Lesson 3: Debating the Ethical and Legal Implications of Genetic Testing

Engage
1) Ask students to draw a line down the middle of a blank page in their lab notebooks. Have students title one column “Ethical” and the other column “Legal.” Using what they know about genetics and biotechnology, ask students to individually brainstorm societal issues raised by genetic testing (includes direct-to-consumer testing, carrier testing, prenatal testing, etc.) and decide if those issues belong in the ethical or legal column.
   - If students need prompting, refer them back to the section they read from DNA: Promise and Peril (McCabe, Linda L. & McCabe, Edward R.B. Regents of the University of California Press, 2008.): use of genetic information in reproductive decision making, free will vs. genetic determinism, coercion or stigmatization due to an individual’s genetic differences

Explore/Explain
1) Briefly discuss the following definitions from Your Genes, Your Choices: Exploring the Issues Raised by Genetic Research by Catherine Baker with students.
   a. “Ethical issues concern what is moral or right.” Example: Should genetic information be used in reproductive decision making?
   b. “Legal issues concern the protections that laws or regulations should provide.” Example: Who owns genetic information?
2) Ask students to review their lists in light of these definitions and make any adjustments to categorization. Are there any issues that could be considered both ethical AND legal?
3) Provide students with “Background Reading: Ethical Perspectives and Theories” and “Ethical Decision-Making Framework” handouts (Appendix I and II, respectively). Divide students into groups of three and ask them to consider the story of Molly and Adam Nash (Appendix III). Have them discuss the questions in the last paragraph and use the one-page “Ethical Decision-Making Framework” handout to analyze the situation. Students should consider and discuss the scenario as a group, but should arrive at their own ethical assessment of the situation (i.e., consensus does not need to be reached).

Extend
1) Divide students into pairs. Half of the pairs will be assigned to debate Scenario A (Appendix IV) and the other half Scenario B (Appendix IV). Half of the Scenario A groups will be on the affirmative (‘PRO’) side, and the other half will be on the negative (‘CON’) side. The same applies to the Scenario B groups.
   - Both scenarios present complex situations with multiple embedded issues. If students have limited time or struggle to focus their arguments, limiting the debate to one issue may be helpful.
2) Go over the rules and the format of debate with students (Appendix V and VI). Students should be
given at least one-and-a-half hours to research their positions.

a. Explain to students the purpose of each speech and question period. Give students the grading rubric (Appendix VII).

b. Explain that students will start out by doing their initial research in pairs, but will consolidate their ideas in groups of four 30 minutes into the research time allowance, and then they will consolidate again into a group of eight or more before the final debate. During each consolidation, the group should select the best arguments and lines of evidence to move forward with. The final group will nominate a speaker for each section of the debate, but all members of the group will be responsible for the content.

3) Students debating Scenario A should read Chapter 11: Reproductive Technologies from DNA Promise and Peril, using the guided-reading worksheet to organize their thoughts (Appendix VIII). Similarly, students debating Scenario B should read Chapter 9: Genes as Commodities, using the guided-reading worksheet to organize their thoughts.

4) Allow students to prepare their written arguments in class using their guided-reading worksheets and online resources. Recommend http://www.ornl.gov/sci/techresources/Human_Genome/medicine/genetest.shtml and http://www.genomicslawreport.com/ as initial resources.

5) Check with each group and explain complex terms and concepts. Students may have trouble separating ethical and legal issues (the law is not always ethical!).

6) 30 minutes in, ask each pair to merge with another pair and consolidate their best collective arguments/evidence into a new brief.

7) Consolidate groups further so that there is one Affirmative group and one Negative group for each scenario. Give groups at least 30 min. to prepare their final briefs and select speakers.

8) As homework before the debates, have students read the scenario they are NOT debating and fill out the top portion of the Position Sheet (Appendix VIII). Students should return to this sheet to take notes as they observe the debate they are not participating in.

9) Each debate should take 25-30 minutes. Allow 10 minutes after each debate for class discussion.
Background Reading: 
Ethical Perspectives and Theories

How Does Ethics Differ from Morals and Values?

