DNA Direct Overview

Ryan Phelan, Founder & CEO
DNA Direct

Secretary's Advisory Committee on Genetics, Health and Society
Roundtable of Personal Genetic and Genomic Service Providers
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About DNA Direct

DNAdirect Our Mission

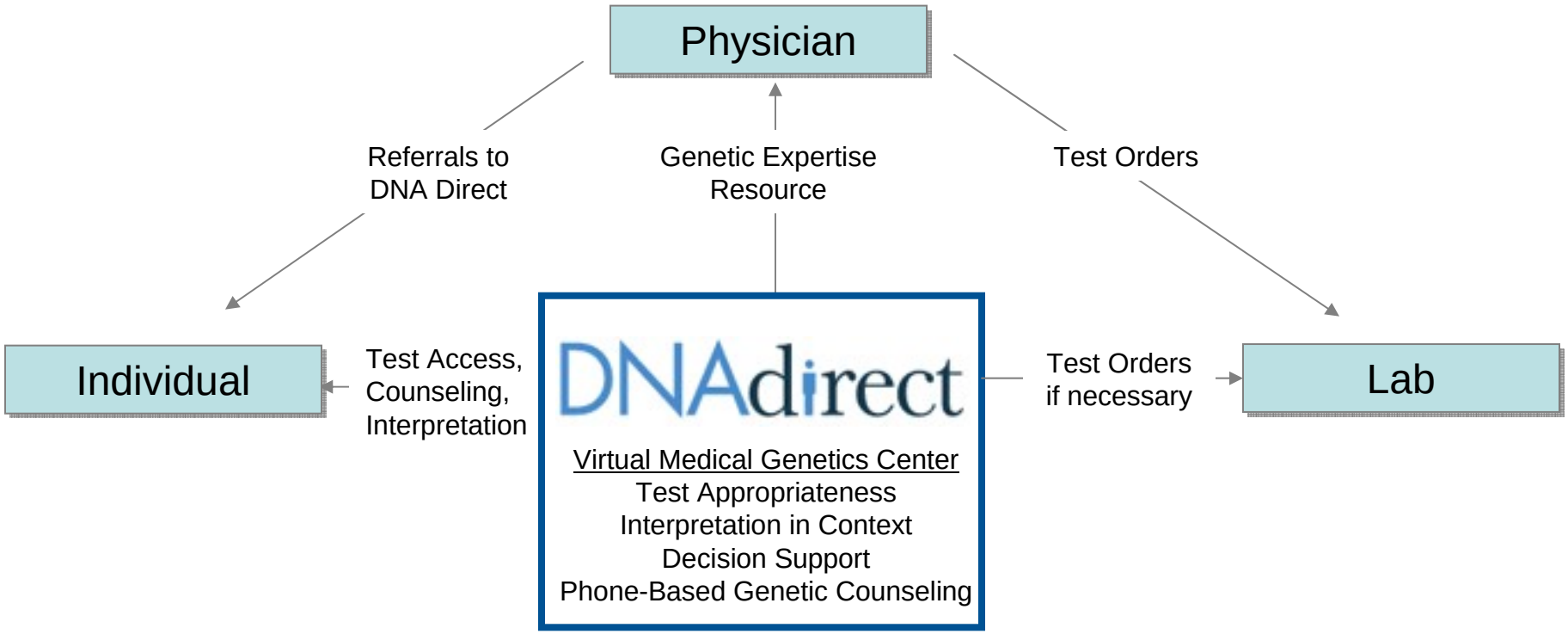
To bring the power of personalized medicine to patients & consumers – reducing health risks, preventing disease, and better targeting therapies.

Company Highlights

- **Launched testing service in March 2005 to provide access to clinically appropriate, valid genetic tests**
- **Assembled team of medical geneticists and board-certified genetic counselors**
- **Core competency is interpretation and "genetic information in context"**
- **Company provides its services:**

1. **Directly to individuals as a virtual provider**
2. **Through healthcare partners as a service provider**

DNA Direct provides scalable access to genetic expertise for individuals and their physicians



Genetic testing areas supported meet clinical criteria

Areas of Genetic Expertise

MEDICAL GENETIC TESTING

- Alpha-1 Antitrypsin Deficiency
- Ashkenazi Jewish Carrier Screening
- Blood Clotting Disorders
- Breast & Ovarian Cancer (BRCA 1 / 2)
- Colon Cancer Screening
- Cystic Fibrosis
- Diabetes Risk - deCODE T2™
- Hemochromatosis
- Infertility
- Recurrent Pregnancy Loss
- Prenatal Testing

DRUG RESPONSE TESTING

- 2D6, 2C9 & 2C19
- Tamoxifen 2D6
- Warfarin

How We Build Expertise

CRITERIA FOR TEST MENU

- Scientific merit / clinical validity
- Evidence-based recommendations
- Medical guidelines
- Clinical actionability
- Consumer actionability
- Personal utility
- Interpretation needs significant

