even though he or she might lack of a particular gene that causes certain disease but there's a possibility that other factors may cause the same disease too. They should clearly state any risks associate with the patients in this testing. They should get certified for performing this genetic testing. They should maintain the privacy of all genetic information and disclose their privacy policies only to the health care that the patients may have. They should expose any clinical evidences might for and against the efficacy of such genetic testing. On the other hand, the federal government should ensure the analytic validity of tests and the quality of genetic testing laboratories. They should ensure the clinical validity of DTC tests and that all DTC genetic-testing laboratories are certified and maintain a publicly accessible list containing the certification status of laboratories. The federal government should make sure the companies are well explain the scientific facts and truthful for these tests and take action if the company that has false advertisement about DTC tests. The federal government should assess whether the consumers are experiencing benefit and/or harm from this test method. They should also compare the claims that the companies have in their advertisement and the consensus results that patients reported.

[Reply to this comment](#)

Comment by Michelle Mejia

[2008-04-15 15:44:34](#)

DTC offers to provide a number of valuable insights with regard to a more complete and conclusive individual health record. However, as was pointed out, protection and privacy of such information is most certainly a large concern. While such testing would provide a greater amount of knowledge regarding predisposition for disorders as well as what links genetics to diseases, without proper federal regulation and protection of such information, there is no doubt that the DTC could harm more than it helps. Even with proper regulation and protection, the knowledge of such information may have significant psychological affects on an individual. For example a person utilizing DTC testing may find out they possess a gene which could lead to the development of a severe disorder. With this knowledge the individual may become severely depressed, or as was stated earlier possibly increase dosage of a particular medicine which could produce adverse effects on their health. I most certainly think that with the progression of these technologies it should be made clear that even though one may possess a gene for a particular disorder, it does not mean without a doubt that one will develop the disorder. There are a number of factors beyond gene expression which influence the development of certain disorders. I strongly support close and precise federal regulation of DTC testing with regard most of all to protection of the individual's genetic information. I do not agree that companies should be able to sell DTC services for any purpose either. I think that there should be a regulation on who is allowed to receive the testing. If there is a specific medical purpose to the testing and perhaps at the suggestion of a physician, an individual is seeking the testing, I believe it should be permissible. However, for a person to be able to access this information for no apparent reason other than personal curiosity seems like a slippery slope and could lead to companies selling these and other technologies purely for monetary gain which I do not agree with at all. There is no doubt that there needs to be regulation on the companies which are allowed to provide these services. Personally, I do not think the world is ready for DTC testing to be offered to the general public by any company that has developed the technology to do so.

[Reply to this comment](#)

Comment by Rosetta Derrick

[2008-04-15 16:02:31](#)

I think you should have the right to know your genotype but you should also be allowed to control who sees it. My concern is with security issues. Some type of government regulation may be needed just to insure the protect of your results. Especially if insurance companies try and cut people off because they may be prone to a specific set of diseases.

[Reply to this comment](#)*Comment by LMY*[2008-04-15 16:17:19](#)

DTC is on the frontline of advanced medical technology. As with any new innovation there comes pros and cons and it is important to find middle ground. Genetic testing has aided many individuals in acquiring personalized medicine proven successful in overcoming medical and cosmetic (such as anti-aging) battles. However, with these successes have come consequences. Imprecise genotyping, lack of genetic counseling, and a failure to link diseases with influences other than genes have misled and harmed patients participating in DTC. I feel it is a consumer's choice to participate in DTC but the federal government should enforce manufacturers offering genetic tests to require the consumer to consult with a genetic specialist upon receiving genetic tests results and before participating in personalized medicine. Additionally, manufacturers need to be required by the federal government to prove the validity of all of their tests before putting them on the market. Genetic testing is complex and consumers need to be aware of both the beneficial and harmful effects of participating in such a market. Without proper guidance and advice, it would be easy to fall into a marketing scam. The motivation behind DTC manufactures needs to be for the health of their consumer. I can understand the appeal of DTC to a consumer suffering from a life threatening genetic illness and from a scientific standpoint the exciting possibilities in advancing medicine and preventing diseases. Therefore, the government needs to work with DTC manufacturers to ensure that genetic testing validity and genetic counseling is provided to the consumer before medical action.