The terms values, morals, and ethics are often used interchangeably. However, there are some distinctions between these terms that are helpful to make.

- **Values** signify what is important and worthwhile. They serve as the basis for moral codes and ethical reflection. All individuals have their own values based on many aspects including: family, religion, peers, culture, race, social background, gender, etc. Values guide individuals, professions, communities, and institutions. One expression of values might be that ‘Life is sacred.’

- **Morals** are codes of conduct governing behavior. They are an expression of values reflected in actions and practices. Morals can be held at an individual or communal level. For example, ‘One should not kill’ provides a guideline for action based upon values.

- **Ethics** provides a systematic, rational way to work through dilemmas and to determine the best course of action in the face of conflicting choices. Ethics attempts to find and describe what people believe is right and wrong, and to establish whether certain actions are actually right or wrong based on the all the information available. For example, ethics might address a question such as ‘If killing is wrong, can one justify the death penalty or kill in self-defense?’

What Are Some Different Ethical Perspectives?

Ethicists defend their positions by using different ethical perspectives and theories. Five of the major perspectives are described here.

- **Moral Rules**
  
  An action is right if it follows certain fundamental moral rules. In Rules-based perspectives, the important feature is that an action itself should be considered, not what happens as a result of that action. This theory emphasizes moral duties and obligations as well as moral rights. Examples of commonly used rules are not to treat people as only a ‘means to an end’ and to ‘treat others as you would like to be treated yourself’. Someone arguing from a rules-based perspective might say that his or her moral rule or duty is to ‘always avoid killing’.

- **Virtues**
  
  An action is right if it conforms to a model set of attributes inherent in a particular community. Virtues-based ethics looks at the overall character that is considered desirable by a community. It then asks, ‘what would the virtuous person do?’ Ancient Greeks identified certain virtues that are
still widely recognized today as important such as compassion, honesty, courage, and forgiveness. Virtue ethics looks at the whole person and their behaviors over their lifetime in many situations. For example, killing may not be considered in harmony with a virtuous character that emphasizes forgiveness.

• **Outcomes**  
*An action is right if good consequences outweigh bad consequences.* Outcome-based approaches look at the results of actions in determining whether they are ethical or not. Often this theory will look for solutions that will create the greatest ‘good’ for the greatest number. For example, killing some people may be justified under this perspective if many more will be saved as a result.

• **Principles**  
*An action is right if it follows the principles:*  
- **Respect:** Respect individuals and their autonomy (right to make independent choices).  
- **Beneficence:** Be of benefit  
- **Non-maleficence:** Minimize harm  
- **Justice:** Treat others equitably, distribute benefits/burdens fairly

The principles provide a combination of rules and outcomes-based perspectives. For example, respect for individuals and justice are focused more on rules, and beneficence and non-maleficence require looking at the outcome of an action. The principles are widely used in biomedical ethics. Suppose a person who was dying wished to be killed. The principle of autonomy might be interpreted to say that in order to respect that individual’s wish, they should be killed. However, suppose the patient had asked a doctor to do the killing. A doctor who had vowed not to harm others might invoke the principle of non-maleficence and decide they could not kill the patient.

• **Care**  
*An action is right if it acknowledges the importance and value of interpersonal relationships.* Care ethics also looks at the underlying power structures of a situation. For example, an ethicist using the perspective of care might look at how an oppressive or exploitative social structure may underlie an act of killing.

Each of these perspectives allows different questions to be asked of an ethical dilemma. For example, in looking at different solutions one might ask, “Which one provides the greatest good for the greatest number?” “Which solutions are the most fair to the parties involved?”, or “Which are consistent with moral rights and duties?” Familiarity with these perspectives can provide you with a language to describe and defend your position, and help you see how your arguments align with established philosophical perspectives.

