Direct-to-Consumer Testing: The Business with Lifestyle Tests

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IFCC Committee on Clinical Laboratory Management
http://www.ifcc.org/ifcc-education-division/emd-committees/c-clm/

Symposium on Improvement in Clinical Laboratory Services: Approaches to Adding Value

IFCC WorldLab Durban
Durban International Convention Centre
Durban, South Africa - October 25, 2017

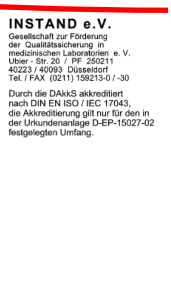
Objectives

- detail many forms of DTCT and how these tests should be considered within the realm of what we traditionally consider POCT
- experiences with DTCT in Germany and the US
- describe differences between clinical pathology labs (healthcare) and non-healthcare lab testing services
- challenges of DTCT in genetics testing (inaccurate promises, discrimination, data protection)

"The best way to find out if you can trust somebody is to trust them."
Ernest Hemingway

Trust

Humatrix has set standards: highest level of automation, first in selling in pharmacies, its unique safekit and ***a year-long partner of major TV stations***. Therefore, you can rely on us in quality and safety



Real Medical Labs (Rilibäk)

5.2 Personnel

Medical laboratory examinations must only be performed by personnel who are professionally qualified corresponding to legal regulations, and who are authorised by management.

The number of personnel must be sufficient with regard to the amount of work.

6.2 Procedures for conducting medical laboratory examinations

6.2.1 The medical laboratory may only use examinations procedures that meet medical requirements.

6.2.2 The medical laboratory may only use validated examinations procedures. It has to document the procedure used for validation and the results obtained.

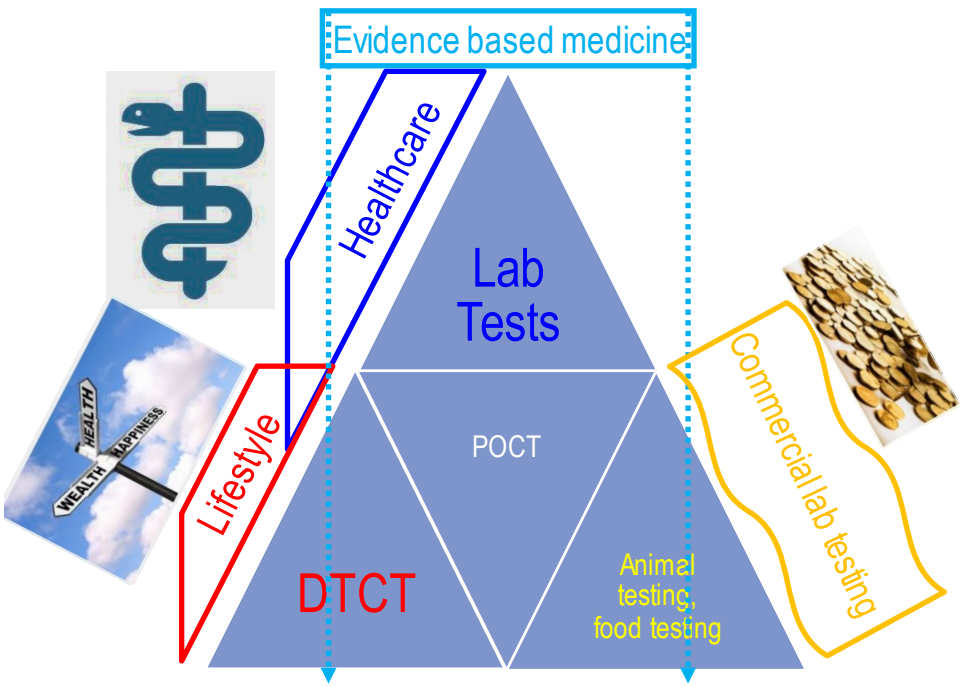
The Directive on Consumer Rights aims at achieving a real business-to-consumer (B2C) internal market, striking the right balance between a ***high level of consumer protection*** *and the* ***competitiveness of enterprises****.*

