



# Personal Genetics Education Project

## Ethical, Legal and Social Issues in Personal Genetics

### Consumer genetics

**Aim:** What are the potential benefits of and concerns about genetic tests being sold directly to consumers?

**Time:** This lesson can be adjusted to fill 2 or 3 classes.

#### **Guiding Questions:**

- What motivates people to learn about their DNA? What are some common reactions to the information one can discover?
- If you were to learn about information contained in your genome, could that impact how you think about your health and identity?
- What are the benefits and challenges of people buying genetic analysis directly from a company, instead of the traditional approach of seeking information through a medical professional?

#### **Learning Objectives:**

By the end of the lesson, students will be able to:

- Analyze the benefits and risks of genetic testing.
- Evaluate why people seek genetic testing and genome sequencing.
- Discuss the issues surrounding direct-to-consumer genetic testing.

**Materials:** Articles and handouts.

#### **Common Core Standards:**

[CCSS.ELA-LITERACY.RH.9-10.6](#). Compare the point of view of two or more authors for how they treat the same or similar topics, including which details they include and emphasize in their respective accounts.

[CCSS.ELA-LITERACY.RH.9-10.8](#). Assess the extent to which the reasoning and evidence in a text support the author's claims.

[CCSS.ELA-LITERACY.RH.9-10.9](#). Compare and contrast treatments of the same topic in several primary and secondary sources.

[CCSS.ELA-LITERACY.RH.11-12.2](#). Determine the central ideas or information of a primary or secondary source; provide an accurate summary that makes clear the relationships among the key details and ideas.

**Next Generation Science Standards:**

*This pgEd lesson integrates some of the NGSS practices and cross cutting concepts associated with the following disciplinary core ideas. The relevant portion of each disciplinary core idea is written out below.*

**[HS-LS3: Inheritance and Variation of Traits](#)*****LS3.A: Inheritance of Traits***

- The instructions for forming species' characteristics are carried in DNA.

***LS3.B: Variation of Traits***

- Environmental factors also affect expression of traits, and hence affect the probability of occurrences of traits in a population. Thus the variation and distribution of traits observed depends on both genetic and environmental factors.

**[HS-LS4: Biological Evolution: Unity and Diversity](#)*****LS4.A: Evidence of Common Ancestry and Diversity***

- DNA sequences vary among species, but there are many overlaps; in fact, the ongoing branching that produces multiple lines of descent can be inferred by comparing the DNA sequences of different organisms.

**Background information and note to teachers:**

*\*Please note that pgEd does not recommend for or against any specific company named in this lesson.*

Genetic testing kits are available for sale, via the Internet and many drug stores, to consumers in the United States (US) and elsewhere. Previously the domain of medical specialists, this growing market is made possible, in part, by the decreasing costs of genome analysis. "Consumer genetics" companies offer a range of tests that report on a person's ancestry, health, and traits. Examples range from the photic sneeze reflex (uncontrollable sneezing when exposed to bright light), to the risk for developing heart disease or diabetes, to how well one might respond to certain medications. In the early 2000s, companies were launched to sell an analysis of a person's DNA looking at areas of the genome that commonly differ between individuals, known as single nucleotide polymorphisms (SNPs). Decreasing costs means some companies are now offering a more comprehensive analysis in the form of a full genome sequence. This lesson serves to help students become informed about the issues related to direct-to-consumer, or "DTC" testing, particularly in regard to health and medical related tests.

Whether people should be able to access their genetic information directly from a company is at the center of an on-going debate. Some people with concerns about DTC testing think that people should only learn about their DNA from a doctor or genetic counselor to ensure that the results are clearly explained. Others argue that people should only learn about risks for disease

that are “medically actionable,” i.e., when screening, therapeutics, or lifestyle change may prevent or treat the disease. Others who support DTC testing think that people have a right to learn about their own DNA if they choose, even if the information they learn is not medically actionable, incomplete, or if the interpretation might change over time.