[Reply to this comment](#)*Comment by Stacey Sigmon*[2008-04-15 16:43:48](#)

As with most new medical technologies that have begun to emerge over the past few years, there are always blurred lines as to what is considered beneficial, acceptable, and even ethical. Although some uses of genetic tests and personalized medicine can certainly be of use to patients and the medical community as a whole; it is apparent that standards and regulations need to be established and followed. Even though genotyping GYP450 genes is approved by the FDA, the majority of these direct-to-consumer tests are not regulated by the FDA - which brings about questions concerning the validity, safety and effectiveness of these private companies and the services they provide. The issues get even stickier when one considers the motives of companies that provide direct-to-consumer genetic tests, but then don't require or may not even suggest seeking guidance and expertise from a medical professional. I feel that the drive for financial profit, in some cases, has taken precedent over the desire to provide the best medical care and advice for an individual. How can it be acceptable to expect someone who has no medical or scientific training to make a decision about the route of his or her health care regiment . . . especially after getting a letter in the mail stating their genetic predisposition for a debilitating neurological condition??

[Reply to this comment](#)*Comment by AMR*[2008-04-15 19:51:34](#)

I'd have to agree that, while DTC genetic testing has the potential for better, more personalized healthcare, it can not attain this goal without further regulation. The major objective of improving drug safety and efficacy cannot be accomplished without first addressing the overall accuracy and validity of the tests, and the relationships between genetic variation and phenotypic outcome. As noted by another blogger, the results of DTC could have an adverse result; personal testing without adequate genetic counselling could easily lead to inappropriate application of the results in the form of unwarranted treatments. Furthermore, the average individual does not have a comprehensive knowledge of penetrance, anticipation, and various other genetic variations. Even without adopting any treatment regime, there are psychological ramifications associated with 'knowing' your genetic future; these are only exacerbated by the fact that your test results could be misleading or incorrect.

Overall, I appreciate the utility of genetic testing, and the need for an expedited availability. With that said, the premature, unregulated application of DTC could undermine its informed, appropriate, uniform use for established genetic abnormality.

[Reply to this comment](#)

Comment by CRL

[2008-04-15 20:06:26](#)

I think that genetic tests for individuals or families for the presence of and/or susceptibility to disease are medical tests and should not be downplayed to a simple "home testing kit". At the present time, genetic testing should only be provided to the public only through the services of an appropriately qualified health care professional. Most people, myself included, are not qualified to interpret the genetic code. It takes years of schooling and experience to successfully predict with any accuracy the outcome of a segment of DNA or gene. The health care professional should be responsible for both ordering and interpreting the genetic tests, as well as for pretest and posttest counseling of individuals and families regarding the medical significance of test results and the need, if any, for follow-up. Due to the complexities of genetic testing and counseling, the self-ordering of genetic tests by patients over the telephone or the internet, and their use of genetic "home testing" kits, it potentially harmful and should be highly regulated.

[Reply to this comment](#)

Comment by Mark Hutto

[2008-04-15 20:28:26](#)

I believe patients using DTC testing should have to go through their physicians first. By going through the physicians, it will allow the patients to think through the consequences more thoroughly and allow the physicians to plainly lay out the effects the results will have on the patient whether beneficial or harmful. I also think there definitely needs to be more laws laid down governing DTC because there is too much freedom right now between the companies offering this product. Companies are not regulated enough regarding the validity of these diagnostic tests.

[Reply to this comment](#)

Comment by Trisha

[2008-04-15 22:15:15](#)

I think its a great idea! People have the right to information - especially about *their own bodies*. We should not have a doctor controlling our access to information about *our own bodies*. That's just wrong.

While some people may not have the background to understand the information they receive that's no reason for the rest of us to be kept from access to information about *our own bodies*.

[Reply to this comment](#)

Comment by Bob Smith 

[2008-04-16 17:03:43](#)

I guess there are two schools of thought:

The “Javitts/Hudson” School of thought:

Most people are stupid, only big government can protect them, the DTC companies are ruining the field for everyone else, and, BTW, bureaucrats need jobs too!

The libertarian school of thought:

People are smart, they have individual rights to their own test results, big government and the FDA cannot even do their current jobs well (Vioxx anyone?)

I think there will have to be a “middle ground”, because there is some truth in both arguments.

[Reply to this comment](#)

Pingback by [The Next Generation's Perception of Genetic Testing](#)

[2008-04-17 13:38:55](#)

[...] by Dr. Hsien-Hsien Lei Posted April 17, 2008 in DNA Testing, DNA in General Don't miss it! An active discussion of the good and evil sides of genetic testing is now taking place over at this Eye on DNA post [...]

[Reply to this comment](#)

Comment by NA

[2008-04-17 16:57:55](#)

One thing that is never talked about is the misuse of the DTC tests. I'm not talking about the usual misuse talk that goes on. What I'm talking about is using the test kits to collect your own DNA samples and then injecting them into animals or using the DNA kits to collect animal samples and then using them to inject the DNA material into another organism.

