

Do No Harm

INTEGRATED
CURRICULUM UNIT
ON BIOETHICS



ConnectEd: The California Center for College and Career

2150 Shattuck Avenue, Suite 1200

Berkeley, CA 94704

510-849-4945

FAX: 510-841-1076

www.ConnectEdCalifornia.org

National Consortium on Health Science and Technology Education

2410 Woodlake Drive

Okemos, MI 48864-3997

www.nchste.org

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ConnectEd: The California Center for College and Career and the National Consortium on Health Science and Technology Education.

Contributing Teacher Team:

Meridian Medical Arts Charter High School

Meridian, ID

Contributing ConnectEd Staff:

Director for Program and Curriculum Development: Paula Hudis

Curriculum Developers: Pier Sun Ho (Lead), Khanh Bui, Aaron Malloy, Charles Stephen

Publishing/Editorial Staff: Barbara Kridl, Andrea Livingston, Natesh Daniel, Patti Gildersleeve,

Alicia Broadway, Leslie Tilley, Dave Abston, Goura Fotadar McCarty, Becky Chapman-Winter

Administrative Staff: Melody Rose

Contributing NCHSTE Representatives:

Health Science and Biomedical Program of Study Project Director: Beverly Campbell

Executive Director: Carole Stacy

Coordination, Site Sponsorship, and Teacher Team Support: Nancy Allen, SeAnne Safaii, Cindy Beck,

Fran Beauman, Rhonda Patterson, Karen Batchelor, Thalea Longhurst, Jen Staley, Michael Mitchell,

Clarice Morris, Scott Snelson, Bruce Bird, Paul Jackson

Acknowledgments

ConnectEd: The California Center for College and Career and The National Consortium on Health Science and Technology Education (NCHSTE) want to thank the many people who supported this work and helped develop these integrated curriculum units. We would especially like to thank the academic and health science teachers from 12 high schools who participated in our curriculum design workshops and created and tested many of the original lessons in their classrooms. We also want to thank the principals of these schools for encouraging curriculum integration and supporting their teachers' work. Enthusiastic and creative teachers and supportive administrators have been essential to the success of the project.

The following high schools participated at various stages of the project:

California

Arthur A. Benjamin Health Professions High School
(Sacramento)
Palmdale High School, Health Careers Academy
(Palmdale)

Idaho

Meridian Medical Arts Charter High School (Boise)

Illinois

Westinghouse Career Academy (Chicago)
Dunbar Health Academy (Chicago)
New Millennium High School (Chicago)

Indiana

Owen Valley High School (Spencer)

Minnesota

John Marshall High School (Rochester)

New York

Gorton High School Academy of Medical Professions
(Yonkers)

South Carolina

Beaufort High School (Beaufort)

Texas

Ben Barber Career and Technology Academy (Mansfield)

Utah

Northridge High School (Layton)

We also want to thank many contributing representatives from NCHSTE and local school districts who helped coordinate beta testing activities, sponsored school sites, and provided support to the teachers. These individuals include Nancy Allen, Karen Batchelor, Fran Beauman, Cindy Beck, Bruce Bird, Jan Cabbell, Paul Jackson, Thalea Longhurst, Rhonda Patterson, Michael Mitchell, Clarice Morris, SeAnne Safai, Scott Snelson, and Jen Staley. Carole Stacy, NCHSTE's Executive Director, played many essential roles at every stage of this work.

Thanks, also, to Intermountain Healthcare and the Mayo Clinic. Both of these organizations generously provided facilities and opportunities for guided study tours that were an important component of our teacher professional development workshops.

A talented group of curriculum designers at ConnectEd worked with the original lessons created by the teacher teams and expanded their material to create full curriculum units. The team was led by Pier Sun Ho, and also included Khanh Bui, Aaron Malloy, and Charles Stephen.

We gratefully acknowledge the publishing, editorial, and design work provided by MPR Associates, Inc. staff, including Barbara Kridl, Andrea Livingston, Natesh Daniel, Patti Gildersleeve, and Alicia Broadway. They were assisted by Leslie Tilley, Dave Abston, Goura Fotadar McCarty, and Becky Chapman-Winter. Melody Rose ably provided project administrative support.

Major funding for this work came from the James Irvine Foundation and from MPR Associates, Inc. The State Directors of Career Technical Education in California, Idaho, Illinois, Indiana, Minnesota, South Carolina, Texas, and Utah, along with the Director of Career Development and Occupational Studies, Yonkers (New York) Public Schools provided funding for teacher professional development and classroom-based curriculum design and testing. We were fortunate to receive seed money at the start of the project from The Office of Vocational and Adult Education at the U.S. Department of Education.

Acknowledgments

Finally, we want to thank two individuals who provided tremendous support for this effort. Anne Stanton, Director of the Youth Program at the James Irvine Foundation and Gary Hoachlander, President of ConnectEd and MPR Associates, Inc. have encouraged a new way of thinking about how to engage students in learning with the goals of improving academic outcomes and closing the achievement gap. They have encouraged us to create interdisciplinary curriculum material that delivers challenging, college- and career-preparatory academic and technical learning through authentic, career-focused applications. We hope that using this curriculum enlivens your classroom, excites your students to learn, and helps them achieve academic and career success.

Paula M. Hudis
Director for Program and Curriculum Development
and Project Director for
ConnectEd

Beverly Campbell
Principal, BEC Consulting Group and
Health Science and Biomedical Program of Study
Project Director for
NCHSTE

September 2007

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Do No Harm

UNIT OVERVIEW

Essential Question for This Unit

What is the right government role in medical decisions that affect the lives of individuals?

Unit Summary

In this unit, students will learn about the roles government plays in setting policy and supporting and regulating various aspects of the healthcare industry, and about the impact these activities have on the lives of ordinary citizens. The unit will focus on three areas in which federal or state governments have influenced biomedical research and healthcare practice: stem cell research (Subunit 1), pharmaceutical advertising (Subunit 2), and vaccination against communicable disease (Subunit 3).

In Subunit 1, students will begin to study the multiple roles of the government in biomedical research by focusing on stem cell research. They will learn how biomedical research is funded and how it is conducted by federal agencies (such as the National Institutes of Health), universities, and private companies. Students will explore the science behind stem cell research by investigating normal and abnormal cell division and differentiation. These processes serve as foundation knowledge for understanding the potential of stem cell therapy. By understanding stem cell research and the federal legislation surrounding it, students can explore how government policy and funding decisions shape the path of biomedical research. In this subunit, students will also explore another important role of government in medical research—protecting the rights of citizens. They will learn how the history of human experimentation in the United States and other countries has evolved and led to the principle of informed consent that guides all ethical medical research today.

In Subunit 2, students will consider the history of pharmaceutical advertising and its impact on the public. As with biomedical research, the federal government regulates the marketing of medical products. Advertising materials provide students with a rich medium to analyze the characteristics and various rhetorical devices of persuasive writing. Students will compare pharmaceutical advertising from the

1920s to the present, characterize changes in advertising strategies, and analyze the role of regulations in producing these changes. A culminating event for the subunit will be a project to design an advertisement for a fictional pharmaceutical product.

Subunit 3 focuses on the balance between individual rights and the public good. Students will learn that government actions have implications at the individual level, where decisions about certain types of medical procedures are subject to legislation. This subunit centers on requiring vaccination for enrollment in the public schools. Recent FDA approval of a cervical cancer vaccine has prompted heated discussion over whether vaccination should be mandated by the government or should remain a private decision made by parents. To fully engage in this debate, students will investigate the physical structure of viruses and explore pathways of viral infection. Students will also learn how vaccination protects against infectious disease. They will review past cases of government intervention in medical treatment, particularly for minors, and examine the sometimes conflicting positions of various stakeholders in this issue.

Culminating Event

Any of the three subunits can be the foundation of a culminating event that will lead students to answer the unit's essential question: What is the right government role in medical decisions that affect the lives of individuals? For example, they can debate the pros and cons of embryonic and adult stem cell research, current pharmaceutical advertising to the public, or mandated vaccinations for children or adults. They can write research papers supporting various positions on one of these issues and conduct a research symposium attended by outside experts. Or they can prepare draft regulations or legislation on one of these issues based on the results of their research and deliberations.

Key Questions/Issues

- What is the controversy surrounding stem cell research? What are the positions and arguments of the various interested parties? If someone you loved had a fatal illness and a potential cure was

invented, what lengths would you go to in order to secure treatment? (Health Science I, Biology and U.S. History)

- Many serious medical conditions, including heart disease, are potential candidates for stem cell therapy. Heart disease alone, the number one cause of death in the United States, affects 24.7 million Americans. What is the government's responsibility to support relevant research? What other, sometimes competing, responsibilities do we rely on government to fulfill? (U.S. History or U.S. Government)
- How is concern for individual rights balanced against the public good? What are the limits of research that can be done "in the name of science"? (U.S. History or U.S. Government)
- Have you ever been swayed by a commercial? What writing techniques are used in effective advertising? How is advertising used to inform healthcare professionals and the public about advances in healthcare? Why is this important? How can advertising be used to manipulate public opinion and actions? How has advertising changed over the years? Would you consider vintage medical advertisements unethical? (English Language Arts)
- Should parents have the right to refuse life-saving medical treatment for their children on the grounds of their personal beliefs? Should the government be allowed to mandate medical treatments? Who should decide? (U.S. History or U.S. Government)

Learning Scenario to Kick Off the Unit

In June 2006, the FDA announced approval for Gardasil, the first vaccine for cervical cancer, for use on females ages 9 to 26. Shortly thereafter, parents (in a hypothetical school district) received letters indicating that the new vaccine would be required for all girls before they enrolled for school this fall. Some parents did not think much of the new rule; the school district already requires many vaccines for students. To enroll in public school, a student must be vaccinated against measles, mumps, rubella, polio, hepatitis B, and several other diseases. This new vaccine seemed like just one more.

The vaccine's action mechanism is to protect women against strains of the human papillomavirus (HPV),

which can cause cancerous lesions on the cervix. Health officials and some parents applauded the school rule as an important advance in public health for their daughters. Cervical cancer affects 10,000 women every year, and tests indicate that the vaccine is almost 100% effective against two of the most common cancer-causing HPV strains.

However, other parents were not happy at all. The new vaccine had been approved by the FDA in only 6 months. Even though all the tests conducted indicate that the new vaccine is safe, not everyone is convinced that enough testing has been conducted. And there is another problem. HPV is well known as a sexually transmitted disease. Some parents worry that allowing their daughters to get the vaccine will send a subtle message encouraging risky premarital sexual activity. They argue that HPV is not a readily transmitted disease, like measles, and as parents, they should be able to decide for themselves if their daughters should be vaccinated. Officials argue that school mandates are the most effective way to increase immunization rates, and it is illogical not to vaccinate girls if there is a safe vaccine available. What do you think? How should school districts balance the risks to public health against the individual rights of parents to make this medical decision?

Biomedical/Healthcare and Education Partner Roles

- Local biomedical research institutes can provide students with opportunities to observe and participate in the lab activities involved in cancer, viral, and stem cell research.
- Independent review board (IRB) members from partner universities can provide speakers to discuss the process for obtaining government funding and approval for research involving human subjects.
- Local businesses—including pharmacies, pharmaceutical companies, and healthcare providers—can provide advertising copywriters to speak to students about the process of developing an effective advertising campaign and the ethical considerations and legal regulations and codes that guide their work.

Do No Harm

UNIT OVERVIEW

SUBUNITS AND MAJOR TOPICS (ACROSS ACADEMIC AND TECHNICAL SUBJECT AREAS)

Subunit 1

Biomedical Research

HEALTH SCIENCE I · BIOLOGY ·
U.S. HISTORY · ENGLISH LANGUAGE ARTS

- Role and powers of the executive and legislative branches of U.S. government
- Roles of government and the private sector in funding scientific and medical research
- History of human experimentation in the United States and key events in the evolution of modern medical research ethics, from the Nuremberg Code (1947) to the federal policy on the protection of human subjects, 45 CFR 46 (“The Common Rule” 1991)
- Processes of cell division and differentiation
- Cancerous cell growth
- Function and characteristics of embryonic vs. adult stem cells

Subunit 2

Pharmaceutical Advertising

ENGLISH LANGUAGE ARTS · U.S. HISTORY
U.S. GOVERNMENT

- Analysis of advertising print materials for direction and misdirection in informational content, including audience manipulation
- Comparison of advertising in various decades of the 20th century
- Changes in governmental regulation of advertising
- Consumerism in the 1920s and its historical growth

Subunit 3

Medical Decisions

BIOLOGY · ENGLISH LANGUAGE ARTS ·
ALGEBRA I · U.S. HISTORY ·
U.S. GOVERNMENT

- Processes of viral infection and replication
- Treatment and prevention of viral infection
- Function and processes of the immune system
- Governmental evaluation and regulation of mandatory medical treatments
- Freedom of religion and parental rights vs. the public interest

Biomedical Research

SUBUNIT 1 OVERVIEW

Essential Question for This Unit

What is the right government role in medical decisions that affect the lives of individuals?

Subunit Goals

Subunit 1 focuses on ethical issues involved in biomedical research. By the end of Subunit 1, students will be able to explain the institutional structure and funding of biomedical research in the United States. They will also be able to use and build on their existing knowledge of the cell to describe the processes of normal cell growth and differentiation and the causes and mechanism of abnormal cell growth and differentiation (cancers), and apply that knowledge to the theoretical principles and methods of stem cell therapy. Students conclude the unit by analyzing major instances of human subject experimentation by the United States and other countries in the 20th century and relating that history to changes in government regulation of scientific and medical research.

Subunit Key Questions

- How and by whom is biomedical research conducted in the United States? (U.S. History and Health Science I)
- How can stem cells be used to treat serious medical conditions? What determines if a disease is a candidate for stem cell therapy? (Biology)
- What is the controversy surrounding stem cell research? What are the positions and arguments of the various interested parties? (If someone you loved had a fatal illness and a potential cure was invented, what lengths would you go to in order to ensure they received treatment?) (Biology and English Language Arts)
- In what ways can federal and state governments influence the direction and scope of scientific and medical research in the country? (U.S. History or Health Science I)
- How is concern for individual rights balanced against the public good? What are the limits of research that can be done “in the name of science”? (U.S. History and Biology)

Lesson Summaries

Lesson	Subject	Description
1.1	Health Science I	Introduction to Bioethics Students are introduced to the concept of ethics, in particular as it pertains to the health and biomedical sciences. Students read and discuss a variety of ethical scenarios.
1.2	Biology	Cell Division and Differentiation Students observe cell division and differentiate between various stages of the cell cycle.
1.3	Biology	Cells Gone Wild Students analyze the stages of tumor development and distinguish the characteristics of healthy and cancerous cells.
1.4	Biology and English Language Arts	Stem Cell Research Project Students research the function and mechanism of embryonic stem cells and develop a position regarding their use in medical research.
1.5	U.S. History or Health Science I	Shaping the Research Agenda Students analyze public policies governing scientific and biomedical research funding.
1.6	U.S. History	Bad Blood Students explore research ethics and regulation by evaluating the Tuskegee Syphilis Study and other significant human subject experiments of the 20th century.

Introduction to Bioethics

LESSON 1.1

HEALTH SCIENCE I

Time

50 minutes

Materials

Bioethics Scenario Cards

Prior Student Learning

None

Essential Question for This Unit

What is the right government role in medical decisions that affect the lives of individuals?

Objectives

After completing this lesson, students should be able to

- Describe the field of bioethics.
- Identify and think critically about the ethical issues raised by real-life health situations.

Lesson Activities

Lesson Springboard

Ask students to consider the following scenario:

A pharmaceutical firm is deciding on its research budget for the upcoming year. The research and development division has a promising lead on a new drug that could add several inches to an individual's height. This drug could be a boon to young people who are likely to end up as very short adults or to teenagers who want to become star athletes. If the research team is asked to focus solely on this project, it could produce a trial medication in about a year. The research division also has some new information on Creutzfeldt-Jakob disease (CJD), an invariably fatal brain disorder that usually starts around age 60. The disease is rare but devastating to patients and their families. If asked to focus on this disease, the research team could make significant progress on developing a treatment, but a successful medication is probably 5–10 years away.