Some questions about DTC genetic testing have subsided over the years, while others persist. It was originally thought that health insurers might use genetic test results to deny coverage or raise premiums or that employers could fire people based on their genetic information. Some of these fears were allayed in 2008 when the US Congress passed the Genetic Information Nondiscrimination Act (GINA), prohibiting these practices. There continues to be privacy concerns about consumers’ DNA data, such as how genetic testing companies are [selling](#) (anonymized) data to pharmaceutical companies for research and drug development, as well as the ability of [law enforcement](#) agencies to request information from the testing companies.

It is an on-going question whether DTC testing should be subject to the safeguards associated with medical testing devices. Regulatory bodies, such as the US Food and Drug Administration (FDA), have concerns about the accuracy of information and counseling given to consumers. In 2013, the agency ordered 23andMe, one of the leading DTC genetic testing companies, to halt the sale in the US of its disease-risk related products. Since then, the company has received FDA authorization for some health-related genetic tests and is again selling such tests directly to consumers. These include tests for “carrier status” for conditions such as cystic fibrosis and sickle cell anemia. They also offer tests that provide information about the genetic risk of diseases including late-onset Alzheimer’s and Parkinson’s. Additionally, they are selling a test for 3 variants in the *BRCA* genes that are common causes of breast and ovarian cancers in individuals of Ashkenazi Jewish descent. Notably, the FDA did not *approve* these tests, but merely authorized them to be sold with certain warning statements and labeling information.

In the years since the FDA’s initial clampdown on DTC genetic testing, new consumer genetics companies started offering “hybrid” models of sales. In such cases, a customer’s order needs to be approved by their own doctor, or a doctor arranged by the company whom the patient might never meet. These companies sometimes provide customers with access to company-affiliated genetic counselors to answer questions about the test results. Whether, or how, these and similar consumer genetics products should be regulated remains an active area of discussion among companies, regulators, and bioethics experts in 2018.

As the landscape for genetic testing kits continues to evolve, the general argument in favor of DTC genetics is that genetic information could encourage some people to opt for earlier or more frequent medical screenings or adopt lifestyle changes to avoid a specific disease. In this lesson, students explore some of the hopes and challenges in DTC genetics. How do consumers react to genetic information gleaned from DTC services? What information can be learned through a genetic test, and do people need or want a doctor or genetic counselor to access this information?

**Note:** As the DTC genetic testing landscape evolves at a rapid pace, we recommend visiting <http://pged.org/direct-to-consumer-genetic-testing/> for regular updates related to this lesson.

**Here is an outline of the resources and activities in this lesson:**

1. Reading for students (page 4)
2. Do Now exercise (page 4)
3. "Panel of Experts" debate (pages 5-8, handouts on pages 11-13)
4. Homework assignment (page 8, handout on page 14)
5. List of additional resources (page 9)
6. Short quiz (page 15, answer key on page 10)

**Reading for students:**

For homework, students should read John Tierney's January 2011 *New York Times* article, "[Heavy Doses of DNA Data, With Few Side Effects.](#)" The article discusses the impact on people when they learn about their genetic information, including whether or not they have a genetic predisposition for diseases such as Alzheimer's or breast cancer. Students will use the article as the foundation for an in-class writing exercise and a debate.

**Activities:** Do Now exercise (10 minutes), "Panel of Experts" debate (65-70 minutes)

**Part 1: Do Now exercise** - Homework response (10 minutes)

Students write about and then discuss the *New York Times* homework article using a specific strategy, called 3-2-1, from Facing History and Ourselves. This technique will clarify points from the article and inform any students who have not done the reading. Have students answer the following questions in their journal or on a separate piece of paper. Then, spend a few

minutes discussing their responses as a class to ensure they understand the main ideas of the article.

- Three things that they learned from the article.
- Two questions that they still have.
- One aspect of the text that they found interesting or surprising.

## **Part 2: Panel of experts testifying before Congress (65-70 minutes)**

This lesson asks students to think about the ways people can learn about their DNA and the implications for themselves, their families and society. For this activity, students will research different opinions about DTC genetic testing and role-play a Congressional hearing.