Challenges by DTC/DAT

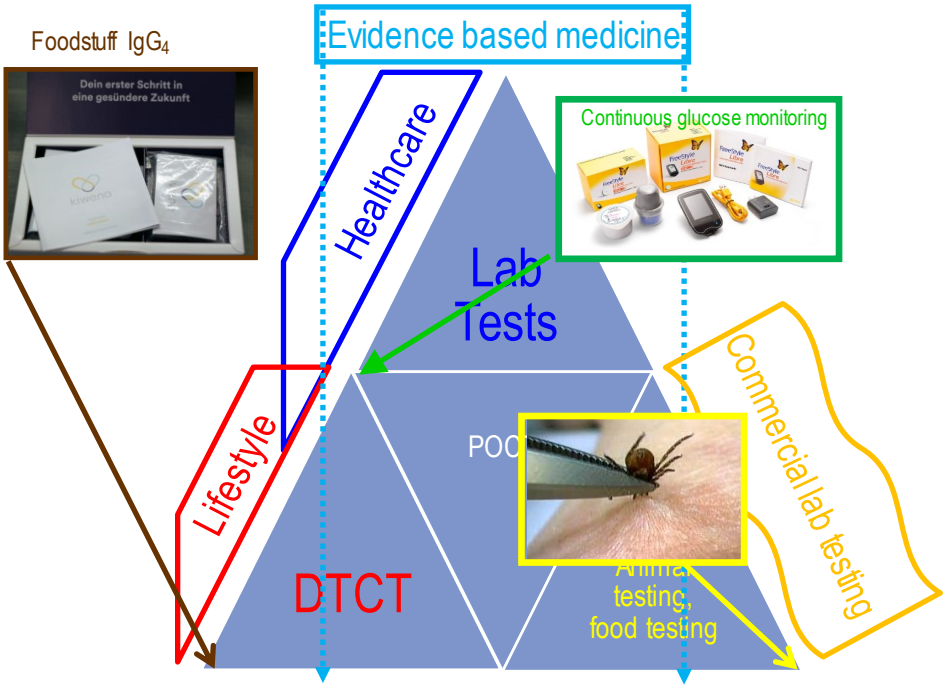
no quality criteria at all have to be followed if laboratory tests are performed by non-health care professionals allowing a free movement of services under the consumer rights directive 2011/83/EU
Orth, M. and P. Luppa (2014). Dtsch Arztebl 2015; 112(5): A-174

laboratory = a facility that performs certain testing on human specimens in order to obtain information that can be used for the diagnosis, prevention, or treatment of any disease or impairment of a human being

CLIA regulations and standards do not differentiate between facilities performing DAT and facilities performing provider ordered testing. All facilities must obtain **CLIA** certificate prior to conducting patient testing, *including* DTC/DAT. **FTC** regulates advertisements.



Orth M. Point of Care 2017;16(3):124-27 doi: 10.1097/poc.0000000000000144]



Healthcare -- „Medical Act“

- Restriction of healthcare (=diagnosing illnesses, prescribing diagnostic examinations, using invasive/risky diagnostic techniques, determining medical treatment, prescribing medications, clinical monitoring of patients with problematic health, pregnancy care and deliveries, isolation measures) to physicians
- *Healthcare = principle of solidarity and principle of demand*
- *Healthcare **NOT** principle of market economy*
- *Physician may not extend services by hiring employees unlike a commercial firm*
- *Prohibition of (exclusive) telemedicine*
- *Critical: (external) IT service provider essential in medical process*

primum non nocere, secundum cavere, tertium sanare

Examples of laboratory testing requiring supervision by a physician in Laboratory Medicine

- INR self-testing
- Reporting of complex laboratory tests
- Blood Coagulation testing
- Assessing medical necessity
- Establishing clinically relevant cut-offs
- Verification of methods: a medical evaluation
- Evaluation of the laboratory errors: a medical act
- Setting up und updating rules auto-validation rules

Value-based care

Rockwell KL JAMA 2017 (317), 2485-6

DTCT

Low-value testing

Follow up costs

An Unwelcome Side Effect of Direct-to-Consumer Personal Genome Testing

Raiding the Medical Commons

Amy L. McGuire, JD, PhD
Wylie Burke, MD, PhD

IT IS NOW POSSIBLE FOR INDIVIDUALS TO LEARN ABOUT their genetic susceptibility to dozens of common and complex disorders, such as coronary artery disease, diabetes, obesity, prostate cancer, and Alzheimer disease, without ever seeing a physician. Direct-to-consumer personal genome testing companies hope to empower consumers to take control of their health by providing tailored assessments of genetic risk based on reported associations between genomic variation and susceptibility to disease.