A drug that could significantly increase height would generate millions of dollars for the company, which it can then reinvest into researching other medical conditions. However, people do not die from being short. Delaying research on CJD potentially causes more people to die of the disease than would have otherwise. However, it is extremely expensive to conduct research, and the company would not profit much from developing the cure. In the long run, the company may have less money to research other diseases if it spends too much time and too many resources on rare conditions. Plus, there is no guarantee that either of these leads will turn into an effective treatment or medication.

If the decision were up to you, how would you allocate the research funds? What issues would you consider to arrive at your decision?

Subunit 1—Biomedical Research
Introduction to Bioethics

LESSON 1.1

Lesson Development

Discussion

Allow students to share their thoughts about the scenario and encourage them to defend what they think is right. Introduce bioethics as a field that investigates situations such as the one just discussed; bioethics deals with the ethical issues involved in health, medical, and biological research decisions. Bioethicists have varied backgrounds: they can be physicians, social scientists, lawyers, philosophers, theologians, or scientists. The field requires knowledge of science, medicine, social issues, and the humanities, which is used in determining the underlying principles in ethical conflicts and coming up with a balanced conclusion.

Small Group Work

Divide the class into groups of three to four students. Hand out one Bioethics Scenario Card to each group and give students a couple of minutes to read the card. Circulate among the groups to answer any clarifying questions about the situations described.

Give the groups 10 minutes to identify, agree upon, and record the conflicting needs of the characters in their situation and the underlying ethical issues involved. Students may have trouble stating what the ethical problems are, although the overt conflicts between individuals in the story are obvious. They may need guidance and support on how to identify a more general ethical question from a specific incident.

Then allow another 10–15 minutes for the groups to try to reach a conclusion about what should be done in their scenario. Have groups record the elements where they agreed and where they disagreed, along with their thoughts about why they disagreed on some issues.

Discussion

Ask groups to consider how they would defend their conclusions about the right thing to do. How can you be sure if you're right or wrong in these situations? What are the values and principles that you drew upon when forming your conclusions, and where did these values come from?

Lesson Closure

Have each group briefly describe their scenario to the class and discuss how they came to agreement about the correct course of action. As a homework assignment, ask students to write a short essay reflecting on the lesson and the group's decision-making process. What were the small group discussions designed to accomplish? Was this a good way to learn about bioethical issues? If they wanted to learn more about bioethics, what other methods would help them expand their knowledge?

Possible Prior Misconceptions

Students may not have realized the scope of bioethical issues that we face today. They may think that these ethical issues involve only health-care professionals and biomedical researchers and not members of the general public.

Student Assessment Artifacts

Notes recording results of small group discussions
Reflective essays

Variations and Extensions

Students could be asked to create and analyze their own bioethical scenario or to research current events involving bioethics.

National and State Career Technical Education Standards

NATIONAL

NCHSTE National Healthcare Skill Standards

Foundation Standard 6: Ethics

Healthcare workers will understand accepted ethical practices with respect to cultural, social, and ethnic differences within the healthcare environment.

6.11 Differentiate between morality and ethics and the relationship of each to healthcare outcomes

6.15 Discuss bio-ethical issues related to healthcare

6.16 Analyze and evaluate the implications of medical ethics

STATE

List your state-specific standards in the space below.

Name _____ Date _____ Period _____

Bioethics Scenario Cards

Scenario 1: Needing an Organ

Jerome is a wealthy father of four young children who works as a pediatrician at the local clinic. He falls seriously ill, and while in the hospital he is told that unless he receives a new kidney within the next few weeks, he will likely die. His entire family is tested to see if they can donate a kidney, but no one is a good match. Jerome is placed on the kidney transplant list. But time is running out, and there isn't a good chance that he will get the kidney he needs since there are many people in his situation who need kidneys, too.

Jerome's wife, Marilyn, desperate to save her husband's life, learns that there are other ways to get a matching kidney. She can offer a small amount of money to people in certain poor countries who are willing to take a test to see if they are a match for Jerome. Once Marilyn finds a match, she can pay that person to donate a kidney. A person can live normally with just one kidney. Jerome's family can offer enough money to give a donor a comfortable life in his home country. The surgery to remove a healthy kidney for donation is painful and sometimes recovery is difficult.

What is the ethical thing to do?

Scenario 2: The Emergency Room

A 5-year-old child and her mother are rushed to the emergency room after the mother's car is hit in a car accident. Both the child and the mother have serious injuries and are bleeding heavily. The mother clearly states that she does not want blood transfusions for herself or her child because of strongly held religious beliefs. The mother then loses consciousness. The child looks at the doctor and says, "I don't want to die. Please help me!" If the doctor doesn't give the child blood very soon, she will be in very critical condition.

What is the ethical thing to do?

Name _____ Date _____ Period _____

Scenario 3: Research on Animals

La'keasha, a brilliant research scientist, is confident that she is on the right track to finding the cure for a certain type of brain cancer. It is one of the most common forms of brain cancer. In order to further her research, she will have to perform tests on orangutans. The apes will live in the laboratory and receive chemical treatments that will give them brain cancer. Half the orangutans will receive no treatment, and the other half will get the experimental treatment. At different stages of the experiment, Belinda needs to autopsy a brain to check the progress of the tumors. Of course, this examination will kill the animal. This is the only research method available for getting closer to a cure, other than similar experimentation on humans.

What is the ethical thing to do?

Scenario 4: The Perfect Baby

The year is 2085. Gwen and Steven are expecting their third child. Their first two are girls, and they hope to have a boy to complete the family, as they are not interested in having any more children. The couple tells their doctor about this the next time they see her for a checkup. The doctor tells them of an exciting new technology that can determine the sex of the baby very early during the pregnancy. Not only that, when performed very early in a pregnancy, new genetic engineering techniques can change the sex of the baby without endangering the baby's viability. "I can even make sure he has blue eyes like his mother," the doctor adds with a smile. "You can design your perfect baby."

Gwen and Steven discover that the baby is a girl.

What is the ethical thing to do?

Name _____ Date _____ Period _____

Scenario 5: Sharing Trade Secrets

Genomeallia, a groundbreaking new genetics research company, discovers a combination of genes that has a strong correlation with the onset of Type II diabetes. The scientific community is thrilled, and all of the top universities in the world call the company asking for the details of their research so that they can help find the cure to diabetes. Genomeallia spent hundreds of millions of dollars of their investors' money to achieve their success, though, and the investors need their money back. If they don't make a profit, investors will no longer invest in biomedical research companies, and discoveries like these will not happen as often.

The CEO of Genomeallia wants to patent the actual combination of genes. Then his company can use their knowledge exclusively or sell it to others at a huge profit. Researchers worldwide are adamant that patenting is a bad idea. Important knowledge like this must be shared freely in order to further science, and the more scientists working on the problem, the better.

What is the ethical thing to do?

Scenario 6: Farming Human Parts

The technology used to clone organisms improves dramatically over the next few years, and scientists announce that they are able to clone human tissue. This process can save thousands of lives. Genetic information is taken from a patient who needs a new liver, for example, and using new methods of genetic engineering, a brand-new, healthy liver is grown that is exactly the same as the original one.

These new organs must be grown in human bodies to work, however. Scientists suggest that given enough time and money, they can design human clones that are not conscious or feel any pain. These bodies can grow the needed organs, which are then harvested for transplant into the sick patient. Depending on the organ, the cloned bodies may be able to grow another body part that can be harvested later. Thus some cloned bodies can be useful indefinitely. Other bodies must be disposed of after harvesting certain organs, as they cannot be used again.

What is the ethical thing to do?

Name _____ Date _____ Period _____

Scenario 7: The Frequent Flyer

Kendall loves his job as a marketing consultant. He flies all over the world to meet with clients and give important presentations. One day he is contacted by a public health official and told that he was recently on a 10-hour flight with someone just diagnosed with a contagious airborne disease. It will need to be treated with strong medication, but the disease is not threatening if diagnosed early. The official estimates that people on the plane have a 25% chance of being infected, given the duration of the flight. Kendall won't know whether or not he contracted the disease for another two weeks, the illness's incubation period.

In the next two weeks, Kendall has four major meetings in three different countries. If he doesn't attend the meetings, he risks losing the accounts and damaging his reputation. He also values his privacy and doesn't want to tell others that he might have a contagious illness unless he is sure that he might infect people.

What is the ethical thing to do?

Scenario 8: Confidential Records

Doctors at a certain clinic notice that for the past few months, patients have been reporting a strange combination of symptoms that do not have a clear diagnosis. When they mention this to public health officials, an investigation uncovers a new disease that mainly affects people in crowded urban areas. The course of the illness is sometimes serious enough to need hospitalization. It is still unknown how the disease is spread and what its long-term effects are. People are afraid, and some people are talking about wearing face masks and staying away from public places to protect themselves.

Health officials want to know how widespread the disease is, its causes, and its effects so that they can prepare for its consequences. One of the ways to do this is to ask clinics and hospitals in the region to check their medical records for all the patients that have complained of the same symptoms. Then those patients can be contacted and asked questions to help learn about the illness. Lists of patients can be distributed to public health offices so that as many officials can investigate the problem as fast as possible.

What is the ethical thing to do?

Name _____ Date _____ Period _____

Scenario 9: Suing for Wrongful Life

Quang and Sue had prenatal testing done when Sue was pregnant with their first child. They were assured that the baby had no abnormalities. When the baby was born, however, it was discovered that he had severe spina bifida, a birth defect that left his legs permanently paralyzed. The parents are horrified at their son's condition—they think it is wrong to bring a baby into the world that would have such harsh difficulties all of his life. Spina bifida should have been detected from the prenatal testing when it was early enough to terminate the pregnancy.

Quang and Sue demand money from the hospital to compensate them for what they consider the wrongful life of their son.

What is the ethical thing to do?

Scenario 10: Not in My House

Harold is a 75-year-old man who suffered a stroke and is now unable to take care of himself at home. His Medicare benefits help him to pay for a home health aide to visit him every day to make sure he is taking his medications, eating, and getting enough movement for his weakened muscles. One day his aide announces that she is moving to another position. Later that day, Harold's home health agency calls to tell him that they are trying to locate another person to come to his home.

"I stick to my own," Harold tells the agency administrator. "Make sure you don't send me any blacks, Jews, or gays. I know how those people are, and I don't want them touching me."

What is the ethical thing to do?

Name _____ Date _____ Period _____

Scenario 11: Paying for Your Mistake

Julia is a single mother of five who never earned her high school diploma because she got pregnant and quit school. Despite working two jobs, she can't make enough money to pay for health insurance and relies on clinics paid for by the state. One day, Julia gets a letter in the mail inviting her to bring her young son, Carl, to the clinic for free vaccinations. Julia doesn't have her son vaccinated because she is so busy. During the one afternoon she had free that month she had her hair done and took a nap.

Carl contracts chicken pox and has serious complications that require hospitalization. Julia cannot pay for the treatment without great hardship and asks the government to foot the entire bill.

What is the ethical thing to do?

Scenario 12: Get Off My Back

Suresh is an experienced doctor who takes his work seriously. One day a 32-year-old woman comes to see him complaining of mild symptoms that don't suggest serious infection or the need for antibiotics. Upon hearing that Suresh will not give her a prescription, the woman insists that he is ignoring her needs and is incompetent. She knows her body better than he does, she states, and she must have the antibiotics before her illness gets worse.

Suresh believes that the antibiotics won't help her and might even be harmful. A sugar pill might do the trick. Suresh could tell the woman that taking the harmless pill will make her condition improve, and her relieved mind might take care of the rest.

What is the ethical thing to do?

Subunit 1—Biomedical Research

Cell Division and Differentiation

LESSON 1.2

BIOLOGY

Time

100 minutes

Materials

- Overhead and markers
- Microscopes
- Prepared slides of onion root tips

Prior Student Learning

Students should be familiar with the basic parts of the cell, including the nucleus.

Students should be familiar with the concepts of genetic material and chromosomes.

Essential Question for This Unit

What is the right government role in medical decisions that affect the lives of individuals?

Objectives

After completing this lesson, students should be able to

- Diagram the stages of cell division in *mitosis*.
- Explain the role of the *cell cycle* in growth.
- Describe the general concept of *cell differentiation*.

Lesson Activities

Lesson Springboard

Begin a class discussion by asking students to think about how much their physical size has changed in the last few years. What do they think is actually happening when they grow? You may also have students speculate about the ages at which the fastest growth occurs.

Lesson Development

Direct Instruction

Introduce or review the concept that cell division, the process in which a parent cell divides into two daughter cells, is at the heart of growth. Individual cells are quite small and usually never undergo much increase in size. In order for an organism to grow, the number of cells increases, rather than the size of the existing cells.

Microscope Observations

Have students observe under the microscope slides prepared from onion root tips. Students should move the slide and identify cells in as many different phases of the cell cycle as possible. Have students draw the different phases they observe (hopefully four or five).

When students have finished their drawings, call several students up to the board to make drawings of what they observed until you have a complete set of the four stages of *mitosis* (*prophase*, *anaphase*, *metaphase*, and *telophase*) and *interphase*. Tell students that the slide has captured each cell in one of the various phases of the cell cycle. Ask students to try to place them in sequential order based on their appearance. This may be done individually or as a class. Remind students that

Classroom Management

Have students draw their diagrams on small squares of transparency, if possible. This allows you to display and rearrange them on the overhead during instruction.

Support Strategy

Provide an outline template or graphic organizer to facilitate note taking.

Cell Division and Differentiation

LESSON 1.2

although a prepared slide captures many cells in different phases, the cell cycle itself is a continuous process.

Support Strategy

Have cell cycle diagrams prepared that students can label and annotate, rather than making drawings themselves. Alternatively, have annotations printed that students can match with their own drawings.

Direct Instruction

Instruct students on the correct order of the cell cycle and what is occurring during each stage. Have students draw and color an original diagram of the cell cycle, complete with annotations for each of the four mitotic stages and interphase.

Class Discussion

Ask students if cell division is sufficient for an organism to grow from a single cell at conception into an adult. Prompt students to consider whether or not all their cells are the same. Do they have a similar appearance? Do they serve similar functions?

Introduce and discuss the concept of cell differentiation with a simple organism. Each cell in *C. elegans* has a well-established cell lineage. Compare *C. elegans* to the more complex system in mammals.

Lesson Closure

Assign students the task of making a Mitosis Animation. Students can either draw the animation by hand (drawing each frame on the sheets of a single square Post-it notepad is an easy way to compile and edit them) or do a simple online animation. Students should share and critique the accuracy of their animations in the next class session.

Possible Prior Misconceptions

Students often mistakenly identify the X structure in metaphase as a pair of chromosomes, rather than an individual replicated chromosome.

Some students may believe that chromosome pairing and crossing over can take place in mitosis.

Students may believe that cells are haploid prior to the chromosome duplication that occurs in mitosis.

Student Assessment Artifacts

Illustrated chart of cell division (Each student should illustrate the cell cycle, complete with annotations for each stage and the average percentage of the total time a cell spends in each.)

Mitosis animation

Variations and Extensions

Allow students to make their own slides of onion root tips. A variety of methods are possible, although the Feulgen squash technique is the only method done at room temperature. This will likely require an extended class session, because slide preparation can take a lot of time.

Extend the lesson to cover the cell cycle control system, including cyclins and cyclin-dependent kinases.

Cell Division and Differentiation

LESSON 1.2

National and State Academic Standards

NATIONAL

NRC National Science Education Standards

The Cell

- Cells can differentiate, and complex multicellular organisms are formed as a highly organized arrangement of differentiated cells. In the development of these multicellular organisms, the progeny from a single cell form an embryo in which the cells multiply and differentiate to form the many specialized cells, tissues and organs that comprise the final organism. This differentiation is regulated through the expression of different genes.
- Cells store and use information to guide their functions. The genetic information stored in DNA is used to direct the synthesis of the thousands of proteins that each cell requires.

STATE

List your state-specific standards in the space below.

Cells Gone Wild

LESSON 1.3

BIOLOGY

Time

100 minutes

Materials

- Microscopes
- Prepared slides of cancerous and noncancerous cells or digital images
- [http://www.unm.edu/~vscience/images/31-2360%20Human%20Simple%20Squamous%20Epithelium,%20sec%20\(400x\).jpg](http://www.unm.edu/~vscience/images/31-2360%20Human%20Simple%20Squamous%20Epithelium,%20sec%20(400x).jpg)
- [http://www.unm.edu/~vscience/images/31-2444%20Human%20Glandular%20Epithelium%20sec.%20\(400x\).jpg](http://www.unm.edu/~vscience/images/31-2444%20Human%20Glandular%20Epithelium%20sec.%20(400x).jpg)

Prior Student Learning

Students should be familiar with the stages of the cell cycle and the stages of mitosis.