The hearing is for Senators to learn about the potential benefits and implications of genetic analysis as they decide whether new laws governing the sale of genetic tests are needed. Students are assigned a role with a specific viewpoint and an accompanying article (or more than one, if time allows). After researching their positions, students will testify before Congress using a variation on a debate format. Students will debate the various perspectives around learning about one's DNA and what role, if any, the government needs to play in overseeing safety and reliability of genetic testing. Even though students become an "expert" on their perspective, they should listen carefully during debate to hear all sides before forming their own opinions. The discussion following the debate will allow them to voice their personal opinions based on the research they have done and new information they have.

### ***Step 1: Assigning characters***

Break up students into 7 groups of 3-4 each. Assign each group of students to one of the seven characters from the list below, and distribute the handout on pages 11-12 that explains each character in more detail. Each "character" comes with a pre-assigned perspective on the issues that the group will represent in the debate. This role-play has a large number of characters that can be modified depending on class size; e.g., you could easily have one Senator instead of two.

**The characters are as follows:**

Characters who support direct-to-consumer (DTC) genetic testing (Panel A):

1. Doctor A – Believes DTC testing is beneficial
2. Patient A – Wants access to DTC genetic testing
3. Founder of a DTC company
4. Senator A – Leaning toward supporting DTC testing; questions witnesses

Characters who are against or doubtful of DTC genetic testing (Panel B):

5. Doctor B – Thinks genetic testing through a doctor is valuable, but is skeptical of DTC testing
6. Patient B – Against DTC genetic testing
7. Senator B – Is skeptical of DTC tests; questions witnesses

**Step 2: Researching positions** (20 minutes)

Next, distribute the articles, listed below, that each student needs to read to learn about the issues they will be discussing. Assign students the article(s) that will provide information about their point of view; if time allows, assign at least one reading with the opposite point of view. If you only have 2 days, assign one reading; if you have 3 days, include additional readings.

Also, distribute the Congressional Testimony worksheet (page 13 of this document) for students to complete while doing their research and hand in after the debate.

Articles in support of DTC genetic testing (Panel A):

- [For \\$99, Eliminating the Mystery of Pandora’s Genetic Box](#), *New York Times*, 2013 (DTC Founder, Patient A)
- [Routine DNA Sequencing May Be Helpful And Not As Scary As Feared](#), *National Public Radio*, 2017 (Patient A, Doctor A)
- [Direct-to-consumer genomics: Harmful or empowering?](#), *Science Daily*, 2017 (Doctor A, Patient A)
- [How to Free Personal Genetics](#), *Pacific Standard*, 2017 (Doctor A, Senator A, DTC Founder)
- [A government ban on 23andMe's genetic testing ignores reality](#), *The Guardian*, 2013 (Senator A, Doctor A)

Articles against/doubtful of DTC genetic testing (Panel B):

- [What are the risks and limitations of genetic testing?](#), Genetics Home Reference, U.S. National Library of Medicine, updated 2018 (Doctor B)
- [Why You Should Think Twice About At-Home Genetic Testing](#), *U.S. News and World Report*, 2016 (Doctor B)
- [Another Reminder That Consumer DNA Tests Are Not 100% Accurate](#), *Gizmodo*, 2018 (Doctor B, Patient B)
- [It's Legal For Some Insurers To Discriminate Based On Genes](#), *National Public Radio*, 2013 (Patient B, Senator B)
- [Genetic Testing for Women: When DNA Screenings Lead To Devastating Mistakes](#), *Huffington Post*, 2013 (Doctor B, Senator B, Patient B)

**Step 3: Congressional Testimony** (40 minutes)

Each group of students (or the teacher) will choose one person to be the main speaker who must be able to answer the questions asked by the senators. You may want to assign the other students in the group to act as "aides," so that they can add to what the speaker says and to hold all students accountable for the work.

Below is our suggested format to assign roles for and structure the debate. To create other roles for students within each group, refer to [Assigning Roles](#) from Facing History and Ourselves.

*Opening Statement Presenter:*

One speaker from each group creates a short opening statement, but does not offer specific information. For example, a speaker from Panel A might say, "We support DTC testing because of points X, Y and Z." The teacher may want to identify one person as a Congressional aide who introduces the topic as part of the testimony.