DTC companies are popping up all over the place now. The more companies that offer DTC testing, there will be more misuses of the technology.

[Reply to this comment](#)

Comment by Trisha 

[2008-04-17 22:00:49](#)

I think Bob Smith has the situation pretty well summed up.

I guess I'm one of the 'libertarians'!

My only concern about them is if they are really accurate enough. Maybe there should just be regulation to make sure they are really able to test accurately what they say they are.

[Reply to this comment](#)

Comment by Mark

[2008-04-18 02:07:09](#)

People certainly have the right to know in regards to their own body, but I am a strong supporter of regulations in order to ensure accuracy and validity. I am unaware of how the results of DTC tests are read and scored, and this makes me hesitant to be an advocate of people having these tests done because I don't want there to be too much false hope and a few years from now the companies come back and say the tests were not read/done properly.

[Reply to this comment](#)

Comment by [Dana Waring](#) 
[2008-04-18 14:26:05](#)

Nice to see some familiar names from Dr. Korey's class!

I think Ashton hits on an interesting point. With genetic tests in the hands of parents, what sorts of rights (if any) do their children have? This whole question of privacy and consent within families is going to be one of the hardest nuts to crack, both in terms of genetic testing and more broadly, whole genome sequencing.

I see value in some of the regulatory and legislative approaches - certainly the validity of the tests is a crucial issue- but I think our collective energy is better spent on broad based education initiatives. An informed and educated public is the best antidote to charlatans and even well-meaning DTC companies that return complex and ambiguous results. We have a serious shortage of docs and genetic counselors who are able to advise on and explain genetic testing. The power is shifting away from the traditional medical establishment (see Patients Like Me or My Daughter's DNA) and I don't know what would cause that trend to be reversed!

Bronwyn makes a great point about insurance, and that people who use DTC tests might find themselves in a difficult situation with both their doc and insurer - Amy Harmon at the NYT did a great piece on this issue here:

<http://www.nytimes.com/2008/02/24/health/24dna.html>

[Reply to this comment](#)

Comment by [Steven Murphy MD](#) 
[2008-04-18 19:20:04](#)

Dana,

You are correct. This is precisely why we need to call our Senators and demand GINA be passed!

It may not be a perfect bill, but it will be the best we have for now.

-Steve

<http://www.thegenesherpa.blogspot.com>

[Reply to this comment](#)

Comment by [Chris Korey](#)
[2008-04-20 12:54:22](#)

I have enjoyed reading all of the perspectives on DTC. One thing that seemed to come up a lot is the need to have these tests done through the medical profession in order to ensure that consumers are correctly informed of the ramifications of a particular test. My concern is one that Steve brought up in a recent post:

<http://thegenesherpa.blogspot.com/2008/04/why-biostatisticians-should-get-paid.html>

Are our medical professionals (doctors, PA, and nurses) really that much more prepared to understand these tests as compared to the general public? Certainly, they have an expertise in human biology, but I would suggest that they do not have the genetics or statistical background that will be required to deal with this information in an informed way. Most undergraduate science majors and medical curriculums are not heavy in general genetics, medical genetics, and biostats. Certainly there are Clinical Geneticists around but, as others have pointed out, not nearly enough to deal with the upcoming deluge of genetic information. My own bad experience with a positive triple screen blood test (a standard, non genetic test for neural tube defects and downs) during my wife's first pregnancy gives me little confidence that our medical professionals are trained to be the gate keepers of DTC information.

[Reply to this comment](#)

Comment by [Steven Murphy MD](#)

[2008-04-20 14:34:07](#)

Chris,

I agree with your concerns. Often Prenatal Genetic Evaluations can be difficult. Sometimes an Ob/GYN or a prenatal genetic counselor can have difficulties in presenting this information. Sometimes this is due to training issues. Such as a Genetic Counselor not being trained in medicine, or an Ob/GYN not being trained in genetics. Other times, there can be a simple difference of personalities and opinions. I apologize for the poor experience you had.

Triple screen/quad screen, I feel, is a genetic test of sorts. It tests for risk of genetic anomalies. Down Syndrome is a genetic condition.

I will counter that...as woefully prepared as the health community is. Most laypersons are even worse off when it comes to genetic and health literacy. So, I think we all have a lot of learning to do. Especially if we plan on buying Do It Yourself genetic testing.