Students should know that the nucleus is the control center for a cell, and that the information used to direct the cell's development and behavior is encoded in the genes within the nucleus.

Students should be aware that any changes in a cell's genetic code are referred to as *mutations*, and that the effects of a single mutation can vary widely.

Essential Question for This Unit

What is the appropriate government role in medical decisions that affect the lives of individuals?

Objectives

After completing this lesson, students should be able to

- Describe the physiological and biochemical differences between cancerous cells and normal cells.
- Diagram the stages of tumor development.
- Explain the various genetic transformations that occur in the development of cancer.
- Define and describe various common forms of cancer and potential methods of treatment.

Lesson Activities

Lesson Springboard

Ask students to volunteer stories about their personal experiences with cancer. Refer to public figures who have battled cancer, and remind students that approximately 15 million Americans are currently living with cancer and that almost 1.5 million new cases of cancer are diagnosed each year.

Classroom Management

Sharing personal stories about cancer may be inappropriate if a student's experience is too recent.

Remind students of the recent lessons on the cell cycle and normal cell growth.

Lesson Development

Direct Instruction

Define cancer as a category of diseases in which abnormal cells divide without control and have the ability to invade and spread to other tissues in the body. Have students generate a list of common cancers.

Support Strategy

Provide students with a graphic organizer or outline template for note taking.

Introduce the stages of tumor development and their accompanying genetic mutations, beginning with the initial mutation that makes a cell more likely to divide than normal. The altered cell and subsequent daughter cells grow and divide too often, resulting in a condition known as *hyperplasia*. At some point, these cells undergo another mutation, further increasing their tendency to divide. Cancer reaches *dysplasia* when these latter mutated cells continue to divide excessively and their descendents take on an abnormal appearance. A third mutation occurs, and the mass of cells becomes extremely abnormal in both appearance

and growth. While the tumor that has formed is contained within the original tissue, the cancer is considered *in situ*.

Once additional mutations occur that allow the tumor to invade neighboring tissues, the cancer is considered *invasive*, and the tumor is considered *malignant*. A malignant tumor can shed cells into the circulatory or lymphatic systems, where the escaped cells may establish *metastases* (new tumors) in other locations around the body.

Support Strategy

Students may label rather than create the tumor stage diagram.

Modeling

Have students diagram the stages of tumor development for **homework**. A sample diagram and a good overview of cancer can be found on the National Institutes of Health website at <http://science.education.nih.gov/supplements/nih1/cancer/guide/understanding1.htm>.

Direct Instruction

Distinguish between *benign* and *malignant* tumors. Benign tumors are noncancerous growths that do not invade nearby tissue or spread to other parts of the body. However, they may continue to grow in size abnormally. This growth can crowd surrounding tissue and cause health complications. Malignant tumors are composed of cells that have invaded other tissues in the body.

Classroom Management
Students can work in pairs using microscopes and cancer slides.

Lab Observations

Have students compare cancerous cells to normal cells, either using prepared slides under the microscope or by looking at digital images.

Direct Instruction

Introduce the action mechanism behind various common treatments for cancers and compare the benefits and limitations of each. Be sure to talk about leukemia and the stem cell transplantation treatment for children.

Class Discussion

Ask students what they recall about stem cells from the news. Remind students of the essential question, and ask them to keep it in mind as they move forward to Lesson 1.4.

Classroom Management
Although it is a good idea to allow students to select their own topic, grading will be easier if you have students choose from a list of cancers about which you already have information and statistics.

Lesson Closure

For **homework**, assign or have students select a specific cancer to research more thoroughly. Have students create an informational, trifold brochure about the specific cancer they have chosen that would be appropriate for communicating with a patient. The brochure should include symptoms, causes, preventative measures, and typical treatments, as well as incidence and mortality statistics.

Possible Prior Misconceptions

Some students may believe that cancer is a communicable disease—that is, you can “catch cancer.” Be sure to distinguish between *cancer* and *carcinogens* (some of which are communicable diseases).

Some students may believe that all tumors are cancerous.

Some students may believe that all cancers are fatal.

Some students may believe that cancer happens all at once and is a quick disease. In fact, although cancer can progress rapidly after a late diagnosis, the development of cancer is typically a complex, multistep process that takes years.

Some students may believe that cancer is a single disease and there is one common treatment for all types of cancer.

Student Assessment Artifacts

Informational cancer brochure

Variations and Extensions

Invite a cancer researcher or an oncologist to speak to students about recent research or treatment advances.

Have students visit a local hospital to learn about and view a biopsy analysis.

Have students conduct simplified, mini-case studies where they are given a cancer patient scenario. Based on the type, location, and stage of advancement of the cancer, students will discuss several treatments and recommend one.

National and State Academic Standards

NATIONAL **NRC National Science Education Standards**

The Cell

- Cell functions are regulated. Regulation occurs both through changes in the activity of the functions performed by proteins and through the selective expression of individual genes. This regulation allows cells to respond to their environment and to control and coordinate cell growth and division.
- Cells can differentiate, and complex multicellular organisms are formed as a highly organized arrangement of differentiated cells. In the development of these multicellular organisms, the progeny from a single cell form an embryo in which the cells multiply and differentiate to form the many specialized cells, tissues and organs that comprise the final organism. This differentiation is regulated through the expression of different genes.
- Changes in DNA (mutations) occur spontaneously at low rates. Some of these changes make no difference to the organism, whereas others can change cells and organisms. Only mutations in germ cells can create the variation that changes an organism's offspring.

STATE

List your state-specific standards in the space below.

Stem Cell Research Project

LESSON 1.4

BIOLOGY AND ENGLISH LANGUAGE ARTS

Time

100 minutes in Biology
50 minutes in English Language
Arts

Materials

Equipment

Computer lab with Internet access

Resources

- Stem Cell Headlines handout
- Guiding Questions: Stem Cells Websearch worksheet
- Human Embryonic Stem Cells Animation (http://www.sumanasinc.com/scienceinfocus/sif_stemcells.html)
- Stem Cell Basics from the National Institutes of Health (<http://stemcells.nih.gov/info/basics>)

Prior Student Learning

Students should be familiar with the basic concepts of cell biology: parts of the cell, *meiosis* and *mitosis*, and the five levels of physiological organization (cell, tissue, organ, organ system, and organism).

Students should be familiar with basic principles of genetics.

Essential Question for This Unit

What is the right government role in medical decisions that affect the lives of individuals?

Objectives

After completing this lesson, students should be able to

- Define stem cells.
- Explain the difference between *totipotent*, *multipotent*, and *pluripotent* cells.
- Distinguish the characteristics of embryonic stem cells, adult stem cells, and differentiated cells.
- Explain the methods of creating an embryonic stem cell line.
- Identify and distinguish the characteristics of diseases that have potential to be treated using stem cell therapy.
- Articulate and evaluate multiple perspectives regarding the ethics of various types of stem cell research.

Lesson Activities

Lesson Springboard

Introduce the topic of stem cell research. Pass out the Stem Cell Headlines handout and ask students what they have heard about stem cell research. Accept all responses. Focus the discussion on the concept that, before evaluating or taking sides in a controversy, it is important to be informed and understand the different issues and positions being argued.

Lesson Development

Direct Instruction

Biology

Define stem cells for students as cells with two special characteristics: (1) they are unspecialized cells that renew themselves for long periods through cell division; and (2) under certain physiologic or experimental conditions, they can be induced to become cells with special functions, such as the beating cells of the heart muscle or the insulin-producing cells of the pancreas.

Divide the class into two “specialty” groups to research some specific questions about stem cells. (Distribute the Guiding Questions: Stem Cells Websearch handout.)

Classroom Management

The “specialty” research groups are a simplified version of “jigsaw cooperative learning groups.” Since there are only two “Expert” topics, students may be divided into multiple groups with the same Expert topic.

Expert group research can be done online or with preprinted information.

Subunit 1—Biomedical Research
Stem Cell Research Project

LESSON 1.4

- Where do embryonic stem cells come from, and what is their biological function?
- Where do adult stem cells come from, and what is their biological function?

Reorganize groups so that several members from each “specialty” research group are together. Have them share their information in order to determine the difference between adult and embryonic stem cells.

Re-assemble the class for a discussion on the advantages and limitations of adult and embryonic stem cells.

Show the class the Sumanas Animation on human embryonic stem cells (http://www.sumanasinc.com/scienceinfocus/sif_stemcells.html). Pause after the explanation of embryonic stem cells to check for understanding. Go on to the second half of the animation, which discusses how embryonic stem cells can be used to treat disease.

After watching the animation, ask students what types of diseases have the potential for stem cell treatment and what types of diseases are probably not candidates for this treatment.

Return to the Stem Cell Headlines handout and the controversy on stem cells. Having seen the potential benefits of stem cell therapy, ask students to discuss why there is controversy. Why doesn't everyone support this kind of research? What are the ethical issues involved in embryonic stem cell research? Ask students to compare the ethics of embryonic vs. adult stem cell research.

English Language Arts

Remind students of the stem cell controversy they have learned about in Biology. This type of controversial topic is an ideal one for students to tackle when learning to write a persuasive essay.

Introduce or review elements of the persuasive essay. In addition to defining the issue at hand for the audience, the writer must take a clear position on the issue. Furthermore, the writer must present a convincing argument. A persuasive essay is not just an opinion paper. It presents an argument backed by data that persuades the reader that the writer's position is valid. The writer assumes the audience is skeptical of or antagonistic to the position presented in the paper, so it is important to convey an objective and professional tone. Anticipating objections and including conciliatory language will make the paper more persuasive.

Lesson Closure

In class, have students compile and summarize arguments on both sides of the stem cell research debate. Students should form their own opinion and create an outline for an essay in which they argue their position on the issue. Remind students that a good persuasive essay also considers and addresses the arguments of opposing opinions.

Subunit 1—Biomedical Research
Stem Cell Research Project

LESSON 1.4

Possible Prior Misconceptions

Some students may believe that all stem cells come from embryos.

Some students may believe that stem cells are harvested from embryos created by in vivo fertilization.

Some students may believe that stem cell research could be used to cure any and all diseases. Other students may believe that there is no evidence to indicate that stem cells could be used to cure any diseases.

Student Assessment Artifacts

Stem cell research position essay

Variations and Extensions

Have a class debate the ethics of stem cell research.

Visit a biomedical facility engaged in stem cell research.

Have students revise their position essays into editorials and submit them for publication to the school or local newspaper.

National and State Academic Standards

NATIONAL

NRC National Science Education Standards

The Cell

- Cell functions are regulated. Regulation occurs both through changes in the activity of the functions performed by proteins and through the selective expression of individual genes. This regulation allows cells to respond to their environment and to control and coordinate cell growth and division.
- Cells can differentiate, and complex multicellular organisms are formed as a highly organized arrangement of differentiated cells. In the development of these multicellular organisms, the progeny from a single cell form an embryo in which the cells multiply and differentiate to form the many specialized cells, tissues and organs that comprise the final organism. This differentiation is regulated through the expression of different genes.

Science and Technology in Local, National, and Global Challenges

- Science and technology are essential social enterprises, but alone they can only indicate what can happen, not what should happen. The latter involves human decisions about the use of knowledge
- Understanding basic concepts and principles of science and technology should precede active debate about the economics, policies, politics, and ethics of various science- and technology-related challenges. However, understanding science alone will not resolve local, national, or global challenges.

NCTE Standards for the English Language Arts

5. Students employ a wide range of strategies as they write and use different writing process elements appropriately to communicate with different audiences for a variety of purposes.
6. Students apply knowledge of language structure, language conventions (e.g., spelling and punctuation), media techniques, figurative language, and genre to create, critique, and discuss print and non-print texts.

STATE

List your state-specific standards in the space below.

Name _____ Date _____ Period _____

Stem Cell Headlines

Bush OKs Limited Stem Cell Funding Science

President steers a middle course on his most sensitive policy issue so far, saying he'll allow some U.S.-backed studies that don't destroy more human embryos.

—*Los Angeles Times*, August 10, 2001

White House: Bush Stem Cell Decision Thoughtful

President Bush gambled by announcing his decision about embryonic stem cells with the glare of a nationally televised address, which drew huge attention to an issue that many of his allies considered a political loser.

—*Washington Post*, August 10, 2001

Senate Approves a Stem Cell Bill; Veto Is Expected

Following two days of often personal debate, the Senate defied a veto threat by President Bush on Tuesday and approved legislation that would expand federal support of medical research using embryonic stem cells. White House officials said Mr. Bush planned to veto the measure as early as Wednesday, ignoring the substantial support it won from Senate Republicans, including the majority leader, Bill Frist of Tennessee. It would be the first veto of Mr. Bush's presidency ...

—*The New York Times*, July 19, 2006

First Bush Veto Maintains Limits On Stem Cell Use

President Bush's veto put him at odds with many members of his own party and what polls say is a majority of the public.

—*The New York Times*, July 20, 2006

Stem Cell Work Gets States' Aid After Bush Veto

Two governors have offered state money for research, and the issue has sprung to the forefront of crucial elections.

—*The New York Times*, July 25, 2006

Catholic Group Urges Candidates to Return Cash

The Missouri Catholic Conference is urging candidates for state offices to return contributions from an organization that advocates for stem cell research.

—*The New York Times*, July 25, 2006

Name _____ Date _____ Period _____

Guiding Questions: Stem Cells Websearch

Go to http://www.pbs.org/newshour/extra/features/july-dec01/stem_cells.html and answer each question using complete sentences.

1. What is the stem cell controversy all about?
2. What elements of stem cell research can be funded by federal money, and what cannot?
3. What is a stem cell?
4. What does *pluripotent* mean?
5. Where are stem cells found?
6. What type of stem cells is more useful, according to most scientists?
7. What is an *embryo*?
8. What is a *blastocyst*?
9. What happens to the embryo once stem cells are removed?
10. What are some possible potential uses for stem cells?
11. Why are some people opposed to stem cell research?
12. Why do some people support stem cell research?

Name _____ Date _____ Period _____

Go to http://www.pbs.org/newshour/bb/health/july-dec01/bushspeech_8-9.html and answer all questions using complete sentences.

1. Where would the stem cells for research come from?
2. What is *in vitro fertilization*?
3. What happens to leftover embryos after a couple has successfully had children?
4. What are the other sources of stem cells?
5. Why do most scientists prefer embryonic stem cells?
6. Why should the United States provide federal funding for scientific research?
7. What ethical questions did President Bush have to consider before making his decision?
8. What is the connection between stem cell research and cloning?
9. According to President Bush, how many stem cell lines exist?
10. What was President Bush's final decision about funding stem cell research?
11. Where do you think the controversy on this issue will go in the future, and why?

Shaping the Research Agenda

LESSON 1.5

U.S. HISTORY OR HEALTH SCIENCE I

Time

100 minutes

Materials

- H.R. 810 (<http://thomas.loc.gov/cgi-bin/query/z?c109:H.R.810>;))
- Congressional actions on H.R. 810 (<http://www.govtrack.us/congress/bill.xpd?tab=main&bill=h109-810>;))
- Administration Policy Statement (<http://www.whitehouse.gov/omb/legislative/sap/109-2/hr810sap-s.pdf>)
- California Proposition 71 full text (<http://www.cirm.ca.gov/pdf/prop71.pdf>)
- Proposition 71 summary (<http://www.smartvoter.org/2004/11/02/ca/state/prop/71>)

Prior Student Learning

Students should be aware of how laws are made at the national, state, and local levels.

Students should be aware of how legislators are elected at the national, state, and local levels.

Students should be aware of the basics of determining the federal budget.

Essential Question for This Unit

What is the right government role in medical decisions that affect the lives of individuals?

Objectives

After completing this lesson, students should be able to

- Explain the process by which federal support is provided for scientific research.
- Understand the role of the legislative and executive branches in allocating funds for research.
- Identify the primary government agencies that fund biomedical and scientific research.
- Identify and explain the key legislative events regarding stem cell research.
- Compare current federal policies and programs regarding stem cell research with state policies and programs (where appropriate).