*Topic Presenters:*

These are two or three speakers who create and present the main arguments for the group. Each presenter provides details to support their argument; the goal of such details is to provide evidence to support points X, Y and Z. Each presenter covers a different aspect of the issue.

*Questioners:*

This role can be formalized or the teacher can open up a period for questions from the other students in the class.

*Closing Statement Presenter:*

One speaker from each group presents a closing statement. This presenter summarizes the main arguments and does not present new information.

*Audience:*

Some teachers choose to invite another class (often from a different grade, so they are more impartial) to watch the debate and vote on which side was more persuasive. If that is not possible, the students in the class can vote on whether DTC genetic testing should be allowed, after the teacher explains why they should be impartial in their judgment.

**Step 4: Wrap-up** (5-10 minutes)

After students have testified in the role of their character, give them the opportunity to discuss their own reactions and opinions to the topic. Ask if they have changed their minds from what they originally believed and why.

**Homework assignment:**

Have students write one page (or longer) explaining their personal opinion about whether they think the benefits of knowing about one's genetic predisposition towards disease outweigh the risks. Students should use the information learned in preparing for and participating in the debate to explain their argument. They also should address the following questions, included on a handout on page 14:

1. Would you want to know more about your own genetic make-up? Why do you or do you not want to know this information?
2. Should people be allowed to order a direct-to-consumer kit to learn about their genetic make-up on their own, or should people have to go through a doctor? Explain.
3. Should the government regulate (create rules for) the sale of direct-to-consumer genetic tests? Explain.



**Additional resources for teachers:**

["My risk-benefit ratio for personal genetics,"](#) January 2014, by Virginia Hughes, Phenomena, *National Geographic*.

["Your entire genome can now be sequenced for \\$999—and the results sent to your smartphone,"](#) March 2016, by Akshat Rathi, QZ.

["Should Consumers be Allowed to Order their Own Lab Tests?,"](#) April 2016, *The Wall Street Journal*.

["A single \\$249 test analyzes 30 cancer genes. But do you need it?,"](#) April 2016, by Sarah Zhang, *Wired*.

["The rise and fall and rise again of 23andMe,"](#) October 2017, by Erika Check Hayden, *Nature*.

["How to Spend \\$1,900 on Gene Tests Without Learning a Thing,"](#) October 2017, by Antonio Regalado, *MIT Technology Review*.

["No, FDA Didn't Really Approve 23andMe's BRCA Test,"](#) March 2018, by Cecile Janssens, *The Scientist*.

["Genetic tests ordered by doctors race to market, while 'direct-to-consumer' tests hinge on FDA approval,"](#) March 2018, by Ike Swetlitz, *STAT*.

**“Consumer genetics” quiz answer key (see page 15 for quiz):**

1. C

2. F

3. T

4. Reasons to be excited to learn about one’s DNA might include:

- Learning information about traits or health risks could enable a person to act in a positive way to prevent illness or seek out early treatments.
- Learning about one’s ancestry, particularly for people who are adopted or are disconnected from biological relatives, might reveal interesting histories that were previously unknown.

Reasons to be hesitant to learn about one’s DNA might include:

- Learning health information that is not easily acted upon or treated might be stressful.
- Learning DNA-based ancestry information might contradict one’s personal or cultural understanding of family history.

## Student handout – what is your role in the debate?

### Panel A:

1. **Doctor A** believes direct-to-consumer (DTC) genetic testing is beneficial to patients.

- How could DTC tests improve healthcare for patients?
- How can these tests give people a better understanding of their genetics and their health?
- How might DTC testing save money and lives?

2. **Patient A** supports DTC genetic testing.

- How can discovering your risk for developing a disease help you to prepare before you start to have symptoms (if you ever do)?
- Should Congress be allowed to say you cannot have direct access to your own genetic information? If you cannot have access, who can?

3. **The founder of a DTC company** thinks that personal genetics is the future of medicine and that DTC testing creates informed, engaged citizens who can partner with their healthcare professionals to improve their lives and health.

- Why should reputable companies like ours be scrutinized because some other DTC companies might be unethical or make claims they cannot prove?

4. **Senator A** is leaning toward supporting DTC tests and questions witnesses.