From the Northwest Alliance for Biomedical Research, www.nwabr.org
## Ethical Question:

1. Relevant Facts (known)  

2. Questions that remain (unknown, need to know)  

3. Stakeholders  
   (people and/or entities affected by the decision)  

4. Concerns/Values of each stakeholder  

5. Possible Solutions  
   a.  
   b.  
   c.  

6. Decision  
   Justification  
   a.  
   b.  
   c.  

---

From the Northwest Alliance for Biomedical Research, www.nwabr.org

*Modified from the Hastings Center, 1990*
Appendix III

Using Preimplantation Genetic Diagnosis to Save a Sibling: The Story of Molly and Adam Nash
(Steinbock, Bonnie. Ethical Issues in Modern Medicine, Contemporary Readings in Bioethics. 7th edition. McGraw Hill. 2009.)

Molly Nash was born on July 4, 1994 with multiple birth defects due to Fanconi anemia, a deadly genetic disease that causes bone marrow failure, eventually resulting in leukemia and other forms of cancer. Her best chance for survival was a bone marrow transplant from a perfectly matched sibling donor. Lisa and Jack Nash had considered having another child, not as a source of bone marrow but because they very much wanted another child. They had decided against it because there was a one-in-four chance that the infant would have the same illness as Molly, and aborting an affected fetus was not an option Mrs. Nash would consider. Then they learned about preimplantation genetic diagnosis (PGD), which would enable them to screen embryos for the disease, and implant only the healthy ones. Moreover, the embryos could also be tested to find which ones shared Molly’s tissue type. The baby would be not only disease-free, but could also provide bone marrow to Molly. Moreover, because blood cells saved from the baby’s umbilical cord and placenta could be used, there would be no need to extract the bone marrow from the baby’s body, a procedure which is both painful and carries some risk.

The odds of producing an embryo that is disease-free, a perfect match, and capable of initiating a pregnancy are daunting. In January 1999, Lisa Nash produced 12 eggs, 2 of which were healthy matches. She became pregnant, but miscarried. In June she produced only four eggs, one of which was a match, but she did not become pregnant. In September, she produced eight eggs, only one of which was a healthy match, but again she did not become pregnant. Molly was getting sicker and her physician recommended proceeding with a transplant from a nonrelated donor, although the odds that such a transplant would work were virtually nil. The Nashes decided to try a different IVF clinic, one known for being more aggressive. Lisa’s hormone regimen was changed and in December 1999, 24 eggs were retrieved. Only one was a match, but this time she became pregnant. She was confined to bed to prevent a miscarriage. On August 29, 2000, after 52 hours of labor (Lisa resisted a cesarean section because more cord blood could be collected during a vaginal birth), Adam Nash was delivered by C-section. In October 2000, doctors at Fairview-University Hospital in Minneapolis, which specializes in bone marrow transplants for children with Fanconi anemia, successfully transferred tissue from Adam’s umbilical cord into Molly’s body. Molly, by all accounts, is doing very well. She is back at school, or rather a visiting teacher, who must wear a mask during lessons, comes to her home. She takes ballet lessons. Her transplant did not cure her of Fanconi anemia, but merely prevented her from developing leukemia. She is likely to suffer Fanconi’s other complications, particularly cancers of the mouth and neck, but that is far off in the future.

Adam Nash was not unique in being conceived to save a sibling. Ten years earlier, another couple, Abe and Mary Ayala, decided to have Abe’s vasectomy reversed, in the hopes that Mary would become pregnant with a child who could be a bone marrow donor for their daughter, Anissa, aged 17, who had been diagnosed with leukemia. Surprisingly, the reversal worked and Mary, aged 42, became pregnant. Moreover, the baby, Marissa Eve, born on April 3, 1990, turned out to be a compatible donor.

1) Is using PGD to select an embryo in order to save another child ethical? Explain.
a. If yes, are there any situations in which it would not be ethical?

b. If no, are there any situations in which it would be ethical?

2) How do you think the child who was selected in order to save the sibling would answer this question?

3) Is there any difference ethically between the Nash family scenario and the Ayala family one?