PROCESS FOR TESTING AREAS

- Clinical reviews by Subject Matter Expert
- Content approved by multiple reviewers
- Development of algorithms for web-enabling genetic expertise
- Specialized training for genetic counseling staff

Our Process:
Determining testing appropriateness

For all tests offered by DNA Direct, an appropriateness questionnaire is required prior to testing

For all tests offered by DNA Direct, access to phone-based genetic counselors is available prior to testing

Hereditary Breast and Ovarian Cancer Pre-Test Questionnaire

▸ clear all answers

1 Have you ever been diagnosed with breast cancer? why we ask

- ○ Yes: Before age 50
- ○ Yes: After age 50
- ○ No

2 Have you ever been diagnosed with ovarian cancer? why we ask

- ○ Yes
- ○ No

3 Have any close blood relatives, male or female, ever been diagnosed with breast cancer. (For example, a parent, grandparent, sibling, aunt/uncle, cousin, or child) why we ask

- ☐ Yes: A female relative diagnosed before age 50
- ☐ Yes: A female relative diagnosed after age 50
- ☐ Yes: A male relative
- ☐ No / Don't Know

4 Have any close blood relatives ever been diagnosed with ovarian cancer? (For example, a mother, grandmother, aunt, sister, daughter or cousin) why we ask

- ○ Yes
- ○ No

5 What is your ethnic ancestry? (please check all that apply) why we ask

- ☐ European Caucasian
- ☐ Ashkenazi Jewish
- ☐ African
- ☐ Asian
- ☐ Hispanic
- ☐ Other

For some tests, such as BRCA, a consult with a genetic counselor is required prior to testing

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Our Process:
Facilitating Test Access

- All cases are reviewed by MD medical geneticist who authorizes genetic test
- DNA Direct provides cheek swab kit or access to blood draw site to facilitate testing
- All samples - with a unique patient identifier- are sent to CLIA-certified, appropriately licensed labs
- All costs of lab tests are a pass-through (no mark-up)

Our Process:
Interpreting Test Results

Customized to family & medical history

Phone-based genetic counseling always available, and required for some tests, such as BRCA

DNAdirect close report

Breast Ovarian Cancer Report 2008-02-14

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1 Your Test Results

You have been tested for an inherited condition known as hereditary breast and ovarian cancer, or HBOC. The test you took, called **full sequencing**, looks at the full DNA of the two genes most commonly associated with hereditary breast and ovarian cancer. These genes are called BRCA1 and BRCA2 (short for "***br***east ***ca***ncer"). This test is a comprehensive analysis, which can identify the majority of changes believed to cause HBOC.

It is estimated that 1 in every 500 to 750 people in the general population carry a genetic change that gives them a higher-than-average lifetime risk for breast and ovarian cancer. Both men and women carry these genetic changes with equal frequency.

Your test found that you have a gene change associated with hereditary breast and ovarian cancer. This gene change is a mutation called 3036del4 located on the BRCA2 gene.

Your Test Results Explained

You told DNA Direct that:

- You were diagnosed with breast cancer at age 35 years and had a right mastectomy in 1996.
- You have a significant family history of cancer.
- Your sister was diagnosed with bilateral breast cancer.
- Your mother was diagnosed with breast cancer at age 40 and died after the cancer spread to her liver at age 55.
- Your maternal aunt was diagnosed with ovarian cancer.
- Your maternal first cousin was diagnosed with ovarian cancer at age 50.
- Your maternal ethnic background is German and English.
- You do not have a paternal history of cancer.
- Your paternal ethnic background is Irish, Swedish, and English.

Because you carry the 3036del4 mutation, you have an increased risk to develop another cancer. Your personal risks are summarized in the table below:

Type of Cancer	Risk
Second Breast Cancer	50-60%
Ovarian Cancer	10-20%

25 - 50 pages depending on test & result

Provides access to additional resources

Helps build an action plan for next steps

Embeds lab report, physician letter & family letter

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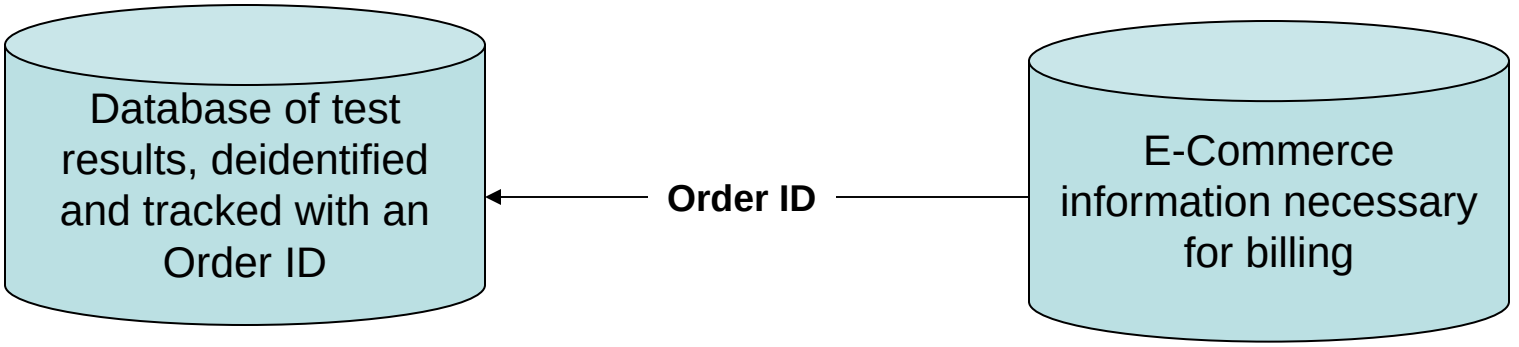
Our Process:
Ensuring Data Security & Privacy

- Genetic data and identifying data stored in two separate databases, tracked by an order id
- Access to genetic data restricted to clinicians and customer service personnel
- Access to identifying data restricted to billing personnel



Genetic data stored in a fully secure, password-protected database with encryption-based access

Customer data - either ecommerce or genetic - never shared without explicit consent

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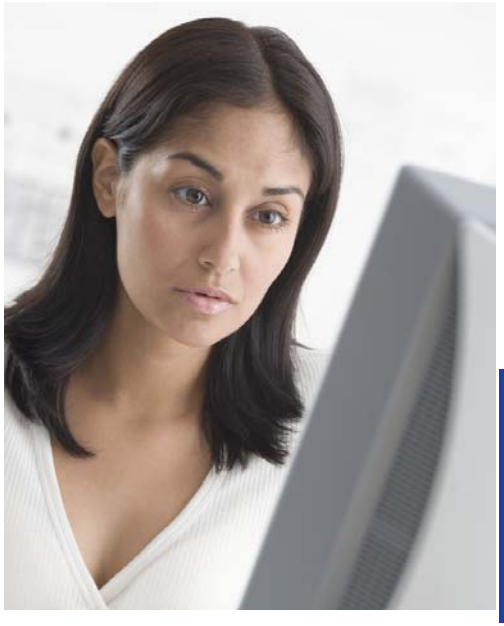
Why do consumers seek our services?

Need access - either no genetic services in their region or their doctor didn't see value in testing



Desire convenience- esting at home and counseling at home best or them

Seek anonymity- want to keep their concern and results private

Want peace of mind- esolve question about ast and current roblems

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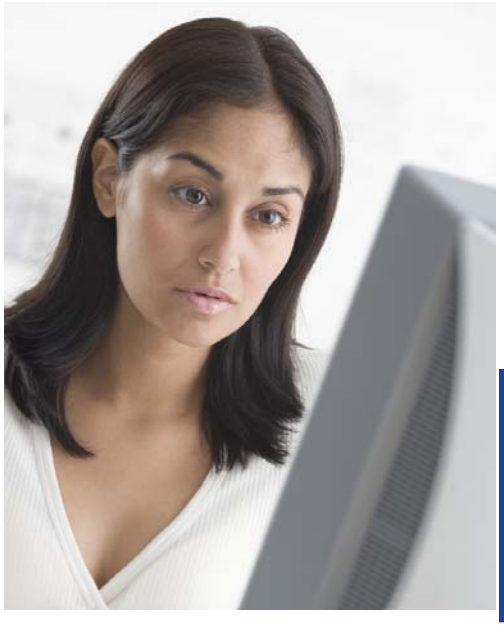
Our actual experience with customers

46% have a family history



21% have a known family mutation

18% have a personal diagnosis

53% have both a personal & family history

34% have tested positive

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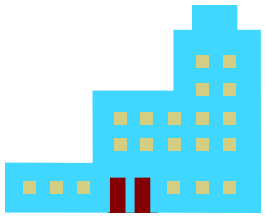
DNA Direct's view of the appropriate level of support

Genetic Test Classifications	Examples	Support Services: In-Person Consult	Phone Consult	Physician Support	Web Report
Genome-Wide Testing	SNP Array		*	*	▤
Genetic Screening: Carrier, Risk Assessment, Drug Response	Cystic Fibrosis Carrier			▤	▤
Predictive Testing for Serious Health Conditions	BRCA		▤	▤	▤
Diagnostic Testing for Genetic Diseases	Huntington's Disease	▤	▤	▤	



* Condition Dependent

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What Support Services Are Appropriate for Which Tests?

Genetic Test Classifications	Examples	What Services To Include?
Genome-Wide Testing	SNP Array	Is MD oversight necessary? Does web-based consultation suffice?
Genetic Screening: Carrier, Risk Assessment, Drug Response	Cystic Fibrosis Carrier	Can it be delivered through web-based consultation with access to phone consults and MD oversight?
Predictive Testing for Serious Health Conditions	BRCA	Can it be delivered through phone-based consultation with MD oversight?
Diagnostic Testing for Genetic Diseases	Huntington's Disease	Should it only be facilitated at a clinic by physicians, also supported by genetic counselors?