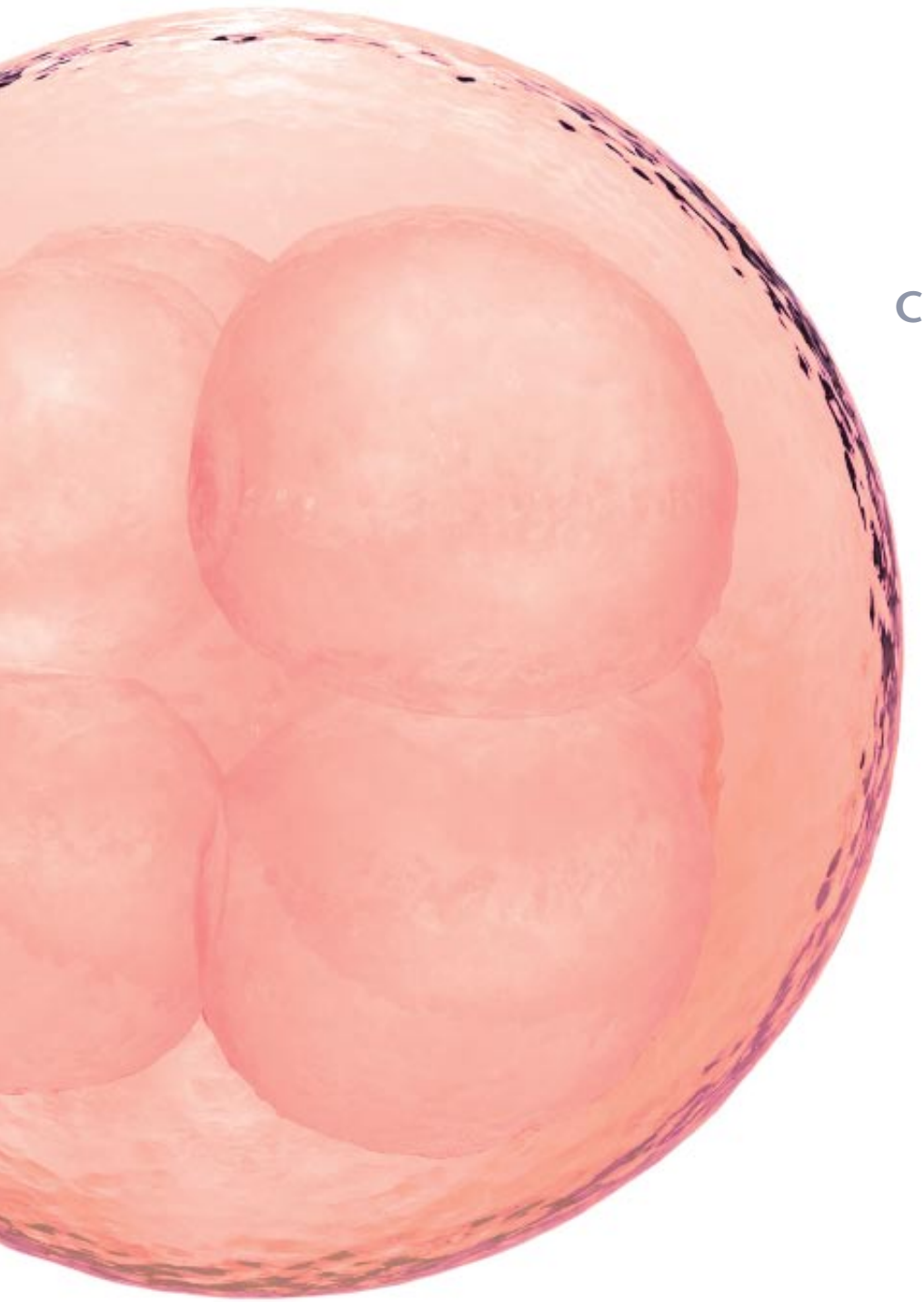
Health Science & Biomedical Program of Study

Do No Harm

INTEGRATED CURRICULUM UNIT ON BIOETHICS

UNIT OVERVIEW



ConnectEd
The California Center for College and Career
Transforming today's education for tomorrow's economy

National Consortium on Health Science & Technology Education

Do No Harm

CONTENTS

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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 role 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, 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.

- Additional individuals can be invited to participate as speakers or to help evaluate the culminating event. These include:
  - Clinical Data Management Specialist
  - Clinical Trials Research Coordinator
  - Medical Editor/Writer
  - Product Safety Associate
  - Quality Assurance Technician
  - Regulatory Affairs Specialist

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

Subunit 1 *Biomedical Research*	**Subunit 2** *Pharmaceutical Advertising*	**Subunit 3** *Medical Decisions*
HEALTH SCIENCE · BIOLOGY · U.S. HISTORY · ENGLISH LANGUAGE ARTS	**ENGLISH LANGUAGE ARTS · U.S. HISTORY U.S. GOVERNMENT**	**BIOLOGY · ENGLISH LANGUAGE ARTS · ALGEBRA I · U.S. HISTORY · U.S. GOVERNMENT**
• 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	• 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	• 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