4) Does this scenario have any greater implications for the medical community and for society?
Medical ethicists’ perspective (For Teachers Only)

At the time, the reaction from medical ethicists was generally negative. Philip Boyle, an associate at the Hastings Center, said, “It’s troublesome, to say the least. It’s outrageous that people would go to this length.” Alexander Capron, professor of law and medicine at the University of Southern California, suggested that having a baby to save another child was ethically unacceptable because it violated the Kantian principle that persons are never to be used solely as a means to another person’s ends. Others, however, challenged the view that Marissa was being used as a means only, or that she was not given the respect due to persons. The crucial thing, they argued, was that her parents and siblings intended to love the new addition to the family as much as her older brother and sister, whether or not she could donate bone marrow. The risk to Marissa was minimal; indeed, if Anissa already had a baby sister with compatible marrow, no one would have questioned using the infant as a donor. Why should the moral situation be different if the choice is to create a child in the hopes that she will be a donor?

Unlike the Ayalas, who thought they had completed their family, the Nashes wanted another child. When they were told that the same technique that could prevent the birth of a child with Fanconi might also identify a compatible donor for Molly, they jumped at the chance. As Mrs. Nash put it, “You could say it was an added perk to have Adam be the right bone marrow type, which would not hurt him in the least and would save Molly’s life. We didn’t have to think twice about it.”

Are there ethical objections to what the Nashes did? Some oppose PGD even for its ordinary use, to prevent the birth of a child with a serious disability. Others do not oppose PGD in principle, but think that it should not be used to save the lives of existing children. One concern is that the parents of fatally ill children will be unable to refuse to go through IVF if it is presented as their only chance for saving their child. Furthermore, not every story of a Fanconi child has the happy ending afforded the Nash family. Some women go through cycle after cycle of IVF, only to fail to produce a compatible embryo, or to suffer repeated miscarriages. It may be argued that this is not a choice that doctors should offer desperate parents, given that the odds of success are relatively low. At the same time, many women choose to undergo the rigors of IVF to have babies. If it is not unethical to give them this choice, is it unethical to give them the chance to save their child’s life, if they are fully informed about the burdens and risks, and the odds of success?

Some ethicists object to the idea of having a baby for “spare parts.” Clearly it would be wrong to create a baby for spare parts if that would be harmful to the child. One could not create a baby for his heart or lungs or even kidney. In what sense has Adam Nash been harmed? He owes his very existence to the fact that he was a perfect match for Molly. Of course, many embryos were discarded and this is considered immoral by those who view preimplantation embryos as tiny children. This, however, is not an objection to using PGD to create donors, but to PGD generally, and indeed to all of IVF.

Finally, many are profoundly disturbed by the possibility of “having babies to spec,” of choosing who will be born based on their genetic characteristics. “If we can screen an embryo for tissue type, won’t we one day screen for eye color or intelligence?” Some ethicists fear that the use of PGD to get compatible donors today will lead to a world in which parents will be able to select their children’s physical, mental, and emotional traits. From one perspective, PGD offers parents of desperately ill children the hope of a miracle. From another, it opens the door to “genetic engineering” and a new eugenics.
Appendix IV

Scenario A
(Courtesy of Alexandria Yonker, MS, CGC)

You are a prenatal genetic counselor at a city hospital. A woman comes in to your clinic to visit with you and is 7 weeks pregnant. She informs you that her husband has a family history of Huntington Disease (HD). His father was diagnosed with the condition at age 42 and died 2 years ago at the age of 56, and his sister tested positive for HD last year at age 32. His sister is not yet symptomatic, but elected to undergo presymptomatic testing saying “I just couldn’t live with this hanging over my head and not knowing.” Your patient’s husband is 28 years old and, she claims, has stated emphatically that he does not want to be tested. He has a 30-year-old brother who has also elected not to undergo presymptomatic testing.

Your patient is very concerned about this family history. She says watching her father-in-law deteriorate for years before finally dying--unable to recognize those around him or provide even the most basic care for himself--was incredibly painful. She disagrees with her husband’s decision not to be tested; she wants as much information as possible. She says they have had many discussions about the subject, most of which have ended up as arguments. Her husband now says he does not want to talk about this anymore.