Lesson Activities

Prior to Lesson

Remind students about their research on stem cells. Assign students to find out which federal agencies support biomedical and scientific research and how much money was earmarked in last year's budget to support this work (**homework**).

Lesson Springboard

At the start of this class, have students share their findings. The primary federal funding agencies for biomedical research are the National Institutes of Health (NIH) and the National Science Foundation (NSF), but grants are also administered by the Centers for Disease Control and Prevention (CDC), Department of Defense (DoD), the Environmental Protection Agency (EPA), and other federal agencies. Discuss these research agencies and their primary missions.

Lesson Development

Primary Sources

Have students read the text and major congressional actions for the Stem Cell Research Enhancement Act (H.R. 810), along with the related administration policy statement.

Class Discussion

Have students analyze the history of the bill and place it in context.

- Who introduced the bill and why?
- Who was opposed to the bill and why?

Subunit 1—Biomedical Research

Shaping the Research Agenda

LESSON 1.5

- What influence did this bill have on the national dialogue, and vice versa?
- What potential impact did the bill have for biomedical research?
- What is the current status of the bill?
- What was the impact of the President's policy statement? What was the response from the research community?

For **homework**, have students read the history and text of California Proposition 71.

Local issues—In response to earlier federal policy on stem cell research, legislation was introduced in California as well. Have students compare the California and federal legislation. What types of research are supported by the California legislation? Are there any restrictions similar to those of the federal legislation?

Have students look at the media response to the California legislation. Discuss the impact of California's legislation on the national dialogue, the California economy, and the field of biomedical research. Are there any potential disadvantages to California's legislation?

Debate

Based on their own research and beliefs, have students debate what the state and national policy on stem cell research should be. Students may draw on arguments they presented in their persuasive essays from Lesson 1.4.

Lesson Closure

Remind students of the essential question. Were students surprised by how much influence the government has over biomedical research? Why or why not? Have their opinions on stem cell research changed in one direction or the other as they've gained new information? Have students write their own policy statement regarding stem cell research.

Possible Prior Misconceptions

Some students may believe that the President alone, or Congress alone, is responsible for the federal budget.

Some students may believe that research and politics are independent of each other.

Some students may believe that stem cell research is illegal in the United States—i.e., the government has banned all research on stem cells, rather than having restricted access to federal grant money.

Student Assessment Artifacts

Stem Cell Policy Statement

Shaping the Research Agenda

LESSON 1.5

Variations and Extensions

Have students identify local and state representatives and research their voting records on the issue of stem cell research. Students may write letters to their representatives expressing support for those positions or urging reconsideration of their vote.

Have students research and discuss the history of the Public Health Service Act.

Have students research and find other examples of bills that either helped to open up new fields of research or restricted certain types of research.

Discuss how government-funded research compares with privately funded research. Identify major sources of private funding for biomedical and health science research. What are the specific goals or missions of the various private foundations? How do various institutions differ in the actions they take to accomplish their goals?

National and State Academic Standards

NATIONAL

NCSS Curriculum Standards for Social Studies

VIII. Science, Technology, and Society

Social studies programs should include experiences that provide for the study of relationships among science, technology, and society, so that the learner can:

- c. analyze how science and technology influence the core values, beliefs, and attitudes of society, and how core values, beliefs, and attitudes of society shape scientific and technological change;
- d. evaluate various policies that have been proposed as ways of dealing with social changes resulting from new technologies, such as genetically engineered plants and animals;
- e. recognize and interpret varied perspectives about human societies and the physical world using scientific knowledge, ethical standards, and technologies from diverse world cultures;

X. Civic Ideals and Practices

Social studies programs should include experiences that provide for the study of the ideals, principles, and practices of citizenship in a democratic republic, so that the learner can:

- i. construct a policy statement and an action plan to achieve one or more goals related to an issue of public concern;

NRC National Science Education Standards

Science and Technology in Local, National, and Global Challenges

- Science and technology are essential social enterprises, but alone they can only indicate what can happen, not what should happen. The latter involves human decisions about the use of knowledge
- Understanding basic concepts and principles of science and technology should precede active debate about the economics, policies, politics, and ethics of various science- and technology-related challenges. However, understanding science alone will not resolve local, national, or global challenges.
- Progress in science and technology can be affected by social issues and challenges. Funding priorities for specific health problems serve as examples of ways that social issues influence science and technology.
- Individuals and society must decide on proposals involving new research and the introduction of new technologies into society. Decisions involve assessment of alternatives, risks, costs, and benefits and consideration of who benefits and who suffers, who pays and gains, and what the risks are and who bears them. Students should understand the appropriateness and value of basic questions—“What can happen?”—“What are the odds?”—and “How do scientists and engineers know what will happen?”

STATE

List your state-specific standards in the space below.

Bad Blood

LESSON 1.6

U.S. HISTORY

Time

100 minutes

Materials

- Tuskegee Study recruitment letter (<http://en.wikipedia.org/wiki/Image:Tuskegeeletter.jpg>)
- CDC fact sheet on syphilis (<http://www.cdc.gov/nchstp/od/tuskegee/syphilis.htm>)
- Tuskegee Study accounts (http://www3.georgetown.edu/research/nrcbl/hsbioethics/units/cases/unit3_7.html and <http://www.infoplease.com/spot/bhmtuskegee1.html>)
- President Clinton's Apology for Tuskegee (<http://clinton4.nara.gov/textonly/New/Remarks/Fri/19970516-898.html>)

Prior Student Learning

Students should be aware that the federal government is divided into three branches, each of which has different roles and responsibilities.

Essential Question for This Unit

What is the right government role in medical decisions that affect the lives of individuals?

Objectives

After completing this lesson, students should be able to

- Recount the events of the Tuskegee Syphilis Study.
- Compare the ethical standards of research in the 1930s, the 1970s, and the present.
- Analyze how the historical, cultural, and social context influenced the events surrounding the Tuskegee Syphilis Study.
- Debate the ethical issues of human subject experimentation.

Lesson Activities

Lesson Springboard

Have students read the Tuskegee Study recruitment letter distributed by the Macon County Health Department. Based on the letter, what do they think the Health Department was studying? What appear to be the advantages or disadvantages of participating in the study? Does the letter's offer seem attractive?

Lesson Development

Direct Instruction

Read the case of the Tuskegee Syphilis Study to the class or have students read some relevant text on the case. Several summaries of the Tuskegee Study can be found online. Briefly review the biology of syphilis as a disease using the Centers for Disease Control and Prevention (CDC) fact sheet so that students can place the study in an epidemiological context.

Class Discussion

Have students discuss this case. Some guiding questions might include

- Were the men involved in the study the only victims? Who else did the Tuskegee Study affect?
- Doctors swear by the Hippocratic Oath to "First do no harm" when practicing medicine. Would you consider that the doctors involved in the Tuskegee study were adhering to this medical standard? If not, what do you think allowed them to rationalize their behavior?

Classroom

Management

The majority of this lesson is classroom discussion. You may wish to move student desks to facilitate discussion.

Support Strategy

For students who need extra support in classroom discussion, cue students prior to class on the specific question(s) that you will be asking them.

Bad Blood

LESSON 1.6

- The Tuskegee study lasted 40 years. During that time, almost 20 articles on the study were published in medical journals, and no one raised any objections. Could similar events happen today? What social and political changes have taken place that would make a similar study unlikely?

Have students reread the recruitment letter. Now that they understand the actual intentions of the study, has their view of the letter changed? Ask students if they know of other examples of human subject experimentation. (Students may bring up involuntary experimentation during World War II or modern voluntary pharmaceutical trials.)

Have students find at least two instances of human subject experimentation for **homework**.

Classroom Management
You may wish to have a large (empty) timeline prepared for filling in student responses and your own events

Class Discussion

Ask students for examples they discovered in their homework research. Place them on a timeline on the board or overhead. Introduce some of the key events in the history of human subject research, which hopefully will overlap with what students have found.

- 1796: Edward Jenner performs smallpox experiments (swinepox, cowpox) in search of a vaccine.
- 1825: Dr. William Beaumont studies digestion by carrying out experiments through a hole in patient Alexis St. Martin's stomach, Mackinac Island, Michigan.
- 1900: Walter Reed gets first written consent forms in his yellow fever experiments in Cuba.
- 1932: Syphilis experiments begin in Tuskegee, Alabama; not widely acknowledged until 40 years later.
- 1944: United States begins secret radiation experiments on humans; experiments continue through 1974 but are not widely publicized until the late 1980s.
- 1946: Nuremberg trial of Nazi doctors who tortured prisoners under the guise of experimentation.
- 1956: Willowbrook hepatitis experiments initiated.
- 1963: Terminally ill patients given live cancer cells without their consent at Jewish Chronic Disease Hospital.
- 1963: Milgram "obedience to authority" studies are published, showing that people are willing to inflict pain on others.
- 1971: Zimbardo Mock Prison Experiment at Stanford University—psychological research.
- 1990: First human somatic cell gene therapy trial—gene therapy for Severe Combined Immune Deficiency.

Have students discuss what role government should have in monitoring or regulating medical research.

Introduce and discuss the major developments in formalization of ethics for research on human subjects, including the following:

- Nuremberg Code 26 (1947)
- Helsinki Declaration (1964)
- National Research Act (1974)
- Belmont Report (1979)
- 45 Code of Federal Regulations 46—Protection of Human Subjects (“The Common Rule”) (1991)

Have students create an annotated timeline of the major events in human subject research and associated policies or legislation that resulted.

Lesson Closure

Remind students of the essential question. This subunit has provided an analysis of various ways that the government influences medical research. Ask students if there is enough influence, or too much, both in the present and the past. Have past oversights caused the government to overreach itself? Or is there still more the government should be doing?

Possible Prior Misconceptions

Some students may think that the government has always regulated research in the United States.

Some students may not realize that there is any government regulation of research.

Students may not be aware of the distinction between government-funded and privately funded research.

Student Assessment Artifacts

Human subject research and regulation timeline

Variations and Extensions

Explore the Tuskegee Study in greater depth by having students read *Bad Blood* (1981) by James H. Jones, a history of the Tuskegee study, either in U.S. History or English Language Arts. Discuss the roles of the major participants in the study. How did each justify their participation? Were all the participants equally at fault? Were any acting “more” unethically than others?

Watch *Miss Evers’ Boys*, an HBO dramatization of the Tuskegee study. Have students compare the events in the movie to the actual events. Does the movie seem to portray the events and people involved fairly?

Have students read the 1999 case of Jesse Gelsinger, the first patient to die from gene therapy. Compare the ethical issues of the Gelsinger case with the Tuskegee study.

National and State Academic Standards

NATIONAL

NRC National Science Education Standards

Science and Technology in Local, National, and Global Challenges

- Individuals and society must decide on proposals involving new research and the introduction of new technologies into society. Decisions involve assessment of alternatives, risks, costs, and benefits and consideration of who benefits and who suffers, who pays and gains, and what the risks are and who bears them. Students should understand the appropriateness and value of basic questions—“What can happen?”—“What are the odds?”—and “How do scientists and engineers know what will happen?”

NCSS Curriculum Standards for Social Studies

II. Time, Continuity, and Change

Social studies programs should include experiences that provide for the study of the ways human beings view themselves in and over time, so that the learner can:

- e. investigate, interpret, and analyze multiple historical and contemporary viewpoints within and across cultures related to important events, recurring dilemmas, and persistent issues, while employing empathy, skepticism, and critical judgment;
- f. apply ideas, theories, and modes of historical inquiry to analyze historical and contemporary developments, and to inform and evaluate actions concerning public policy issues.

VI. Power, Authority, and Governance

Social studies programs should include experiences that provide for the study of how people create and change structures of power, authority, and governance, so that the learner can:

- a. examine persistent issues involving the rights, roles, and status of the individual in relation to the general welfare.

VIII. Science, Technology, and Society

Social studies programs should include experiences that provide for the study of relationships among science, technology, and society, so that the learner can:

- c. analyze how science and technology influence the core values, beliefs, and attitudes of society, and how core values, beliefs, and attitudes of society shape scientific and technological change.

STATE

List your state-specific standards in the space below.

Pharmaceutical Advertising

SUBUNIT 2 OVERVIEW

Essential Question for This Unit

What is the appropriate government role in medical decisions that affect the lives of individuals?

Subunit Goals

In Subunit 2, students examine pharmaceutical advertising and its growing presence in our lives. Students begin by investigating the persuasive techniques common to all advertising and their effectiveness for different audiences and for different products. They apply their knowledge to prescription drug ads and consider how and why these ads have changed so dramatically over the past 50 years. As drug advertising expands, so does government regulation, and by exploring the history of regulation, students gain a deeper understanding of the ethical question at stake: How do we balance the advertiser's right to free speech with the public interest in safe and effective drugs? To help them answer this question, students create their own pharmaceutical ads, write critiques of vintage and modern advertising, and write a cogent report on the benefits or drawbacks of the "direct-to-consumer" drug commercials that are prevalent in the media today.

Subunit Key Questions

- How does advertising persuade consumers? Which persuasive techniques work best for a particular audience or product? (English Language Arts)
- How do pharmaceutical ads persuade their audience? How and why have these ads changed in the past half century? (English Language Arts)
- Why does the government regulate pharmaceutical advertising? How and why has government regulation changed in the past half century? (U.S. History or U.S. Government)
- How do we balance the advertiser's right to free speech with the government's requirement to protect the public interest? (U.S. History or U.S. Government)

Lesson Summaries

Lesson	Subject	Description
2.1	English Language Arts	<i>The Art of Persuasion</i> Students identify the persuasive techniques of advertising and apply these to pharmaceutical ads.
2.2	English Language Arts	<i>Vintage and Modern Pharmaceutical Ads</i> Students contrast the persuasive techniques used in early and contemporary drug advertising and interpret their differences in historical perspective.
2.3	U.S. History or U.S. Government	<i>Regulating Direct-to-Consumer Drug Advertising</i> Students investigate the history of government regulation of pharmaceutical advertising, evaluate the benefits and drawbacks of regulation, and write a report that defends or criticizes continued regulation.

The Art of Persuasion

LESSON 2.1

ENGLISH LANGUAGE ARTS

Time

100 minutes

Materials

Equipment

Computer lab (optional)

Resources

- Advertising Techniques worksheet
- Variety of magazines with product advertisements or Internet access to online advertisements
- Sample ALS Advertisement and Elantra Medication Guide

Prior Student Learning

Students should have the basic understanding that writing style and techniques should reflect the content, purpose, and audience.

Students should have experience in writing persuasive essays and using evidence to support claims.

Essential Question for This Unit

What is the appropriate government role in medical decisions that affect the lives of individuals?

Objectives

After completing this lesson, students will be able to

- Understand and identify persuasive writing techniques used in advertising.
- Recognize strategies used in media to inform and persuade various audiences.
- Analyze the persuasive elements and language present in pharmaceutical advertisements.
- Discuss the responsibility of pharmaceutical companies to consumers.

Lesson Activities

Lesson Springboard

Ask students if they remember the Mirror of Erised from *Harry Potter and the Sorcerer's Stone* by J. K. Rowling (1997). The Mirror of Erised shows “not your face but your heart’s desire.” The goal of advertising is to generate business and increase sales by reflecting, encouraging, or even creating desire for a product. Ask students to share an example of a product they didn’t even know they wanted until they saw an advertisement for it.

Lesson Development

Small Group Work

Have students gather in groups of four and pass out a set of print advertisements from magazines to each group. Advertisements should include a variety of products, including pharmaceuticals. For each advertisement, have students identify and record one or two items that draw attention to the desirability of the product, including text or imagery.

Class Discussion

Have each group share their observations with the class. Record each example on the board. After a large list has been generated, have the class put similar items together in categories and give each category a descriptive label.

Introduce the concept of propaganda and match the student-generated categories to propaganda techniques where applicable. Pass out the Advertising Techniques worksheet. Common techniques include

- Bandwagon
- Nostalgia

Classroom Management

Write each item on a large Post-it note with a Sharpie for easier organization of items into groups.

Subunit 2—Pharmaceutical Advertising
The Art of Persuasion

LESSON 2.1

- Facts and figures
- Star power/testimonial
- Heartstrings
- Glittering generalities
- Avant-garde
- Magic ingredients
- Patriotism
- Diversion
- Transfer
- Bribery
- Card stacking
- Wit and humor
- Hidden fears
- Snob appeal
- Weasel words

Define and discuss the effectiveness of these various techniques for different audiences and for different products. Some of the more common themes within pharmaceutical advertising include

- Newer is better.
- Experts know best.
- If there is mechanism for how it works, it works.
- If my peers are using a therapy, so should I.
- If the manufacturers give gifts, I should support them in return.
- If I see changes after receiving a medication or therapy, the medicine or therapy must be the cause.

Media Analysis

Have students re-examine the pharmaceutical advertisements and identify at least three specific examples of persuasive techniques that were used. Have them read the fine print and discuss what type of information is presented in the ad. Are there any differences in the level of information provided by the different ads? Is there anything surprising about the kinds of information included in the ads? Discuss why pharmaceutical advertising contains negative information (warnings)? Do students think those warnings are there by choice? Would they want pharmaceutical companies to be able to advertise without placing warnings in the ads?

Lesson Closure

Ask students to generate an advertisement of their own announcing a treatment for ALS (Lou Gehrig's disease). Students should design an advertisement that applies some of the elements of persuasion introduced in class. They should also provide a medication guide to accompany their ad.

Student Assessment Artifacts

Notes on advertising techniques
ALS advertisement and information

Subunit 2—Pharmaceutical Advertising
The Art of Persuasion

LESSON 2.1

Possible Prior Misconceptions

Some students may believe that pharmaceutical companies can include any information they want in advertising. Others may believe that some government agency scrutinizes each advertisement before it is made public.

Variations and Extensions

Have each student share his or her ALS ad with another student for analysis and critique.

National and State Academic Standards

NATIONAL

NCTE Standards for the English Language Arts

6. Students apply knowledge of language structure, language conventions (e.g., spelling and punctuation), media techniques, figurative language, and genre to create, critique, and discuss print and non-print texts.

STATE

List your state-specific standards in the space below..

Name _____ Date _____ Period _____

Advertising Techniques

Advertising techniques are tools used to attract attention, engage minds, trigger emotions, and change what people think, usually to make a sale.

Strategy	Definition	Example
Bandwagon	Suggests that “everyone” is using the product, and the consumer should use the product to be part of the group	
Nostalgia	Suggests that the product is practical, and use of the product will return the consumer to “the good old days”	
Facts and Figures	Uses facts and statistical figures to prove the superiority of the product	
Star Power (aka Testimonials)	Uses a celebrity to promote or endorse the product	
Heartstrings	Plays on emotions and makes the consumer feel part of the story	
Wit and Humor	Uses humorous situations to attract the consumer	
Hidden Fears	Suggests that use of the product can protect the consumer from harm or danger	
Weasel Words	Uses words to suggest a positive meaning, when in fact the words are vague and promise no guarantee (e.g., <i>virtually</i> , <i>mostly</i> , <i>almost</i> , etc.)	
Patriotism	Suggests that use of the product shows love for the country	
Snob Appeal	Suggests that use of the product makes you better or more desirable than those who don’t use the product	

Can you think of other examples of techniques used in advertisements?

Name _____ Date _____ Period _____

Sample ALS Advertisement

Elantra

ALS had taken over my life.

But then, I found hope in Elantra.

Elantra...

...Hope for life.

Elantra® is a drug that has been clinically proven to terminate the symptoms of Lou Gehrig's disease. It will improve your condition within two years, guaranteed. As with any drug, Elantra® is not for everyone. Elantra is not for those who are pregnant, may be pregnant, or have a history of mental or neurological complications. Be sure to check with your doctor before trying Elantra. (Results may vary.)

Name _____ Date _____ Period _____

Elantra Medication Guide (sample)

What is ALS?

ALS stands for amyotrophic lateral sclerosis, and it is a disease of the central nervous system that affects a person's ability to move certain muscles. The central nervous system is like a complex telephone network that channels the messages from the brain to the rest of the body. These messages are carried by nerve cells called motor neurons. These motor neurons not only carry the messages, they do the "talking" for the brain and tell the muscles what to do. ALS makes it difficult for messages to get through to the muscles.

How does Elantra work?

As ALS progresses, your body creates a buildup of glutamate. Glutamate is a natural substance found in your body that carries signals to your motor nerves. When you have too much glutamate, your motor nerves cannot function properly, causing you to lose the ability to live normally. Riluzole helps thin these buildups of glutamate so the motor neurons can carry messages to the muscles from the brain. Also, IGF1 helps stimulate myocyte (muscle cell) growth allowing them to be more aware of the messages your neurons are sending from the brain. By combining these two drugs, almost immediately you'll notice increased mobility and energy.

What will Elantra do for me?

Around 330 people were examined in a clinical study. Half of these people took placebos and the other half took Elantra. The pills were administered twice a day for two years. The people who took the placebo pills showed little or no difference, while the people who took Elantra showed that within just a year and a half the symptoms of ALS were disappearing. Elantra is not for everyone though, people with a history of high blood pressure discovered that their blood pressure rose and had to be taken off Elantra. The success rate for Elantra in this study was 97.6%. Elantra is not a cure for ALS; it may not replace everything that has been lost, although many functions will be replaced if not all. IGF1 has been proven to stop the death of cells in the brain.

What about the side effects of Elantra?

Before taking Elantra, discuss and consider the side effects with your doctor. If you have a history of high blood pressure, do not take this drug. It may raise your blood pressure and result in serious consequences. Make sure you make regular appointments and have regular evaluations by your doctor. If at any time you think that you're pregnant or may become pregnant, do not take Elantra. The drugs used in Elantra have not been proven safe to embryos or fetuses. Elantra should be stored in a safe place where it is not available to children. It should be stored in a dry, cool place between 60 and 80 degrees F.

Vintage and Modern Pharmaceutical Ads

LESSON 2.2

ENGLISH LANGUAGE ARTS

Time

75 minutes

Materials

Equipment

- Overhead projector (optional)
- Internet access (optional)

Resources

- Advertising Techniques handout (from Lesson 2.1)
- Vintage Pharma ads from the Internet (http://community.livejournal.com/vintage_ads/88173.html?page=2#comments)
- Gallup & Robinson, Inc. comparison of Prilosec ads
 - <http://gallup-robinson.com/adgamep4.html>
 - <http://www.gallup-robinson.com/choicep4a.html>
 - <http://www.gallup-robinson.com/choicep4b.html>
- Modern Pharma ads selected from magazines or the Internet
- Ad-Busting worksheet

Prior Student Learning

Students should know that writing style depends on the content, purpose, and audience.

Essential Question for This Unit

What is the appropriate government role in medical decisions that affect the lives of individuals?

Objectives

After completing this lesson, students will be able to

- Identify persuasive writing techniques used in advertising.
- Analyze persuasive strategies used in pharmaceutical advertising.
- Contrast vintage and modern pharmaceutical ads and interpret their differences in historical perspective.

Lesson Activities

Lesson Springboard

Ask the class what pharmaceutical advertisements they've seen in magazines or on TV. Why do these ads come to mind and not others? What makes a drug ad memorable? Have students identify the techniques used in these ads. Are they similar to techniques used in advertising for other products, or is there something special about pharmaceutical ads?

Lesson Development

Remind the class that companies use advertising to persuade consumers to buy products they might otherwise not want to have, and that effective advertising uses standard techniques that they will learn about in class today. Yet advertising has also changed over the years, due to changes in American society that the lesson will also discuss.

Begin by showing students one ad for a popular pharmaceutical and have them discuss the various techniques it uses to persuade the audience. Select an ad from a magazine or the Internet for this discussion. Then show students one vintage pharmaceutical ad for comparison. Use an ad from the extensive collection at http://community.livejournal.com/vintage_ads/88173.html?page=2#comments. Point out the differences and similarities between the two ads, not only in content but also in style. Some themes for discussion may include

- Gender relations.
- Appeal to authorities, such as science and the medical profession.
- Appeal to facts versus emotions.
- Emphasis on text versus visual imagery.
- Formal versus colloquial language.

Remind students that as a society changes, so does its advertising. What do the differences between these ads suggest about how America has changed

Vintage and Modern Pharmaceutical Ads

LESSON 2.2

in the past fifty years? Some social thinkers say we have moved from an industrial society that emphasized “production” to a post-industrial society that emphasizes “consumerism.” Do these ads reflect this shift?

In spite of changes in advertising that reflect social change, the **general** strategies available to advertisers do not alter much over the years. Have students take out the Advertising Techniques handout that they received during the previous lesson. Following the handout (from Lesson 2.1), review the various strategies for students. For each technique, have the class try to identify a current example in use, preferably for a pharmaceutical product but otherwise for any product they can think of. Remember that many ads use multiple strategies simultaneously.

You may also have students try to identify advertising strategies not covered by this list. Other common strategies students might recognize include

- Glittering generalities
- Magic ingredients
- Association
- Bribery

Next, hand out several vintage and modern pharmaceutical advertisements. Have students choose one vintage and one modern ad to analyze. Pass out the Ad-Busting worksheet and ask students to answer the questions on it using the two advertisements they’ve chosen.

Lesson Closure

Students will need to finish their advertisement analysis as **homework**. At the beginning of the next class, have them summarize to a fellow student the analysis they were able to complete in class and as **homework**.

Possible Prior Misconceptions

Some students think that pharmaceutical ads differ from other commercial advertising because they merely describe a product rather than entice consumers to want it.

Student Assessment Artifacts

Ad-Busting worksheet

Variations and Extensions

Students may extend their Ad-Busting assignment to pharmaceutical commercials on TV. They might compare the persuasive strategies in a magazine and television ads for the same product, and from this, generalize about the persuasive powers available to print and electronic media.

Vintage and Modern Pharmaceutical Ads

LESSON 2.2

National and State Academic Standards

NATIONAL

NCTE Standards for the English Language Arts

6. Students apply knowledge of language structure, language conventions (e.g., spelling and punctuation), media techniques, figurative language, and genre to create, critique, and discuss print and non-print texts.

STATE

List your state-specific standards in the space below.

Name _____ Date _____ Period _____

Ad-Busting

Uncovering the Truth in Advertising

The language and design used in advertising is carefully chosen to evoke specific feelings and emotions in the viewer. Being aware of the strategies advertisers use to manipulate consumers is the first step to uncovering the truth in advertising.

1. Name of the product advertised

2. Examine the VISUAL aspects of the advertisement.

What colors are used?	What is happening in the ad? What kind of people do you see? How are they dressed, what are their facial expressions?	What overall impression do the visual elements create?

3. Examine the WRITTEN aspects of the advertisement.

What is the slogan?	What key words are used? What adjectives and adverbs are used?	What kinds of claims are being made?

4. Examine the LAYOUT of the advertisement.

How do the words relate to the images?	What is the central focus of the advertisement?	Where is the logo located?	What impression do the font and logos create?

5. Examine the MAGAZINE where the advertisement is placed.

What type of magazine is this?	Who is the target audience for this magazine?	Is there a connection between the magazine subject and the product?

Regulating Direct-to-Consumer Drug Advertising

LESSON 2.3

U.S. HISTORY OR U.S. GOVERNMENT

Time

50 minutes

Materials

- Pros and Cons of DTC Advertising handout
- DTC Advertising—A Regulatory History handout
- Prescription Drug Trends available from the Kaiser Family Foundation (2005) (<http://www.kff.org/rxdrugs/upload/3057-05.pdf>)
- Truth in Advertising available from the FDA Consumer Magazine (2004) (http://www.fda.gov/fdac/features/2004/404_ads.html)
- Marketing and Direct-to-Consumer Advertising (DTCA) of Pharmaceuticals (updated February 20, 2007) (<http://www.ncsl.org/programs/health/rxads.htm>)

Prior Student Learning

Students should be familiar with pharmaceutical advertising in mass media.

Students should have read the Pros and Cons of DTC Advertising and the DTC Advertising—A Regulatory History handouts.

Essential Question for This Unit

What is the appropriate government role in medical decisions that affect the lives of individuals?

Objectives

After completing this lesson, students will be able to

- Describe the history of federal regulation of pharmaceutical advertising.
- Evaluate the benefits and drawbacks of regulation.
- Write a cogent report on regulation that is based on the history of governmental action.

Lesson Activities

Lesson Springboard

Pharmaceutical ads, you may have noticed, are looking more and more like commercials for cars or beer. They use the same hooks—pop music, attractive actors, and major promises. But as one critic notes, falling prey to car commercials results in little more than hefty car payments, whereas falling for a pharmaceutical ad can result in taking powerful drugs, at the risk of serious injury or even death. For this reason, the government takes a special interest in regulating these ads—known as *direct-to-consumer* (DTC) advertising.

Lesson Development

Class Discussion

Have students read the Pros and Cons of DTC Advertising and the DTC Advertising—A Regulatory History handouts prior to class. Tell them that at the end of this lesson, they will be assigned homework: a 300-word report that either defends regulating drug ads aimed at consumers or criticizes the practice. To do this, they must understand the history of federal regulation and the problems that have driven it forward, as listed in the DTC Advertising—A Regulatory History handout. They must also **take notes** during this class discussion.

- Begin the discussion by asking why the government began to regulate drug advertising around 1910. Was this due to changes in the drug industry, in consumer preference, or in the government itself? Raise the topics of *Progressivism*; the rise of large corporations, or *trusts*; and the growing impersonality of economic markets in an urban society.
- Regulation of drug ads greatly increased in the 1930s. What changes in American society brought this about? How did the creation of the FDA follow from the spirit of the New Deal?
- In the 1960s, federal regulators faced a new challenge: TV. Why did TV ads require new kinds of regulation? How does TV differ from print or even radio as an advertising medium?

Regulating Direct-to-Consumer Drug Advertising

LESSON 2.3

- In the 1980s, pharmaceutical companies turned to using DTC advertising in addition to their traditional ads, which targeted doctors. Why hadn't they done this before? And why did consumers like it, as many of them do?
- By the 1990s, DTC advertising was no longer a trickle but a flood. The National Conference of State Legislatures (2007) indicates that in 2006 the pharmaceutical industry spent an estimated \$2.5 billion to reach consumers with their message. And, according to the Kaiser Family Foundation (2005), in 1994 the average American purchased nearly 8 retail prescriptions per year, while that figure increased to more than 12 by 2005. How do these figures relate to FDA regulation of pharma ads?
- In 1997, Congress relaxed its rules about DTC advertising after 2 years of public hearings. Why do you think it did this? What were the results?
- You've read about the pros and cons of DTC advertising and heard from the drug companies as well as from its critics. But there remains another important point of view. How might healthcare professionals feel about DTC advertising?

Lesson Closure

As **homework**, students will write a 300-word report on this question: Some experts defend DTC advertising while others experts denounce it. What are the arguments? Which side presents a stronger case?

Possible Prior Misconceptions

Some students may not distinguish pharmaceuticals from other merchandise, and therefore not see why pharmaceutical ads require special regulation.

Students may not realize that advertising is crucial to informing healthcare professionals about new treatment options and to the success or failure of a pharmaceutical product. They may believe that doctors alone determine the rates at which various medications are used or that pharmaceuticals don't compete for attention and money from the public.

Student Assessment Artifacts

300-word report on the pros and cons of DTC advertising

Variations and Extensions

Students may choose a heavily advertised but controversial drug and describe the government's efforts to regulate it. Possible candidates include Vioxx, Celebrex, Viagra, Trasyolol, or OxyContin.

Students may research the "prehistory" of government regulation of drug advertising, extending back to the mid-1800s. States and localities created a patchwork of legislation to improve the safety of patent medicines and reduce fraud among their salesmen and manufacturers.

Regulating Direct-to-Consumer Drug Advertising

LESSON 2.3

National and State Academic Standards

NATIONAL
NCSS Curriculum Standards for Social Studies

V. Individuals, Groups, and Institutions

Social studies programs should include experiences that provide for the study of interactions among individuals, groups, and institutions, so that the learner can:

- e. describe and examine belief systems basic to specific traditions and laws in contemporary and historical movements;
- f. evaluate the role of institutions in furthering both continuity and change;
- g. analyze the extent to which groups and institutions meet individual needs and promote the common good in contemporary and historical settings;

STATE

List your state-specific standards in the space below.

Name _____ Date _____ Period _____

The Pros and Cons of DTC Advertising

Proponents of DTC advertising say the ads serve to educate the public about health conditions and available treatments, therefore encouraging patients to seek care for undiagnosed health problems. They also say that information empowers patients, and that because pharmaceuticals require a physician's prescription, the ads themselves do not lead to inappropriate drug use. Their arguments can be summarized like this.

DTC ads motivate discussions. Studies have shown that DTC advertising stimulates important discussions between patients and their physicians. If a consumer learns through DTC advertising of new information about or a treatment available for a condition, he or she can raise this topic with the physician. A survey conducted in 1998 found:

- More than 53 million consumers talked to their physicians about medicine they saw advertised.
- An additional 49 million people sought information about the drugs they saw advertised from another source, such as the Internet.
- After viewing DTC advertising, a projected 21.2 million consumers felt encouraged to talk with their doctor about a medical condition or illness they had not spoken about before.

DTC ads increase patient education and knowledge. Many believe that the explosion of DTC drug advertising has led to better-informed consumers. While healthy people cannot be expected to seek out a physician's advice if they do not consider themselves at risk for illness, advertisements may help to raise awareness about symptoms or risk factors for a disease and may prompt a consumer to seek a doctor's advice. Given the current managed-care system that encourages physicians to control costs and decrease unnecessary patient visits, some argue that the cost of advertising targeted to susceptible groups is much lower than the cost of a physician's seeking out and examining every patient perceived as being susceptible to a specific disease. The point has also been raised that DTC advertising provides information about side effects and risks that physicians don't always share with their patients. If consumers are unaware that the symptoms they are experiencing could be side effects of medications, they may not know to consult their doctors and request alternative medications. Also, some doctors may consider some drugs too risky and will not share information about these drugs with their patients. However, unless patients are aware of all options available, they cannot make informed decisions about the best treatment for them.

DTC ads encourage patients to seek treatment. Many diseases may be present for a long time before symptoms occur. Often consumers may experience symptoms that they do not realize are associated with a disease (e.g., thirst as a symptom of diabetes). If they don't recognize their symptoms as a sign of illness, they may put off consulting a physician, thus allowing the disease to progress. Some suggest that advertisements encourage patients in need of medical attention to consult physicians. In the long run, early diagnosis and intervention could improve overall health and reduce treatment costs. Also, for individuals who know they are at high risk for a certain disease, knowledge of a new vaccine or preventive medication would be helpful. It is argued that advertising is more likely to reach them than if physicians are the only source of information. Information about a new drug with an easier dosing schedule or better side-effect profile may lead people who have already been diagnosed with a disease, but have discontinued treatment, to consult their physicians again to try this new treatment. In a recent telephone survey conducted by the FDA, adults were asked about their views on DTC promotion of prescription drugs and its effects on visits to the doctor. When asked if an ad for a prescription drug ever caused them to look for

Name _____ Date _____ Period _____

more information about their health, 51 percent of the respondents said it did. Of those, 81 percent said they went to their doctors for more information, 52 percent consulted a pharmacist, 36 percent looked in a reference book, and 30 percent asked a relative, friend, or neighbor. Another survey conducted in 1999 gauged the public's response to drug ads in general. Nearly a third of adults have talked to their doctor about a drug they saw advertised, and 44 percent of those who talked to their doctor received a prescription for the medication they asked about. Thus, one out of every eight Americans has received a specific prescription after seeing an advertisement for that drug outside the physician's office.

Adapted from Sarah Oetgen, "DTC Advertising of Prescription Drugs" (<http://www.afip.org/Departments/legalmed/legmed2003/Oetgen.pdf>)



Opponents of DTC advertising have argued that pharmaceutical ads induce inappropriate consumer demand for prescription drugs, especially the newer, higher-priced drugs. Additionally, they note that increased consumer demand leads to increased prescription drug use. Opponents also suggest that the ads place an added burden on physicians, who are often required to spend extra time during office visits to properly educate patients about the advertised pharmaceuticals.

These critics suggest that DTC advertising is simply driven by financial motives and provides information of questionable value with little benefit to the consumer. Instead of educating consumers and promoting healthier lifestyles, DTC advertising creates inflated consumer demand and undermines the physician's role in deciding the best treatment strategy for patients. Research suggests that DTC ads are simply promotional pieces that increase brand awareness rather than educational tools to help increase consumer knowledge. In one survey, after watching a series of ads, 70 percent of respondents said they had learned little or nothing more about the health condition the product was supposed to treat, and a majority (59 percent) said they knew little or nothing more about the drug itself.

Finally, it is likely that patients who arrive at office visits with a print advertisement in hand or with requests for drugs they saw promoted on television are another part of the "hassle that often accompanies patient care in modern medical practice." Indeed, some doctors are becoming frustrated with the increasing amount of time they must spend reeducating patients about an advertised drug or decreasing patient expectations of certain pharmaceuticals.

Here is an excerpt from one of these critics, a spokesperson for the nutritional-supplements industry:

"A cute, animated ball bounces around very sadly until he takes a magic potion; suddenly, it becomes happier than ever. No, that isn't the plot of a new children's movie. On the contrary, it's the storyline of a Zoloft commercial—yes, Zoloft, a powerful antidepressant drug. In the 1990s, direct-to-consumer advertising like this increased at a compounded-annually rate of 30 percent, according to Ian Morrison's book, *Health Care in the New Millennium* (2000). In fact, by 1995, drug companies had tripled the amount of money they formerly allotted to consumer-directed advertising, writes Gary Null in *Death by Medicine*. Since then, pharmaceutical advertising has grown to an entirely new, pop culture-savvy level...

We are a 'self-medicated' society. Consumers do not actually write their own prescriptions, but they practically do, based on whatever drugs they see advertised on television. In his book *Death by Prescrip-*

Name _____ Date _____ Period _____

tion (2003) Ray Strand writes, ‘Surveys reported in our medical literature reveal that when a patient comes into a doctor’s office and requests a specific drug that he has seen advertised in the media, the doctor writes the exact prescription the patient requested more than 70 percent of the time!’

So, let’s say that a consumer who has been feeling a little sad lately sees a commercial for the antidepressant drug Zoloft. The commercial demonstrates the symptoms for depression and the consumer identifies with them. Suddenly, he or she thinks, ‘I’m not just sad. I’m depressed, which is a medical condition that can be treated by the prescription drug Zoloft.’ With this in mind, the consumer goes to a medical doctor and says, ‘I’ve been really depressed a lot lately. I’ve been [*the consumer recites the depression symptoms listed in the Zoloft commercial*]. I think I need Zoloft.’ So, according to Strand, there’s a 70 percent chance the doctor will prescribe Zoloft, the exact prescription the consumer requested. That’s how pharmaceutical commercials really work. They directly influence consumer behavior yet the drug companies claim they only ‘educate’ patients, but don’t persuade them to do anything.” (Dani Veracity, <http://www.NewsTarget.com/010315.html>)

Name _____ Date _____ Period _____

DTC Advertising—A Regulatory History

The history of direct-to-consumer (DTC) advertising has taken many twists and turns over the years, and it will continue to change. Take a look at where DTC advertising has been to gain insight on where it might be going in the 21st century.

1708 Boston's Nicholas Boone placed the first advertisement for a patent medicine in an American newspaper.

Early 1800s Newspapers received their greatest income from general advertising, and patent medicine advertisers spent more on it than any other group.

1906 Congress passed the Pure Food and Drug Act, making it unlawful to manufacture adulterated or misbranded foods and drugs.

1914 The Federal Trade Commission Act (FTCA) created a new oversight body to police advertising by acting against unsubstantiated claims. This became the foundation for regulating all drug advertising until 1962.

1938 The Federal Food, Drug, and Cosmetic Act established the Food and Drug Administration (FDA) to regulate food and drugs in the United States.

1962 The Kefauver-Harris drug amendments gave the FDA sole jurisdiction for regulating advertisements and other prescription drugs. This gave the FDA authority over all aspects of prescription drugs and all related promotional and advertising products.

Early 1980s Pharmaceutical marketing attention began to shift from healthcare professionals to the general public.

1981 The pharmaceutical industry first proposed expanding its marketing strategy beyond physician-focused advertising to include consumers. The industry argued that DTC marketing and advertising provided the public with educational benefits. At the same time, there was a movement among political and regulatory groups to allow consumers more choice and to encourage them to share in medical decision making.

1983 In response to pressure from industry and the lack of clear rules regarding advertising, the FDA called for a voluntary moratorium on DTC advertising for pharmaceutical products. In 1985 the moratorium was withdrawn. The FDA allowed drug companies to advertise to consumers, provided they followed the existing standards for advertisements directed at physicians. It was also requested that manufacturers provide DTC ads to the FDA for preliminary review.

1997 Following a public hearing, the FDA issued new guidelines for broadcast DTC advertising that allowed television and radio ads, for the first time, to promote a specific drug without disclosing all of the product's risks. Ads were required to provide a fair balance between descriptions of the product's benefits and side effects, and had to list sources (such as a toll-free telephone number, website, physicians, and pharmacists) for additional information about the product. Although the FDA did not require drug companies to submit their ads for review, the agency had the authority to do this if there was a question as to whether its guidelines were being followed.

2000 The FDA issued warning letters directed at more than 75 different drug advertisements or other promotional materials that violated the law.

Name _____ Date _____ Period _____

2007 The U.S. Senate passes a drug-reform bill providing, among other things, that the FDA require any television or radio ads for a drug to describe its risks “in a clear and conspicuous neutral manner,” with fines for false or misleading commercials.

Current Advertising Regulations

Under the Food, Drug, and Cosmetic Act (FDCA), direct-to-consumer drug ads fall into one of the following three categories:

1. **Health-seeking.** Advertisements educate consumers about a disease or condition, but a specific drug is not named. For example, an advertisement aired by Upjohn in 1989 encouraged men who were concerned about hair loss to see their doctor, but their product, Rogaine, was never mentioned.
2. **Reminder.** Here, ads provide the name of the drug and other minimal information but do not discuss the drug’s use, effectiveness, or safety. No summary of product risk is required.
3. **Product-specific.** These ads mention a drug by name, describe its therapeutic uses, and discuss its safety and effectiveness. The majority of drug advertisements fall into this category.

Medical Decisions

SUBUNIT 3 OVERVIEW

Essential Question for This Unit

What is the appropriate government role in medical decisions that affect the lives of individuals?

Subunit Goals

In Subunit 3, students will begin by learning about viruses and vaccines in order to understand the importance of immunization not only as an individual health protection decision but also as a public health issue. They will apply their knowledge of immunization to examine government interventions mandating vaccination, such as recent state-level attempts to require that girls receive the Gardasil vaccine. Next, students will explore the intersection of government responsibility, judicial intervention, and individual rights in ethical medical decisions. They will be required to think critically about ethical medical decisions as they prepare arguments to support their position on the unit's essential question: What is the right role for government in medical decisions that

affect the lives of individuals? Finally, students will explore the use of mathematics to judge the accuracy of medical tests and the safety of procedures such as amniocentesis. They will discover that mathematics is a tool that can be used for decision making as they learn to apply the concept of weighted scoring to bioethical dilemmas.

Subunit Key Questions

- What are viruses and how do they spread? (Biology)
- Is vaccination always the right decision? (Biology)
- What is the government's role in making medical decisions for society and for the individual? (English Language Arts, U.S. History, U.S. Government)
- How trustworthy are medical test results? How do you know? (Algebra 1)
- How can mathematics help people make medical decisions? (Algebra 1)

Lesson Summaries

Lesson	Subject	Description
3.1	Biology	Viruses Students gain an understanding of the structure of viruses and their transmission mechanisms. Students also simulate a viral infection and track its progress through a population.
3.2	Biology	Vaccines Students gain an understanding of vaccines, their development, and their relation to immunity. Students also identify risks associated with vaccination and the diseases for which vaccinations are available.
3.3	English Language Arts	Mandatory Immunizations Students explore the forces that determine whether vaccination will be compulsory or left to the discretion of the individual in the context of the Gardasil vaccine.
3.4	Algebra I	Accuracy in Medical Testing Students gain an understanding of how to interpret accuracy statistics related to medical testing procedures by applying knowledge of fractions, percentages, decimals, and basic statistical operations.
3.5	U.S. History or U.S. Government	Government Intervention Students explore the intersection between government intervention and the individual in medical care decisions by analyzing controversial events such as the Terry Schiavo case.
3.6	Algebra I	Decision by the Numbers Students explore and apply the concept of weighted scoring as a decision-making tool.

BIOLOGY**Time**

50 minutes

Materials**Equipment**

- Disposable plastic transfer pipettes
- Distilled water
- 1% phenolphthalein solution (acid/base indicator)
- 0.1M NaOH solution (1 ml of 1M NaOH diluted in 9 ml of distilled water)
- Test tubes

Resources

Virus Transmission Simulation worksheet

Prior Student Learning

Students should be familiar with the basics of genetics prior to this lesson.

Essential Question for This Unit

What is the appropriate government role in medical decisions that affect the lives of individuals?

Objectives

After completing this lesson, students will be able to

- Describe the structure and transmission mechanism of viruses.
- Simulate and track the progress of a viral infection through a population.

Lesson Activities**Teacher Preparation**

Prepare for the virus infection simulation by filling numbered test tubes with distilled water (healthy) or 0.01M NaOH solution (infected). A class should have only one or two “infected” students at the start of the simulation. Make a note for yourself which test tube(s) are “infected.”

Lesson Springboard

Tell students they will be observing how viruses spread throughout a population. Any virus can be spread through the sharing of bodily fluids. Some viruses, like AIDS, need significant exchange, as occurs through intimate contact. Many other viruses are transferred through much more casual means. Actions like rubbing your eyes, touching your face, or sneezing can transfer minute amounts of fluid onto your hands. That fluid can be transferred to another person when you shake his hand or pass him an object. The people most likely to make you sick are your best friends, because you have the most contact with them.

Lesson Development**Infection Simulation**

Pass out the Virus Transmission Simulation worksheet and a test tube with a plastic pipette to each student. Each test tube represents the student’s body fluid. Remind students that it is possible to transfer body fluids through even very casual contact, such as sharing a pencil, and that they are most likely to get infected by people in close proximity to them. Ask students to think about whom they have talked to today in class (or earlier in the day). Have the students find at least three other students in the class they have talked to earlier in the day and exchange a dropper-full of solution from their test tubes. Have them record the name of their exchanges on the worksheet.

After everyone has exchanged a dropper-full of solution with three other students, test the class to see which students have been “infected” by adding phenolphthalein to every test tube. Solutions that turn pink are infected. Have the class discuss how they might find out who was the

original source of the infection. Lead the discussion to comparing the order in which the infected students interacted with other students. Any infected students who interacted with students who are not infected were not the original carrier. Eventually, the list will be narrowed down to two individuals, one of whom was the original carrier. The test tube with the most intense color is likely to have been the original carrier, because the original carrier had the most concentrated base solution. Ask students what the greater color intensity might be analogous to within an actual virus.

Based on their information regarding the original carrier, have students determine how many infected students there were at the end of each round of fluid transfer. Have students record that information and then graph the spread of the infection. Ask students to predict what would have happened if additional rounds of fluid exchange had occurred. How many rounds would it have taken before the entire class was infected? Remind students to consider that once a significant portion of the class is infected, each new fluid transfer would not necessarily be with a “healthy” student. How will that affect their predictions?

Direct Instruction

Introduce viruses as agents of infection that are nonliving but contain DNA. Draw and label the parts of a standard virus. Distinguish between viruses and bacteria as agents of infection. Review the steps of a viral infection and replication, including how a virus travels through the body in search of a target cell, secures itself to the cell membrane, and injects the viral DNA into the target cell. Viral DNA takes advantage of the target cell’s metabolism to replicate itself, and the target cell becomes a factory for producing additional copies of the virus. Eventually, the cell lyses and releases the copies that repeat this process in new target cells.

Lesson Closure

Have students build and label a model of a virus using their own materials. You may wish to have students make an animated sketch of a virus attacking and infecting a target cell.

Possible Prior Misconceptions

Students often have difficulty distinguishing between viruses and bacteria. Students may believe that illnesses caused by viruses are treated in the same manner as those caused by bacteria.

Student Assessment Artifacts

Student models of virus action

Variations and Extensions

Extend the lesson to include plant as well as animal viruses.

Ask students to consider if viruses are always harmful. Ask students to consider when injecting different DNA into a cell might be helpful. Introduce retroviruses as a means of genetic manipulation.

National and State Academic Standards

NATIONAL

NRC National Science Education Standards

Personal and Community Health

The severity of disease symptoms is dependent on many factors, such as human resistance and the virulence of the disease-producing organism. Many diseases can be prevented, controlled, or cured. Some diseases, such as cancer, result from specific body dysfunctions and cannot be transmitted.

STATE

List your state-specific standards in the space below.

Name _____ Date _____ Period _____

Virus Transmission Simulation

Exchange 10 drops of solution from your test tube with at least three people in the class with whom you have interacted today.

Exchange 1: _____

Exchange 2: _____

Exchange 3: _____

Infected Students	Exchange 1	Exchange 2	Exchange 3

Make a line graph of the number of infected people after each exchange round.



Vaccines

LESSON 3.2

BIOLOGY

Time

100 minutes

Materials

- Computer lab with Internet access or preprinted reference materials of viruses
- Poster paper
- Markers

Prior Student Learning

Students should be familiar with the physical structure and transmission of viruses.

Essential Question for This Unit

What is the appropriate government role in medical decisions that affect the lives of individuals?

Objectives

After completing this lesson, students will be able to

- Explain how vaccines work and their relationship to natural immunity.
- Identify how illness can be prevented through vaccination/immunization.
- Discuss the benefits and potential risks of vaccination.

Lesson Activities

Lesson Springboard

Begin the class by asking students to imagine they have been transported to America in the 1940s. Describe the intense fears of parents that their children would be afflicted with poliomyelitis.

“In the misshapen ranks of the world’s diseases, poliomyelitis is only an infant-sized killer compared with a giant like malaria. As a disabler, it stands well below mental illness. But polio is the disease most feared by U.S. mothers, for it strikes with cruel suddenness, and (though the proportion of older victims is increasing in many parts of the world) its victims are still mostly children.

This looked like a bad year for mothers. Since Jan. 1, there have been 2,881-cases of polio in the U.S. By the same date in 1946 (the year when the U.S. had the largest number of cases in its history), only 2,165 had been reported. Three states reported more than 50 new cases in a single week: North Carolina, 131; California, 92; Texas, 89. Five citizens of Newport News, Va. petitioned Virginia’s Governor Tuck to close the border with North Carolina, where total cases in the outbreak had reached 679.”

Time Magazine, July 26, 1948

As students are transported back to this time, each of them would be special—they would have a “superpower”: invulnerability to polio. Tell them that their superpower results from the polio vaccine. Ask students if they can identify any other vaccinations they have received. Write a list on the board. Ask students what a vaccination does.

Lesson Development

Small Group Research

Break students into pairs and assign each pair one of the following diseases:

- Measles
- Mumps
- Rubella
- Diphtheria
- Tetanus
- Pertussis
- Hepatitis B
- Polio
- Varicella (chicken pox)
- Pneumonia
- Hib (Haemophilus influenzae type b)
- Tuberculosis
- Typhoid
- Yellow fever

For each disease, ask the students to research its vaccine and produce a poster that covers the following information:

1. Disease
2. History
3. Causative agent/pathogen type
4. Timeline of outbreaks in history
5. When vaccine was discovered/invented
6. How vaccine is made
7. How vaccine works, how long it lasts
8. How vaccine is currently distributed
9. Effectiveness of the vaccine/immunization
10. Current news on disease or vaccine

Poster Walk/Class Discussion

Have students take a tour of the posters and look for patterns in how vaccines are made and how they work. Gather the class to discuss their conclusions and review any major points about vaccines and vaccination that they missed, including the difference between *inactivated* and *attenuated* vaccines and the difference between *active* and *passive immunity*.

Lesson Closure

Ask students if there are reasons not to get vaccinated for diseases. Are there risks associated with vaccination? Several of the diseases from the poster session have vaccines that are not commonly used in the United States. Most, like yellow fever and typhoid, are not used because these are not common diseases in the United States. However, some people choose to forgo vaccination all together. Discuss various reasons for opting out of getting vaccinated.

Possible Prior Misconceptions

Some students may believe that vaccines are not necessary because there are few reported cases of vaccine-preventable diseases in the United States.

Some students may have heard that vaccines cause harmful side effects, sometimes worse than the disease itself.

Student Assessment Artifacts

Disease-vaccine posters

Variations and Extensions

Have students read and discuss the history of vaccines (<http://content.healthaffairs.org/cgi/reprint/24/3/611>), including the story of Edward Jenner, who is credited with creating the first smallpox vaccine using cowpox inoculations. Smallpox was the first disease to be treated with widespread vaccination and is the only disease currently considered to have been eradicated.

Introduce the concept of *herd immunity*, and the protection that herd immunity provides to the unvaccinated. Discuss the general consequences if large numbers of individuals begin choosing to opt out of vaccination programs.

National and State Academic Standards

NATIONAL NRC National Science Education Standards

Personal and Community Health

The severity of disease symptoms is dependent on many factors, such as human resistance and the virulence of the disease-producing organism. Many diseases can be prevented, controlled, or cured. Some diseases, such as cancer, result from specific body dysfunctions and cannot be transmitted.

STATE

List your state-specific standards in the space below.

Mandatory Immunization

LESSON 3.3

ENGLISH LANGUAGE ARTS

Time

50 minutes

Materials

Equipment

Internet access (optional)

Resources

- *New York Times* opinion piece “The Rush to Vaccinate” (<http://query.nytimes.com/gst/fullpage.html?sec=health&res=9D01EED71430F936A15750C0A9619C8B63>)
- FDA press release: “FDA Licenses New Vaccine for Prevention of Cervical Cancer” (<http://www.fda.gov/bbs/topics/NEWS/2006/NEW01385.html>)
- *The Vaccine Controversy* by Kurt Link, M.D. (2005)
- Mandatory Immunization, or Not? worksheet

Prior Student Learning

Students should have basic understanding of viral infections, vaccines, and immunity.

Essential Question for This Unit

What is the appropriate government role in medical decisions that affect the lives of individuals?

Objectives

After completing this lesson, students will be able to

- Demonstrate critical thinking in relation to healthcare decisions.
- Assess an author’s position and credibility.
- Evaluate readings and formulate a cogent written analysis.

Lesson Activities

Lesson Springboard

Almost immediately after the FDA approval of the Gardasil vaccine, there was a drive to make vaccination mandatory. Texas was one of the first states to take action, igniting a controversy. The Texas governor issued an executive order requiring all girls entering the sixth grade to receive the \$360, three-shot vaccination.

Gardasil is Merck pharmaceutical company’s vaccine for human papillomavirus (HPV), the sexually transmitted disease (STD) responsible for a high percentage of cervical cancer cases. Due to this serious potential health consequence, Gardasil is being marketed more as a vaccination against cervical cancer than as a vaccination for the STD HPV. Many states have been pushing for laws that either require immunization, provide funding for it, or mandate that insurance companies cover the cost of Gardasil injections.

Some groups argue that this vaccine can eradicate cervical cancer. Others say it will encourage promiscuity. And some assert that girls who are being vaccinated are not in the population at high risk to develop cervical cancer or die from it. Finally, many question the reason for the rush toward mandatory vaccination, especially since Merck contributed funding for the effort and stands to make a large profit from a mandated vaccination.

Lesson Development

Class Discussion

Ask students what they think about vaccination. Do they think individuals should have the right to choose or should the government make decisions in the interest of public health? Why or why not? Ask students if they know how many vaccinations they’ve had. Explain that most of them were required to have vaccinations in order to enroll in school. Most children are immunized for mumps, measles, rubella, hepatitis, and sometimes the influenza virus and other diseases. Do they feel that

Mandatory Immunization

LESSON 3.3

they needed vaccinations? Are vaccines needed for diseases that people rarely get anymore in the United States, such as mumps?

Ask students who makes and provides these vaccines—government, corporations, or hospitals? After fielding responses to this question, pass out “The Rush to Vaccinate” opinion piece (or have students print it from the Internet).

Tell students that many vaccines have a controversial history and that there are groups that oppose mandated vaccination. One of the latest controversies deals with the Gardasil vaccine. Provide basic information about the vaccine and have students read and analyze “The Rush to Vaccinate” article and then write a one- to two-page report. In their report, students should explain what the argument is. What is the supporting evidence? What is the author’s tone? Who is the author? Is she credible; are her arguments credible? Why or why not? What makes someone or an argument credible? Finally, the students should explain their position and why they have chosen it. They can also support it with information gathered from other sources.

Alternatively, students can read the article and complete the Mandatory Immunization, or Not? worksheet.

Lesson Closure

Tell students that vaccines not only protect the person receiving the vaccination but also protect other people. Vaccines have reduced the threat of disastrous infectious diseases such as measles, polio, and smallpox. Smallpox was responsible for an estimated hundreds of millions of deaths throughout history until it was globally eradicated through worldwide vaccination efforts.

Possible Prior Misconceptions

Students should understand the difference between viral and bacterial infections: Bacterial infections can be treated with antibiotics, while viruses are usually battled by the infected individual’s immune system and/or antiviral drugs (if available). Therefore, one of the best defenses against viruses is immunity through vaccination.

Students may think that anything published in a newspaper is unbiased.

Student Assessment Artifacts

One- to two-page report
Mandatory Immunization, or Not? worksheet

Variations and Extensions

Articles about other vaccinations can be analyzed. A few controversial vaccines include

- Polio: Vaccines contaminated with monkey SV40 virus given to humans.

Mandatory Immunization

LESSON 3.3

- HIV/AIDS: Controversy surrounding ethics in vaccine testing in Africa and Thailand.
- MMR: Issues surrounding the purported link between the measles, mumps, rubella (MMR) vaccines and autism.

National and State Academic Standards

NATIONAL

NCTE Standards for the English Language Arts

1. Students read a wide range of print and nonprint texts to build an understanding of texts, of themselves, and of the cultures of the United States and the world; to acquire new information; to respond to the needs and demands of society and the workplace; and for personal fulfillment. Among these texts are fiction and nonfiction, classic and contemporary works.
6. Students apply knowledge of language structure, language conventions (e.g., spelling and punctuation), media techniques, figurative language, and genre to create, critique, and discuss print and nonprint texts.
7. Students conduct research on issues and interests by generating ideas and questions, and by posing problems. They gather, evaluate, and synthesize data from a variety of sources (e.g., print and nonprint texts, artifacts, people) to communicate their discoveries in ways that suit their purpose and audience.
12. Students use spoken, written, and visual language to accomplish their own purposes (e.g., for learning, enjoyment, persuasion, and the exchange of information).

STATE

List your state-specific standards in the space below.

Name _____ Date _____ Period _____

Mandatory Immunization, or Not?

After reading the *New York Times* opinion piece “The Rush to Vaccinate,” answer the following questions:

1. Should Gardasil vaccination be mandatory? Why or why not?
2. If immunization is not mandatory for everyone, should it be for some people? Who?
3. Who should have to pay for Gardasil vaccinations? What about people who can't afford it?
4. Should boys be vaccinated?
5. Should pharmaceutical companies be allowed to lobby for mandatory immunizations using their own vaccine? Is that a conflict of interest?
6. What is the tone and position of the article?
7. What are some possible counterarguments?
8. Do you feel the author is credible? Why or why not?

Accuracy in Medical Testing

LESSON 3.4

ALGEBRA I

Time

50 minutes

Materials

Equipment

Calculators

Resources

Is There Something Wrong With My Baby? worksheet

Prior Student Learning

Students should already be familiar with percentages, fractions, and decimals.

Essential Question for This Unit

What is the appropriate government role in medical decisions that affect the lives of individuals?

Objectives

After completing this lesson, students will be able to

- Interpret the accuracy of statistics used in medical testing procedures.
- Apply knowledge of fractions, percentages, and decimals to determine the number of people in a sample that would receive a false positive or false negative result given the error rate of the medical test.

Lesson Activities

Lesson Springboard

Ask students if they, or someone they know, have ever questioned the results of a blood test that was ordered by a doctor. Have they ever received a wrong diagnosis based on the results of a screening test? How do they feel about drug testing for a job or sports event? Introduce the terms *false positive* and *false negative* as two possible outcomes of a test. Using pregnancy tests as an example, a false positive is a result stating that a woman is pregnant when she is not, and a false negative is a result stating that she is not pregnant when in fact she is.

Ask the class to consider the possible negative effects a wrong diagnosis would have on an individual. Medical screening tests to discuss could include tests for pregnancy, HIV infection, prenatal birth defects, and drug usage. What are the ethical issues involved in medical testing once one is aware that the test is sometimes wrong? What considerations must be balanced when implementing policies like mandatory drug testing?

In order to evaluate a course of action involving medical testing, it is important to know how often the test produces either a false negative or a false positive.

Lesson Development

Discussion

Define the term *accuracy* in the context of medical testing. Accuracy is the rate at which a test gives a true result. Depending on the students' level, you might also choose to introduce the term *test sensitivity*, which can be explained as the concentration of a reagent needed to be detected by the medical test. For example, if a woman were to take a pregnancy test too soon after conception, the level of hormone in her body would be too low to be detected by the test. The result would show as negative despite the fact that she is actually pregnant. In other words, the test was not sensitive enough to give the true result.

Accuracy in Medical Testing

LESSON 3.4

Small Group Work

Introduce the following scenario:

Students are healthcare professionals who have the difficult job of explaining prenatal testing procedures and results to expectant parents. Amniocentesis is a common prenatal procedure that uses a sample of amniotic fluid to test for chromosomal abnormalities and other birth defects such as Down syndrome and cystic fibrosis.

Hand out the *Is There Something Wrong With My Baby?* worksheet and introduce the problem. Have students work on the problem in small groups. Circulate among the groups to check for understanding.

Discussion

Questions #2 and #5 in the worksheet were left intentionally open ended to allow students to synthesize what they felt was important for the couple to understand. Ask the class to consider what issues other than statistics they would need to know about before advising patients and their families about procedures like amniocentesis. This is a chance to emphasize the importance of understanding math when making healthcare choices, and also to make students aware of the complicated, interdisciplinary nature of real-life decisions.

Have the students share their responses to questions #2 and #5 in their small groups or with the entire class. Ask the class to evaluate each response in terms of the accuracy of its statistical analysis (the math) and its overall relevance to the couple. Is there anything missing in the response? How can the content and manner in which the information is presented affect the decisions that the parents make? Students can then rewrite their answers to reflect the class discussion and also include a paragraph explaining to the couple the remaining unanswered questions that they should research before making a decision.

Lesson Closure

Emphasize the importance of understanding statistics and mathematical reasoning in making informed choices in real-life situations. If time permits, open the discussion to the ethical considerations involved in random drug testing, testing for medical conditions for which there is no treatment or cure, or other high-stakes medical testing situations. Ask students to consider what level of accuracy is needed for these types of tests to be acceptable for wide use.

Possible Prior Misconceptions

Students may have distorted views on the accuracy (or inaccuracy) of medical tests.

Students may already know poorly understood algorithms about conditional and unconditional probability. The class should be encouraged to think about what each question is asking in the worksheet, and show logical work, and provide a reasonable, defensible answer.

Accuracy in Medical Testing

LESSON 3.4

Student Assessment Artifacts

Completed Is There Something Wrong With My Baby? worksheet

Variations and Extensions

The situation can be made more complicated by adding the concept of *test sensitivity*. If the concentration of the substance being tested for is too low, the test will not detect it and will result in a false negative.

Some parents choose to have chorionic villus sampling instead of, or in addition to, amniocentesis. This test has its own accuracy rates, and these can be incorporated into the problem.

Students can role play the conversation between a medical profession and parents who are considering prenatal testing or have received test results.

Accuracy in Medical Testing

LESSON 3.4

National and State Academic Standards

NATIONAL
NCTM Standards for School Mathematics

Algebra I

- understand patterns, relations, and functions;
- represent and analyze mathematical situations and structures using algebraic symbols;
- use mathematical models to represent and understand quantitative relationships;
- analyze change in various contexts.

STATE

List your state-specific standards in the space below.

Name _____ Date _____ Period _____

Is There Something Wrong With My Baby?