Several states limit or forbid this practice as a violation of state law that requires the appropriate involvement of a licensed physician when providing medical diagnostic information.[1] Personal genome testing companies claim that their services are for informational and educational purposes only. They warn consumers that the information should not be used for diagnosis, treatment, or health ascertainment purposes and direct them to their physicians if they have questions or concerns about their health status.[2,3]

sel patients accordingly. Physicians are also accustomed to talking with patients about health information disclosed on the Internet or through other media outlets. At the same time, primary care physicians have limited time with patients, face many competing demands,[3] and are poorly reimbursed for time spent counseling patients about preventive care. Patient concerns about direct-to-consumer test results have the potential to exacerbate these problems and strain already limited health care resources.

Raiding the Medical Commons

The clinical value, if any, of most direct-to-consumer personal genome tests remains unproven. A statistically significant association between a particular genomic variant and a disease does not necessarily mean that the presence of that variant in a given individual is clinically meaningful. Many of the variants discovered in genome-wide association studies are associated with only marginal increases in risk, with odds ratios often 1.5 or less.[4] The usefulness of this information for clinical decision making is unclear.

Although physicians need to be prepared for patient inquiries about personal genome test results and arguably have

JAMA, December 10, 2008—Vol 300, No. 22 2669

Hiatt, H. H. (1975). "Protecting the medical commons: w ho is responsible?" N Engl J Med 293(5): 235-41

NATURE | COMMENT

Research integrity: Don't let transparency damage science

Stephan Lewandowsky & Dorothy Bishop

25 January 2016

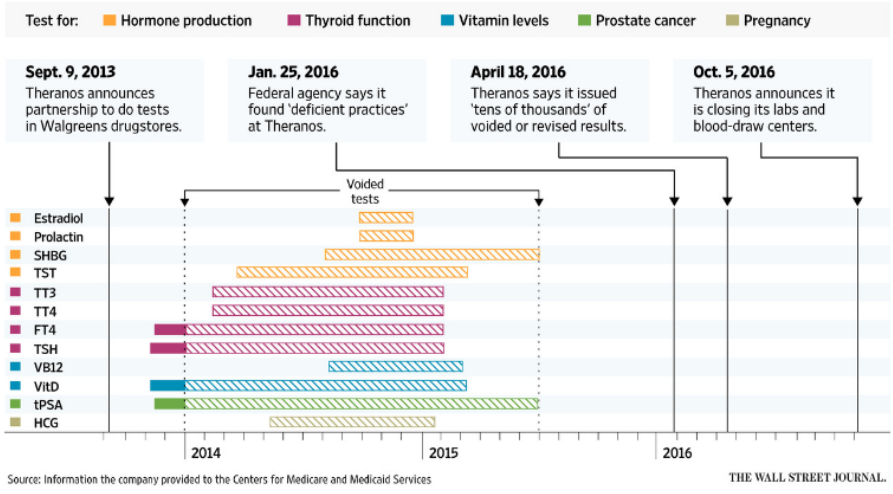
Stephan Lewandowsky and Dorothy Bishop explain how the research community should protect its members from harassment, while encouraging the openness that has become essential to science.

Yet social media and online comments also offer an easy way to inject biased, incorrect or misleading information. And because engagement with critics is a core element of scientific practice, researchers may feel obliged to respond even to 'trolls' (online harassers).

Nature 529, 459–461 (2016) doi:10.1038/529459a

The Short, Troubled Life of Edison Blood Tests

Theranos voided the results of almost every blood test ever done on patients with its Edison machines. It stopped doing most of the tests more than a year before throwing out the results and notifying patients and doctors.



Source: Information the company provided to the Centers for Medicare and Medicaid Services

THE WALL STREET JOURNAL.