Your patient is asking for prenatal testing to determine whether or not her baby has the genetic mutation which causes Huntington Disease. The test is possible, but is not routine. If the test result comes back negative for the mutation, your patient informs you she plans to carry the pregnancy to term and not inform her husband she had the testing done. If the test result comes back positive for the mutation, she intends to tell her husband the result and discuss terminating the pregnancy with him. You remind your patient that a positive result for the baby would also indicate a positive result for her husband, as your patient has no family history of Huntington Disease herself. Your patient responds that this baby is just as much hers as it is his, and she cannot continue the pregnancy without knowing what lies ahead. She says she has experienced a lot of stress and is worried that if she does not get any answers soon, she may lose the baby anyway as she typically has somewhat high blood pressure even without high levels of stress.

What would your next steps be? Would you, as a professional, perform this test? What ethical challenges do you identify in this scenario? Are there any legal considerations? What implications does this test have for your patient? For her family? Does this scenario and similar ones have any greater implications for the medical community and for society?

PRO team – As a prenatal genetic counselor, you will perform this test.

CON team – As a prenatal genetic counselor, you will not perform this test.
Scenario B

A genetic testing company that offered whole genome sequencing directly to the general public is going out of business. As part of their privacy policy, after customers were provided with their results, the testing company removed all identifying information from the sequence data, and the only information still linked to the data is anonymous customer surveys outlining detailed, individual medical histories.

As part of the bankruptcy settlement, a venture capital company will take over all of the testing company’s assets, including its whole genome sequencing data. These data are considered quite valuable because of the linked medical histories. In order to offset the testing company’s debts, the venture capital firm will likely sell this information to a biotech company interested in mining the data for its ongoing research. Former customers of the testing company learn about the plan to sell the anonymized sequencing data to the biotech company and object to the sale on the grounds that their informed consent with the testing company did not include further research applications of the data. However, further research was not specifically prohibited in the consent statement either.

Should the customers have a say in how the data are used? Would you allow the sale to go forward? What legal challenges can you identify in this scenario? Are there any ethical considerations? What implications do these have for the customers? For the biotech company and biomedical research in general? Does this scenario and similar ones have any greater implications for the medical community and for society?

PRO team – The sale should be allowed to go forward.

CON team – The sale should be blocked.
Appendix V

Debate Instructions
(adapted from the Northwest Association for Biomedical Research’s Ethics Primer)

Preparation
• Obtain current information from reputable sources.
• Prepare a quality brief with all sections complete and properly formatted.
• Present your information effectively and convincingly.
• Reflect clearly on the ethical or legal theories/principles involved with the issue. If your scenario has both legal and ethical issues, be sure to distinguish your argument(s) as one or the other in your brief.
• Your formal brief, which will be presented in your opening statement, must contain three arguments, each supported by three statements. Each statement should be supported by a legal or ethical theory/principle with evidence from three relevant quotes from reputable sources. Argument structure is outlined below.

Components of the Debate Brief
Example question: Should thawing unused frozen pre-embryos be permitted?

Statement/Point #1:
Primary authority for frozen pre-embryos rests with the two gamete providers, and they must agree to any disposition of the pre-embryos.

Ethical Theory/Principle: Respecting the individual gamete providers and their autonomy.

Quote A: One sentence summary of the quote, its source, and documentation of the entire quote in context (e.g., photocopy, screen capture).

Quote B:
Quote C:

Statement/Point #2:
Theory/Principle:
Quote A:
Quote B:
Quote C:

Statement/Point #3:
Theory/Principle:
Quote A:
Quote B:
Quote C:

Note that in addition to preparing arguments for their position, each team should anticipate their opponents’ arguments and identify possible flaws or weaknesses in those arguments.
**Debate Format:**