Imagine that you are a healthcare professional who has the job of explaining prenatal testing procedures and their results to expectant parents. A common test is amniocentesis, a process that extracts amniotic fluid from the womb by a needle through the abdomen. The amniotic fluid is then analyzed to test for chromosomal abnormalities, including Down syndrome, cystic fibrosis, and Huntington’s chorea. When talking to patients, you reference the following statistics:

- If the test is done during the second trimester of pregnancy, there is a 0.5%–1% risk of miscarriage.
- The test is 99.4% accurate when the results show a chromosomal abnormality.
- The test is 99% accurate when the results show no chromosomal abnormality.

1. The major risk of amniocentesis is miscarriage after the procedure. Statistically, how many women will miscarry due to amniocentesis if
 - a. 200 women are tested?
 - b. 1,000 women are tested?
 - c. The hospital performs 653 procedures this year?

Show your work here:

2. Write down how you would interpret the test statistics when you are talking to a couple who is trying to decide whether or not to have the amniocentesis test. What are the important things that the parents should know? What else would you tell them? Make sure the information you give is accurate, unbiased, and easy to understand.

Name _____ Date _____ Period _____

3. Suppose 500,000 women go through amniocentesis this year, and 99.75% of these tests are negative for Down syndrome.
- Of those tested, how many women receive negative results? How many women receive positive results?
 - How many women get a negative result, but actually have a baby with Down syndrome (false negative)?
 - How many women get a positive result, but actually have a baby without Down syndrome (false positive)?
 - According to your calculations, what is the overall accuracy rate of amniocentesis in regard to diagnosing Down syndrome?

Show your work here:

4. Ten percent of the women who originally got negative results and 100% of the women who received positive results have the test done again just to make sure of the diagnosis. Of those who had negative results, the second test was positive for five women. Of the women who had positive results, there was one negative result in the second round of testing.

What is the likelihood that someone has the wrong diagnosis if

- They received two negative results?
- They received two positive results?
- They received one positive, and one negative?

What is the overall accuracy of a series of two amniocentesis tests in diagnosing Down syndrome?

Show your work here:

Name _____ Date _____ Period _____

5. Write what you would say to a couple who just found out that their amniocentesis result was positive for Down syndrome. They are unsure about what to do with the news. The mother experienced cramps during the procedure and found it very uncomfortable. She is also afraid that another test might hurt the baby. The father is convinced that the first test was wrong and wants to get another result. Again, make sure that what you say is accurate, easy to understand, and unbiased. Address all of the couple's concerns.

Subunit 3—Medical Decisions

Government Intervention

LESSON 3.5

U.S. HISTORY OR U.S. GOVERNMENT

Time

50 minutes

Materials

Equipment

Computer lab with internet access

Resources

- CBS News: Schiavo Timeline (<http://www.cbc.ca/news/background/schiavo>)
- PBS Frontline: Chronology of Dr. Jack Kevorkian's Life and Assisted Suicide Campaign (<http://www.pbs.org/wgbh/pages/frontline/kevorkian/chronology.html>)
- Rights of the People: Individual Freedom and the Bill of Rights: Privacy (<http://usinfo.state.gov/products/pubs/rightsof/privacy.htm>)
- Questions for Consideration worksheet (optional)

Prior Student Learning

Students should have a basic understanding of the rights guaranteed under the U.S. Constitution.

Essential Question for This Unit

What is the appropriate government role in medical decisions that affect the lives of individuals?

Objectives

After completing this lesson, students will be able to

- Formulate and articulate an opinion on a controversial topic.
- Synthesize key issues and rebut an opposing position.
- Apply knowledge of ethical principles and issues to debate end-care decisions.

Lesson Activities

Lesson Springboard

Many people consider blood transfusions, pain medicine, cancer treatment, or life-support therapies valuable medical options for those in need. Others will not accept certain medical treatments, even if their life depends on it. For instance, Jehovah's Witnesses are forbidden from receiving blood transfusions, and there are cases in which Witnesses have refused potentially lifesaving blood transfusions. There are also questions about when certain life-preserving treatments become excessive and should be terminated. The case of Terri Schiavo brought national media attention to an important issue: how should the medical community treat individuals who are in a permanent vegetative state? Should these individuals be kept alive indefinitely? Should they be allowed to die?

Terri Schiavo lived in a vegetative state for 15 years; she could breathe on her own but needed a feeding tube to receive nutrients. After her husband asserted that Terri would not want to live in a vegetative state, a judge permitted removal of her feeding tube. Terri Schiavo's family contested the ruling, igniting a legal battle that lasted over a decade. This kind of situation leads to the question: who should determine whether people in a permanent vegetative state are kept alive?

In 1999, Dr. Jack Kevorkian, a pathologist, was charged with second-degree murder for administering a lethal injection to a terminally ill patient with Lou Gehrig's disease (ALS). The assisted-suicide was videotaped and later aired on the TV program *60 Minutes*. After participating in over 100 assisted suicides, Dr. Kevorkian was convicted and sentenced to prison. This case also raises important questions: should terminally ill patients be allowed to make the decision to end their own lives, and should it be legal for medical professionals to assist terminally ill patients in taking their own lives?

Government Intervention

LESSON 3.5

Lesson Development

Class Discussion

Ask students if they have heard of any instances in which ethics conflicted with medical treatment, such as in the case Terri Schiavo or other cases of physician-assisted suicide (PAS), which is illegal in every state except Oregon. Both federal and state governments are involved in settling these issues.

Class Discussion (debate)

Pose the question, and ask for a show of hands: If a person is terminally ill, should she or he be allowed to use physician-assisted suicide? Then ask: Should a person living on life support in a permanent vegetative state continue living (assuming the person does not have a living will)? Separate students into two groups, representing affirmative and negative sides of this issue. (You may need to balance out the groups by asking for volunteers to switch or assign students to the smaller group.)

One group will present arguments *for* PAS (i.e., removing a patient's life support), and the other will argue *against* PAS (i.e., not removing a patient's life support).

After separating students into groups, provide them about 15 minutes to review basic information about the issue (information can be retrieved and printed from the Internet) and brainstorm how they will argue their position. Have students use the Questions for Consideration worksheet as a framework for their position.

With the teacher as the moderator, have one group state their position and explain their rationale. Then have the other group state their position and allow the conversation to progress. Students' arguments do not need to be backed by facts (unless time for research is provided; this time could be provided as **homework** prior to the lesson) but should at least be supported with logic and sound opinion.

For **homework** after the lesson, have students write a one- to two-page summary of their beliefs about the issue chosen for debate in which they explain whether the debate altered their opinion. The homework assignment can include instructions to conduct some Internet research if they did not have that opportunity prior to the lesson.

Lesson Closure

Students should understand that situations involving medical ethics vary widely and views about them are not static. Treatments that are controversial today may be eliminated in the future or could become widely accepted. The lobotomy is a good example of a controversial treatment that was frequently used but has fallen into disfavor. Students should understand that it is natural to disagree with someone, especially on complicated issues. It is valuable to listen to and understand opposing opinions when formulating one's own opinion.

Government Intervention

LESSON 3.5

Possible Prior Misconceptions

Students may believe that an *argument* is an aggressive, loud, and upsetting conversation, but that is merely one type of argument—an often unhealthy type. An argument can be as simple as one person asserting his or her written or verbal opinion or two people casually discussing different points of view.

Students may also believe that they need to hold a certain belief to argue a point; this is not always the case. People sometimes find themselves on what they believe is the wrong side of an argument, forced to argue ideals that are contrary to their personal beliefs. An example may be a professional speechwriter.

Student Assessment Artifacts

Questions for Consideration worksheet
1-to 2-page opinion summary

Variations and Extensions

Have students research other countries' protocols for end-care of the terminally ill and patients in need of life support.

Assign students to debate the opposite side of the argument from the one that represents their true position.

National and State Academic Standards

NATIONAL NCSS Curriculum Standards for Social Studies

VI. Power, Authority, and Governance

Social studies programs should include experiences that provide for the study of how people create and change structures of power, authority, and governance, so that the learner can:

- a. examine persistent issues involving the rights, roles, and status of the individual in relation to the general welfare.

CCE National Standards for Civics and Government

III. Principles of American Democracy

D1. Students should be able to evaluate, take, and defend positions on the role and importance of law in the American political system.

D2. Students should be able to evaluate, take, and defend positions on current issues regarding the judicial protection of individual rights.

V. Role of the Citizen

B1. Students should be able to evaluate, take, and defend positions on issues regarding personal rights.

B.5 Students should be able to evaluate, take, and defend positions on issues regarding the proper scope and limits of rights.

C1. Students should be able to evaluate, take, and defend positions on issues regarding the personal responsibilities of citizens in American constitutional democracy.

STATE

List your state-specific standards in the space below.

Name _____ Date _____ Period _____

Questions for Consideration

Answer the following questions with respect to your position on the assigned topic:

1. Should people on life support and the terminally ill be allowed to die by withholding medical treatment?
2. Is there ever a stage of illness when assisted death should be considered for patients? If so, when would that be? Why?
3. Who should be responsible for making decisions about whether a terminally ill person is allowed to die by withholding medical treatment or by direct intervention, such as physician-assisted suicide?
4. If an individual is not able to choose for him- or herself, do they have rights with respect to continuing to live or to die, and who is responsible for protecting those rights? Who is responsible for protecting the person? The government, doctors, spouse, family, or someone else? Why?
5. When should a person be kept alive? Why?
6. What are reasons a person should be allowed to die?
7. Should the government intervene in these decisions? When? (What government agencies were involved in the Terri Schiavo case?)

Decision by the Numbers

LESSON 3.6

ALGEBRA I

Time

50 minutes

Materials

Equipment

Calculators

Resources

- What Should I Do? Making Decisions With Weighted Scoring worksheet
- Example scenario and completed worksheet for teacher reference

Prior Student Learning

Students should already be familiar with percentages, fractions, and decimals.

Essential Question for This Unit

What is the appropriate government role in medical decisions that affect the lives of individuals?

Objectives

After completing this lesson, students will be able to

- Apply the concept of weighted scoring as a decision-making tool.

Lesson Activities

Lesson Springboard

Ask students to describe how their grades are determined in different classes. What are the categories that teachers use to evaluate students (tests, participation, projects, etc.)? How does someone know which category the teacher thinks is most important in determining a student's grade? How does the student know that her or his grade was not simply a random assignment by the teacher?

The conversation should bring out that most teachers have a weighted grading system that emphasizes certain criteria above others by making them worth more in the final grade calculation. Either that value judgment is done at the outset when creating the grading system (e.g., tests are 40%, participation is 10%) or teachers may do it as they go along by making each assignment worth a different number of points depending on its importance. Students can then verify their grades as long as they know their individual scores. (This is a good time to check whether your class can accurately calculate their grades.) This system makes it difficult for the teacher to make a rash or emotional decision about a grade at the last minute, without considering all of the evidence.

Suggest that weighted scoring is an effective decision-making and comparison tool in many situations. It allows people to think about all of the criteria that are relevant to a decision and rank them by importance. Then the final score systematically reflects the values of the decision maker. This process can be especially useful in complicated situations like those that involve bioethics.

Lesson Development

Discussion

Introduction to Bioethics (Lesson 1.1 in Health Science I) includes 12 hypothetical scenarios. Choose one of these scenarios to discuss and analyze for the rest of this lesson or create one of your own. Read the scenario out loud to the class. Discuss all the aspects of the situation that should be considered before making a decision. Record these judgment criteria on the board.

Decision by the Numbers

LESSON 3.6

Have the class come up with two or three alternative actions that are appropriate for the situation, and record them on the board. These are the choices that need to be evaluated so that the best one can be selected.

Individual Work

Hand out the What Should I Do? worksheet, and ask students to record their judgment criteria on the list. Then ask each student to individually assign a numerical value to the relative importance of each criterion. The class can use a scale from 1 to 10, with the score of 10 meaning that the criterion is extremely important. Different criteria can have the same score if the student feels the criteria are of equal importance.

At this point, students can calculate the percentage each criterion contributes to the final score and create pie charts or other graphical representations of their value rankings as a review activity.

Now students record the alternative actions and judge how well they fulfill each of the criteria by filling in the table. Again, a 1–10 or 1–5 scale would be appropriate, with the highest number signifying that the alternative it is assigned to completely fulfills the given criterion.

Students can then calculate the values in the rest of the chart to figure out which alternative most closely suits their values. Again, the results can be left in table form or can be graphically represented if there is enough time.

An example worksheet is provided for teacher reference at the end of this lesson.

Discussion

Ask students to share their results. Students can discuss whether or not this decision-making model clarified their thinking on the subject. Did the results of their quantitative analysis surprise them by suggesting a different action than the one they intuitively thought was the best fit to their ethical values? Did the results fit their initial appraisal of the situation? Students can also explain what it might mean when two people come up with the same final score for an action but started with different weights for the criteria.

Lesson Closure

Compile student scores for each criterion and have the class calculate the average score for each alternative. Then discuss the effect of the weighted averages in this situation—either on a student’s individual decision-making process or on the decision making of a policymaker who represents many different people.

Possible Prior Misconceptions

Students may have believed that quantitative methods have no place in ethical discussions.

Decision by the Numbers

LESSON 3.6

Student Assessment Artifacts

Completed What Should I Do? Making Decisions With Weighted Scoring worksheet

Graphical representation of resulting scores

Variations and Extensions

Students can create their own scenarios (not necessarily having to do with bioethics) where different alternatives must be evaluated relative to each other.

National and State Academic Standards

NATIONAL NCTM Standards for School Mathematics

Data Analysis and Probability

Formulate questions that can be addressed with data and collect, organize, and display relevant data to answer them

- understand the differences among various kinds of studies and which types of inferences can legitimately be drawn from each;
- know the characteristics of well-designed studies, including the role of randomization in surveys and experiments;
- understand histograms, parallel box plots, and scatterplots and use them to display data.

STATE

List your state-specific standards in the space below.

Name _____ Date _____ Period _____

What Should I Do? Making Decisions With Weighted Scoring

1. Write a brief summary of the scenario.

2. List the criteria that play a role in making a decision about the scenario.
 - a.
 - b.
 - c.
 - d.
 - e.
 - f.

3. List the options available for action in the situation.
 - a.
 - b.
 - c.

4. Fill in the decision-making table.

Decision-Making Score Table

Alternatives							
		Option 1		Option 2		Option 3	
Criteria	Weight	Rating	Score	Rating	Score	Rating	Score
1							
2							
3							
4							
5							
6							
Total:							

Name _____ Date _____ Period _____

What Should I Do? Making Decisions With Weighted Scoring (Sample Answers)

1. Write a brief summary of the scenario.
A young child and her mother are badly injured in a car crash. The mother tells doctors not to give blood transfusions to either patient because of religious beliefs, and then falls unconscious. The child says she wants help, and the best way to help her is a blood transfusion. The doctor needs to decide what to do.
2. List the criteria that play a role in making a decision about the scenario.
 - a. *The mother’s right to raise her children under a certain belief system.*
 - b. *The child’s right to life.*
 - c. *Respect for religious beliefs.*
 - d. *The obligation to listen to a child’s opinions about her own belief system and health choices.*
 - e. *The doctor’s obligation to help when he knows how, while respecting patients’ needs.*
 - f. *Societal standards that do not agree with the mother’s wishes.*
3. List the options available for action in the situation.
 - a. *The doctor can give the blood transfusion to the girl.*
 - b. *The doctor cannot give the blood transfusion to the girl, and tries other things to help her.*
 - c. *The doctor can call his lawyer to see what the legal implications are before doing anything.*
4. Fill in the decision-making table.

Decision-Making Score Table

		Alternatives					
		Option 1		Option 2		Option 3	
Criteria	Weight	Rating	Score	Rating	Score	Rating	Score
1	4	0	0	5	20	3	12
2	5	5	25	3	15	1	5
3	4	4	16	5	20	3	12
4	3	4	12	2	6	2	6
5	4	5	20	3	12	2	8
6	2	5	10	0	0	3	6
Total:			83		73		49

Name _____ Date _____ Period _____

5. According to the table, which option is the best fit for your values?

The option to give the blood transfusion.

6. What are three situations where using a decision-making model like this one would be helpful?

7. Explain how the way your grade is determined in this class is related to weighted scoring and decision-making models.