Theranos Inc

Feb 16, 2016
Theranos Files Plan to CMS for Fixing California Lab Problems

Feb 5, 2016
Theranos Gets Additional Week to Respond to U.S. Inspection

Jan 29, 2016
Theranos Is Running Out of Time

Partnership with
- Cleveland Clinic to decrease the cost of lab tests

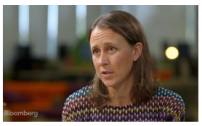
Cleveland Clinic

- Pennsylvania insurers
- AmeriHealth Caritas
- Capital BlueCross

Jan 28, 2016
Walgreens Suspends Theranos California Lab After U.S. Report

Jan 28, 2016
Theranos Lab Faults Jeopardized Patient Health, U.S. Says

Nov 11, 2015
23andMe CEO Says She Won't Sell After DNA Test Firm's Comeback



Oct 28, 2015
Flipboard's Fanfare Fades as Executives Exit, Sale Talks Stall

Oct 27, 2015
Theranos Device Validation Is Flawed, FDA Inspection Finds

Oct 21, 2015
Theranos CEO Defends Blood Testing Company at Conference

C

Agony, Alarm and Anger for People Hurt by Theranos's Botched Blood Tests

By Christopher Weaver

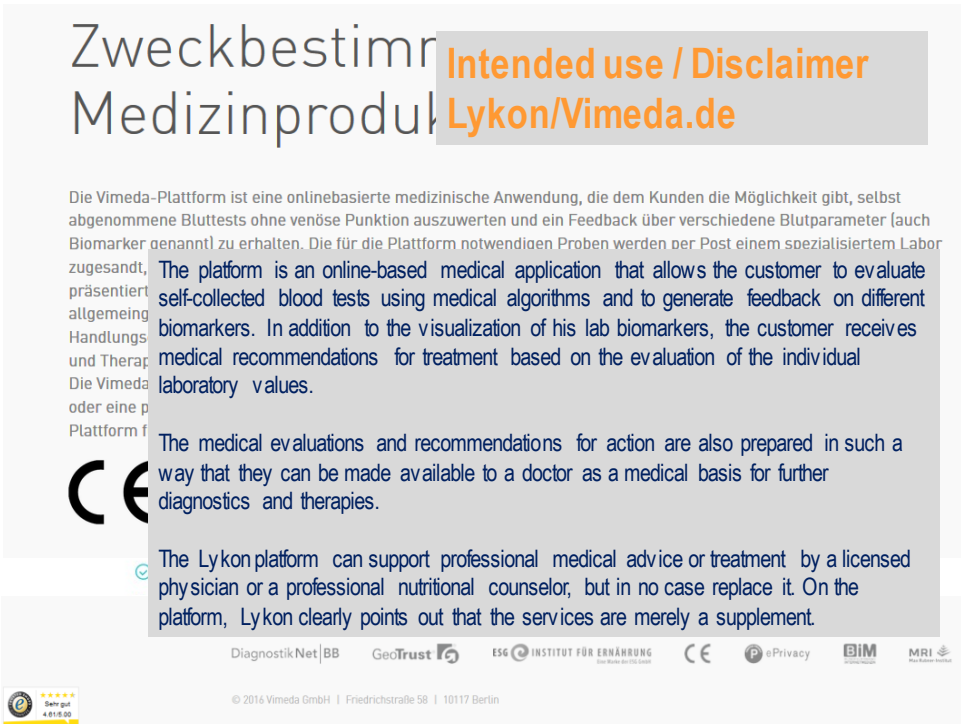
The Wall Street Journal Updated Oct. 20, 2016 9:52 p.m. ET

Douglas Simon

Gee do you think there's a reason that medical training requires a minimum of seven years post graduate education and training? Oh no a Stanford drop out can bypass all this because she's a "genius" with "vision". All of her financial backers and co-conspirators should bear responsibility for this mess. They illegally practiced medicine without licenses and training. Where were the regulatory authorities while this mess was being perpetrated? People should be in jail for this for a very long time.

I and my former medical colleagues worked hard for many years to be qualified to take care of people. These are extremely bright and intellectually curious people who sacrificed years of family time and earnings power to be able to administer blood tests and interpret the results. It's delusional to think that a lone person with minimal education, no matter how innately intelligent, could replace this system with their superior vision and intellect. Where's Elizabeth Warren when people's lives are at stake?