-Steve

<http://www.thegenesherpa.blogspot.com>

[Reply to this comment](#)

Comment by [Bronwyn](#)

[2008-04-21 20:28:49](#)

I think we should be careful and not place all of our trust in these tests. They are good tools to have and can help people, but not everything has a genetic basis. They should be used for helping patients worried about genetic diseases that may show up later on in life, but everyone needs to keep in mind that other factors also play a significant role in our health.

[Reply to this comment](#)

Comment by [RAD](#)

[2008-04-21 23:41:06](#)

Having a sister with autism I generally like the idea of genetic testing and that DTC genetic testing may lead to a more personalized health care but some form of regulation is needed, whether through federal or state government. My concerns are with the validity of the test results, why the test is ordered, and how correct the interpretation is. I read that in New York, DTC companies were required to get permits through the health department and that all tests had to be ordered by licensed health care professionals. I feel as though some people may get tested just because it's the "in" thing leading to false positives that have many worried. Once/If the kinks are worked out I worry that insurance companies may abuse this information. Whether this be increasing premiums or cutting coverage.

[Reply to this comment](#)

Comment by CRL

[2008-04-22 00:30:30](#)

The more I read on the issue, the less convinced I am that I fall on one side or the other whole heartedly. I do think that these tests are capable of good when used properly and interpreted properly. I also think that the government can play an integral part in this system and help to make sure that this technology is not misused. I feel that if private companies are given complete control of this, than they will run with it and use it solely as a mean to make more money. Bob Smith seem to illustrate two very different sides of the issue and I agree with him that there has to be some middle ground found before anything is decided upon.

[Reply to this comment](#)

Comment by Michelle Mejia

[2008-04-22 03:03:07](#)

As I have read more and more regarding DTC testing as well as the current regulatory climate I can't help but think we are not ready for such a powerful biomedical technology to become a commodity. If, without strong regulation, companies are forthright about the fact that their main concern is monetary and NOT necessarily validity of testing and results OR protection of the patient and/or physician input, it's safe to say that not only IS much much more federal regulatory input necessary, it is NEEDED before any further claims are made and DTC tests are advertised, produced, and/or sold. The science to support the validity of genetic markers and indicators of possible genetic pre-dispositions etc needs to come BEFORE dtc tests are marketed and SOLD to the masses at large. There most CERTAINLY needs to be physician mediated attianment an diagnostic use of the results of the tests as well. As I said before, I think this is something the world at large is simply not ready for here and now.

[Reply to this comment](#)

Comment by VT

[2008-04-22 03:23:22](#)

DTC genetic testing will be a good thing to mankind. But consumers should chat with professional and policy groups about DTC genetic testing before going to do the testing. Because their understanding of the results received from direct-to-consumer genetic tests would enhanced the better understanding with patient's individual situation, or also they can implement advisory language for companies to use in providing test analysis directly to consumers. This would allow for continuing improvement in consumer understanding of genetics information to become a more common part of individual health and medical treatment plans

[Reply to this comment](#)

Comment by LMY

[2008-04-22 15:32:10](#)

I agree with the main problem between conflicting parties of interest, the public policy advocating against DTC verse providers, is the lack of communication in advertisements and scientific understanding of the products by consumers and health professionals. It is a horrible idea to ban DTC, due to its already known medical successes and potential for scientific advancement, but is an equally awful idea to remove all regulation. It is imperative for the FDA to implement and enforce effective regulation of prescription and treatment of DTC through medical professionals proficiently educated in this technology. Negative health consequences of DTC occur when consumers use their own instinct on using a DTC genetic test or product. FDA needs to ensure DTC providers primary goal is the safety of their consumer. Additionally, DTC advertising needs to be monitored and approved by FDA in order to prevent consumers from being wrongly influenced by misleading commercialization.

[Reply to this comment](#)

Comment by Stacey Sigmon

[2008-04-22 19:51:54](#)

LMY -

I agree with what you mention about the need for regulations and enforcement via our medical/scientific community. I support that idea that we all want a little privacy, especially when it comes to medical matters, but the the fact that even professionals in this field make mistakes further supports the argument that DTC companies and their consumers need not approach these issues with such a relaxed viewpoint (especially with regards clinical and analytical validity).

[Reply to this comment](#)

Name (required)

E-mail (required - never shown publicly)

URI

Your Comment ([smaller size](#) | [larger size](#))

You may use `` `<abbr title="">` `<acronym title="">` `` `<blockquote cite="">` `<code>` `<del datetime="">` `` `<i>` `<q cite="">` `<strike>` `` in your comment.

Notify me of followup comments via e-mail

Note: Posting will be sporadic while I'm on maternity leave through July 2008

Search Eye on DNA

- [HOME](#)
- [About Dr. Hsien-Hsien Lei](#)
- [Email: hsien@eyeondna.com](mailto:hsien@eyeondna.com)
-  [Subscribe in a reader](#)

Enter your email address:

Delivered by [FeedBurner](#)

Direct-to-consumer genetic testing is...

- Good
- Evil

[View Results](#)



RECENT POSTS

- [DNA Video: Pimp My Genome! Google Tech Talk with Andrew Hessel](#)
- [Books About DNA: Coming to Life by Christiane Nusslein-Volhard](#)
- [How To Make Money Selling Personal Genomic Services](#)
- [What does DNA mean to you? #4](#)
- [Using Disposable Income for Genetic Tests](#)
- [DNA Video: DNA Replication Song](#)
- [Taking My Eye Off DNA](#)
- [Books About DNA: Tomorrow's Table](#)
- [Eye on DNA Headlines for 30 April 2008](#)

- [What does DNA mean to you? #3](#)

• MOST POPULAR

- [100 Facts About DNA](#)
- [Want a job? Submit your DNA](#)
- [5 Cool Things You Can Do With Your DNA](#)
- [Salaries for Jobs in Genetics](#)
- [New Line Genetics and SellMyDNA.com Offer \\$5,000 for Your DNA](#)
- [Books About DNA: Abraham's Children by Jon Entine](#)
- [How to Prepare Yourself for a Genetic Test](#)
- [Highlights from the MedHelp Genetics Forum: BRCA Genetic Testing](#)
- [DNA Toys: Ben 10 and Digimon Digivice](#)
- [DNA Direct Unveils New Genetics Forum at MedHelp](#)



[Join The DNA Network](#)

[Search The DNA Network](#)

RECENT COMMENTS

- [Is the Pink or Blue early baby gender DNA test accurate?](#)
05/13/2008 03:22 pm
48 Comments
- [Gene Genie #18 with the PG Tips Chimp](#)
10/23/2007 09:28 am
31 Comments
- [Gene Genie in Mendel's Garden](#)
06/04/2007 04:27 pm
38 Comments
- [Taking My Eye Off DNA](#)
05/11/2008 01:38 am
14 Comments
- [Wellcome Image Awards: Gene Expression Analysis](#)
03/21/2008 10:44 am
4 Comments

CATEGORIES

- [Business of DNA](#)
- [DNA @ Google Answers](#)
- [DNA and Disease](#)
- [DNA and Genealogy](#)
- [DNA and the Law](#)
- [DNA Around the World](#)
- [DNA Fun](#)
 - [Eye on DNA Headlines](#)
 - [Geeky DNA T-shirts](#)
 - [In Your DNA](#)
- [DNA in General](#)

- [Meaning of DNA](#)
- [The DNA Network Specials](#)
- [DNA Inventions and Gadgets](#)
 - [DNA Products](#)
 - [DNA on Auction](#)
 - [Nutrigenomics](#)
- [DNA Lab Talk](#)
- [DNA Podcasts and Videos](#)
- [DNA Quotes and Excerpts](#)
 - [Books About DNA](#)
- [DNA Testing](#)
- [Gene Therapy](#)
- [Genetic Engineering](#)
- [Genetically Modified Foods and Organisms](#)
- [Jobs Involving DNA](#)
- [Personalities with DNA](#)
- [Polls About DNA](#)

ARCHIVE

- [May 2008](#)
- [April 2008](#)
- [March 2008](#)
- [February 2008](#)
- [January 2008](#)
- [December 2007](#)
- [November 2007](#)
- [October 2007](#)
- [September 2007](#)
- [August 2007](#)
- [July 2007](#)
- [June 2007](#)
- [May 2007](#)
- [April 2007](#)

RANDOMIZED BLOGROLL

- [Duncan Riley](#)
- [A Dozen Steps](#)
- [Sleepy-Head](#)
- [A View from England](#)
- [Mental Health Notes](#)
- [The force that through...](#)
- [The Minnesota Gene Pool](#)
- [Epigenetics News](#)
- [DNA Direct Talk](#)
- [The Antidote](#)



We comply with the [HONcode standard for trustworthy health information](#): [verify here](#).

Eye on DNA is not a substitute for medical advice. Always ask your healthcare provider or genetic counselor for information specific to you.



Powered by [WordPress](#), [Fjords06 Web design](#) by [Peterandrej](#).

Ⓜ