- Do we have the right to say people cannot learn about their own genetic information? Is it patronizing to think adults who seek this information cannot handle what they learn?

### Panel B:

5. **Doctor B** thinks genetic testing through a doctor is worthwhile, but is doubtful about the usefulness of direct-to-consumer (DTC) kits. Doctor B knows that many doctors are unprepared to interpret genetic information\*.

- Will patients be able to understand the results without help from a doctor?
- How helpful is it to know about genetic risks from a test? Family medical history is still the best tool to predict health risks.
- Since many common diseases or conditions are not caused by a single genetic variant (change), how useful do you think these tests are for most people?

\*An article by Klitzman *et al.*, titled "Attitudes and Practices Among Internists Concerning Genetic Testing" in the February 2013 issue of *Journal of Genetic Counseling*, explored the readiness of internists to provide genetic information to patients. The journal is not freely accessible to the public so relevant statistics are included here:

"We surveyed 220 internists from two academic medical centers about their (use) of genetic testing. Rates of genetic (uses) varied widely by disease. Respondents were most likely to have ordered tests for Factor V Leiden (16.8%), followed by Breast/Ovarian Cancer (15.0%). In the past 6 months, 65% had counseled patients on genetic issues, 44% had ordered genetic tests, 38.5% had referred patients to a genetic counselor or geneticist, and 27.5% had received ads from commercial labs for genetic testing. Only 4.5% had tried to hide or disguise genetic information, and <2% have had patients report genetic discrimination. Only 53.4% knew of a geneticist/genetic counselor to whom to refer patients. Most rated their knowledge as very/somewhat poor concerning genetics (73.7%) and guidelines for genetic testing (87.1%). Most felt needs for more training on when to order tests (79%), and how to counsel patients (82%), interpret results (77.3%), and maintain privacy (80.6%)."

6. **Patient B** opposes DTC genetic testing.

- Imagine a person who wants to know about their DNA finds out he or she has a high likelihood to develop a serious disease. How might this person react to this news without it being explained by a doctor?
- What if my family member takes a test and finds out something that impacts me, too, but I do not want to know about it?

7. **Senator B** is skeptical of DTC tests.

- How can we protect consumers from being harmed or cheated by these tests?
- How do we know the tests are accurate if they are not regulated?
- Even though Congress passed the Genetic Nondiscrimination Information Act (GINA), might health insurers or employers still try to discover genetic information about people? Could this hurt people trying to buy life or long-term disability insurance, both of which are not covered by GINA?

Name \_\_\_\_\_

Date \_\_\_\_\_

### Congressional Testimony worksheet

Arguments that support my group's position	Arguments that oppose my group's position	Supporting details from the article(s) we read
1.	1.	1.
2.	2.	2.
3.	3.	3.

## **Student Handout: Homework assignment**

Please write one page (or longer) explaining your personal opinion on whether or not you think the benefits of knowing about one's genetic predisposition towards disease outweigh the risks. Please use the information learned in preparing for and participating in the debate to explain your argument. Your essay should address the following questions:

1. Would you want to know more about your own genetic make-up? Why do you or do you not want to know this information?
2. Should people be allowed to order a direct-to-consumer kit to learn about their genetic make-up on their own, or should people have to go through a doctor? Explain.
3. Should the government regulate (create rules for) the sale of direct-to-consumer genetic tests? Explain.

Name \_\_\_\_\_

Date \_\_\_\_\_

### **“Consumer genetics” quiz**

1. Deciding to learn about your own DNA is
  - a) not possible until you are 18
  - b) can only be undertaken with your doctor
  - c) is increasingly easier because of technology advances and dropping costs
  - d) is a good way to find out all the diseases you are ever going to get in your lifetime.
  
2. When a person finds out they have an increased risk for Alzheimer’s disease, this information always causes long-term harm to the person’s mental health. T/F
  
3. Genetic testing kits that consumers can buy online (called direct-to-consumer tests) offer people the chance to discover information about their potential risk for certain diseases and information about their ancestry. T/F
  
4. Describe one reason why an individual might be excited to learn about their DNA and one reason why that person might have some hesitations.