6 days ago

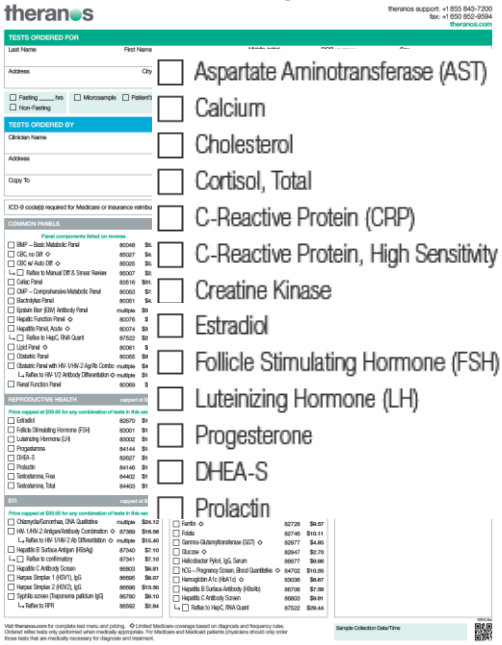


Much lower cost?

Point-of-care (POC) devices used by Theranos phlebotomists – technicians licensed to take blood – draw blood virtually painlessly through a trigger tap on the subject's finger. … The more sophisticated tests require at the very most no more than a drop of blood (around 100 µl). But new technologies developed by the company are pushing this down to the 1 to 3 µl level …
The technology can work on tiny samples due to the application of two methods: dilution and detectors. When a sample is diluted, it is possible to detect signals from multiple substances present in the sample in widely varying concentrations. This enables a more complex analysis …

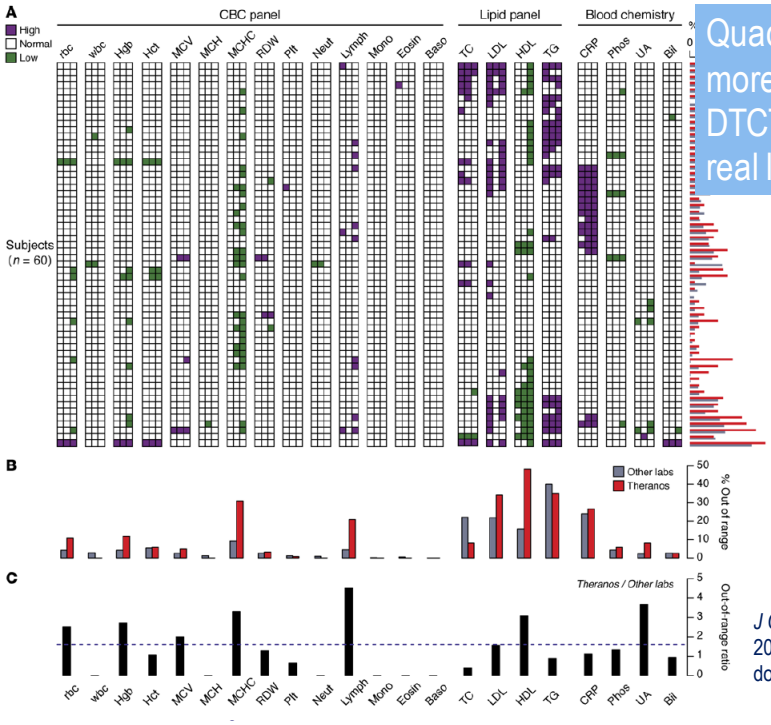
Offering greater accessibility to blood tests, virtual painless testing, and a much lower cost, Holmes' invention helps patients get tested earlier and more frequently. In one example, a women with diabetes **reduced the costs … of tests she required from € 711 using traditional blood analysis methods down to € 28** using Holmes's technology

Testing fees THERANOS - DE (private) - DE (public)



			EBM	GOÄ
Aspartate Aminotransferase (AST)	84450	$3.56	€0.22	€2.33
Calcium	82310	$3.55	€0.22	€2.33
Cholesterol	82465	$2.99	€0.22	€2.33
Cortisol, Total	82533	$11.21	€5.58	€14.57
C-Reactive Protein (CRP)	86140	$3.56	€1.04	€5.83
C-Reactive Protein, High Sensitivity (hsCRP) ◇	86141	$8.90	€4.41	€11.66
Creatine Kinase	82550	$4.48	€0.22	€2.33
Estradiol	82670	$19.21	€4.14	€20.40
Follicle Stimulating Hormone (FSH)	83001	$12.77	€4.05	€20.40
Luteinizing Hormone (LH)	83002	$12.73	€4.05	€20.40
Progesterone	84144	$14.34	€3.42	€20.40
DHEA-S	82627	$15.28	€6.21	€20.40
Prolactin	84146	$13.32	€4.14	€20.40

Orth: Direct to Consumer Testing



Quadruple times more outliers in DTCT than in real lab tests

J Clin Invest. 2016;126:1734–44 doi:10.1172/JCI86318

Genetic exceptionalism

- laws for protection and anti-discrimination
- Protection of individuals (**and their relatives**) from their own curiosity
- Challenging definition of purpose of genetic testing (diagnosing, risk assessment, forensic, lifestyle)
- Post hoc analysis of genetic data is frequent

- BUT: All medical information is precious, private and deserves vigorous protection
- patient/consumers are both capable and better informed about most pros and cons of genetic testing for certain inherited diseases than most physicians

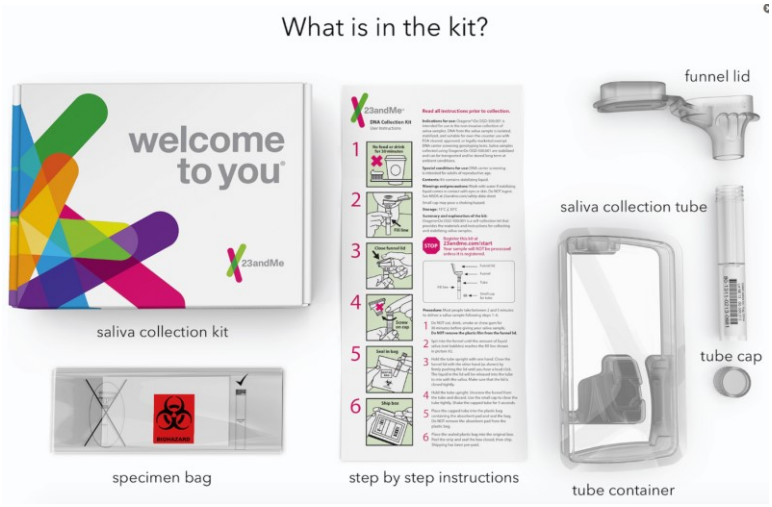
23andMe's co-founder and CEO Anne Wojcicki (was) married to Google co-founder Sergey Brin

HEALTH

23ANDME GETS FDA APPROVAL FOR DIRECT-TO-CONSUMER GENETIC TESTS

IT'S NOW THE FIRST COMPANY OF ITS KIND TO GET THE FEDS' GO-AHEAD

By Alexandra Ossola Posted October 21, 2015



FDA ORDERS PERSONAL GENOMICS COMPANY 23ANDME TO STOP MARKETING DNA TEST

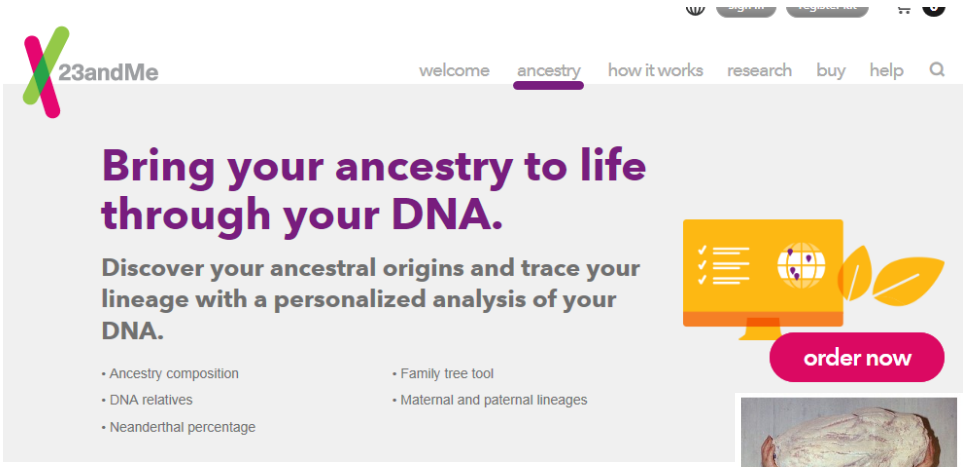
"FDA IS CONCERNED ABOUT THE PUBLIC HEALTH CONSEQUENCES OF INACCURATE RESULTS."

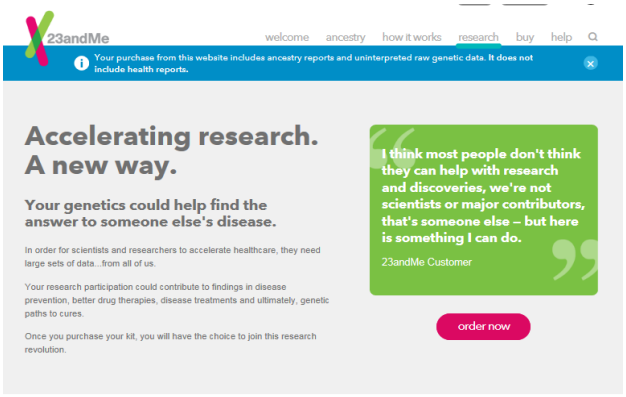
By Paul Adams Posted November 25, 2013

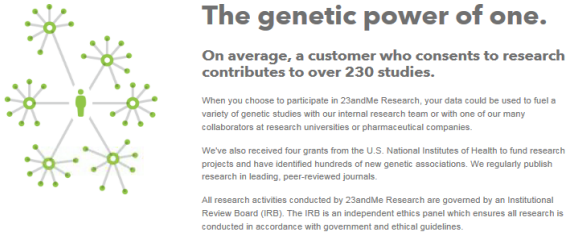
According to the letter, the FDA has been seeking information needed to approve the test for a while, "including more than 14 face-to-face and teleconference meetings, hundreds of email exchanges, and dozens of written communications":

> months after you submitted your 510(k)s and more than 5 years after you began marketing, you still had not completed some of the studies and had not even started other studies necessary to support a marketing submission for the PGS. It is now nine months later, and you have yet to provide FDA with any new information about these tests. You have not worked with us toward de novo classification, did not provide the additional information we requested necessary to complete review of your 510(k)s, and FDA has not received any communication from 23andMe since May. Instead, we have become aware that you have initiated new marketing campaigns, including television commercials that, together with an increasing list of indications, show that you plan to expand the PGS's uses and consumer base without obtaining marketing authorization from FDA.

23andMe has not yet responded publicly.







FDA Letters to Genetic Testing Companies

"FDA appreciates that many consumers would like to be informed about their genomes, and their genetic risk for development of future disease. We agree that access to tests through a DTC model can allow consumers to take responsibility for certain aspects of their health, and to learn more about genetics and its contributions to risk, among other probable benefits. ***We believe that certain types of tests are being appropriately offered through the DTC model***, but others may need to demonstrate that they are safe and effective and that appropriate controls are in place to mitigate risks"

Effects of a Frequent Apolipoprotein E Isoform, ApoE4$_{Freiburg}$ (Leu28→Pro), on Lipoproteins and the Prevalence of Coronary Artery Disease in Whites

Matthias Orth, Wei Weng, Harald Funke, Armin Steinmetz, Gerd Assmann, Matthias Nauck, Jutta Dierkes, Andreas Ambrosch, Karl H. Weisgraber, Robert W. Mahley, Heinrich Wieland, Claus Luley

Arterioscler Thromb Vasc Biol. 1999;19:1306-15

Gene Dose of Apolipoprotein E Type 4 Allele and the Risk of Alzheimer's Disease in Late Onset Families

E. H. Corder; A. M. Saunders; W. J. Strittmatter; D. E. Schmechel; P. C. Gaskell; G. W. Small; A. D. Roses; J. L. Haines; M. A. Pericak-Vance

Science, New Series, Vol. 261, No. 5123 (Aug. 13, 1993), 921-923.

Conclusions of Lifestyle DTCT

- DTCT bears severe risks to its patients/customers
- Lacking claims of usefulness and lack of harm
- Bogus >>> evidence
- Negative impact on medical commons (psychic harm, follow up testing)
- Exclusive situation of healthcare as well as of EBM is jeopardized by DTCT
- Particular risks of healthcare professionals using DTCT data!
- Essential and medically sound regulations for genetic tests are leveraged by DTCT

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