<table>
<thead>
<tr>
<th>Side</th>
<th>Presentation</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Opening Statements and Clarification</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>YES/PRO team</td>
<td>Opening statements using three arguments</td>
<td>5 minutes</td>
</tr>
<tr>
<td>NO/CON team</td>
<td>Asks any clarifying questions</td>
<td>2 minutes</td>
</tr>
<tr>
<td>NO/CON team</td>
<td>Opening statements using three arguments</td>
<td>5 minutes</td>
</tr>
<tr>
<td>YES/PRO team</td>
<td>Asks any clarifying questions</td>
<td>2 minutes</td>
</tr>
<tr>
<td><strong>Rebuttal (No new arguments presented)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>YES/PRO team</td>
<td>Repeats their opponents’ arguments and tells what is wrong with the positions</td>
<td>3 minutes</td>
</tr>
<tr>
<td>NO/CON team</td>
<td>Repeats their opponents’ arguments and tells what is wrong with the positions</td>
<td>3 minutes</td>
</tr>
<tr>
<td><strong>Summary</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>YES/PRO team</td>
<td>Summarizes their position by speaking to their opponents’ counterpoints and closes with why their argument is best</td>
<td>3 minutes</td>
</tr>
<tr>
<td>NO/CON team</td>
<td>Summarizes their position by speaking to their opponents’ counterpoints and closes with why their argument is best</td>
<td>3 minutes</td>
</tr>
</tbody>
</table>

Each side will also be expected to answer questions from the audience.
## Appendix VII

### Grading Rubric for Debate

<table>
<thead>
<tr>
<th></th>
<th>Exceeded</th>
<th>Achieved</th>
<th>Developing</th>
<th>Emerging</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Group cooperation</strong></td>
<td>- Accepts ideas of others and able to compromise</td>
<td>- Accepts most ideas w/o negative comments and able to compromise</td>
<td>- Unwilling to compromise - Few members contribute</td>
<td>- Group does not work together - One person does all the work</td>
</tr>
<tr>
<td><strong>Understanding of ethical/legal conflict</strong></td>
<td>All aspects of the ethical/legal conflict are presented</td>
<td>Some aspects of the ethical/legal conflict are presented</td>
<td>Ethical/legal content is superficially discussed</td>
<td>Ethical/legal content is not presented</td>
</tr>
<tr>
<td><strong>Understanding of state of the science</strong></td>
<td>- The science is presented thoroughly - The science is used to strongly support a view of the ethical/legal conflict - Common misconceptions are cleared</td>
<td>- The science is presented thoroughly - The science is used to somewhat support a view of the ethical/legal conflict</td>
<td>- The science is presented but with some gaps - The science is used somewhat to support an ethical/legal viewpoint</td>
<td>- The science is incompletely presented or is presented with misconceptions - The science presented does not provide support for an ethical/legal viewpoint</td>
</tr>
<tr>
<td><strong>Presentation</strong></td>
<td>- Informative - Engaging - Easily understood</td>
<td>- Informative - Somewhat engaging - Can be understood</td>
<td>- Somewhat informative - Not engaging - Difficult to understand</td>
<td>- Lacks information - Disengaging - Cannot be understood</td>
</tr>
<tr>
<td><strong>Research</strong></td>
<td>- More than three academically acceptable web-based sources are utilized - All sources are cited using APA format</td>
<td>- 2-3 academically acceptable web-based sources are utilized - All sources are cited</td>
<td>- Only 1-2 academically acceptable web-based sources are utilized - Sources are not cited or cited insufficiently</td>
<td>- Only 1 source of information or sources are not academically acceptable - Sources are not cited or are insufficently cited</td>
</tr>
</tbody>
</table>
Appendix VIII

Reading Guide for DNA: Promise and Peril

For all the following questions, provide evidence from the reading, such as which paragraph, quotes, etc., where it is appropriate to do so. The reading guide is intended to help you to more carefully consider the content, intent, and relevance of the reading.

1) What is the main topic of this section?

2) What is/are the ethical, legal, or social component(s) of this issue?

3) Does anything from this chapter resonate with your own personal experience?

4) Briefly describe how your understanding of the topic changed as you read the chapter.

5) What thoughts or questions would you like to have shared or asked the authors that are relevant to the content of the chapter?
Position Sheet

Based upon my prior understanding of this controversial issue, my position is:

The main reasons that lead me to this position are:

1)

2)

3)

Questions for Debate Presenters:

YES/PRO

1)

2)

NO/CON

1)

2)

NOTES:

Based upon my reflections on the debate, as well as my prior knowledge, I now/still conclude that: