Lesson 2: Forged, Fake, and Phony Pharmaceuticals

This lesson will take two 45-minute class sessions

Preparing to teach
- Post lesson outcomes.
- Make one copy of the Handouts 1, 2, 3, 4, and 5 for each student.
- Day 2: Make one copy of Handout 6 for each small group.
- Make and post Transparency/Poster 1: Steps for Writing Your Law

Lesson overview
In this lesson, students will learn about the marketing and sale of counterfeit drugs. On the second day of the lesson they will draft a law about counterfeit drugs.

Outcomes
As a result of this lesson, students will be able to:

- Define the term “counterfeit”
- Explain the path counterfeit drugs take from manufacturing to market/sales
- Describe the role of the Food and Drug Administration and Consumer Protection Safety Commission.
- Identify at least three victims of counterfeit drugs
- Explain the connection between counterfeit drugs and trademarks, patents, and copyrights
- Understand law as a means of serving the public interest raised by counterfeit drugs

Handouts (day 1)
- Handout 1: Definitions (1 copy per student)
- Handout 2: The U.S. Food and Drug Administration (1 copy per student)
- Handout 3: FDA Scavenger Hunt (1 copy per student)
- Handout 4: The Rose Bud Story (1 copy per student)
- Handout 5: What Can Be Done? (1 copy per student)

Ask students to bring handouts back for second day of lesson.

Handouts (day 2)
- Handout 6: Drafting a Law (1 copy per group)

Transparency/poster
- Transparency/Poster 1: Steps for Writing Your Law
Community resource people
Consider inviting a lawyer specializing in intellectual property law, someone from your county prosecutor or state attorney general’s office, or someone employed with the U.S. Food and Drug Administration to serve as a resource person for this lesson. Send a copy of the lesson when confirming the date and location of the class. (See handout on Guidelines for Using Resource People at the end of this lesson.)

Web resources
Compelling cases

General information
- http://www.fda.gov/oc/initiatives/counterfeit/

Federal laws
- http://www.usdoj.gov/criminal/cybercrime/18usc2320.htm
## National standards

<table>
<thead>
<tr>
<th>ePIP lesson</th>
<th>U.S. History</th>
<th>Language Arts</th>
<th>Technology</th>
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<th>Science</th>
<th>Music</th>
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</thead>
<tbody>
<tr>
<td>Lesson 2</td>
<td>8th grade</td>
<td>K–12</td>
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<tr>
<td>Forged, fake, and phony pharmaceuticals</td>
<td>Economic, social, and cultural developments in contemporary United States.</td>
<td>Students use a variety of technological and information resources (e.g., libraries, databases, computer networks, video) to gather and synthesize information and to create and communicate knowledge.</td>
<td>Students understand the ethical, cultural, and societal issues related to technology.</td>
<td>Students compare multiple purposes for creating works of art</td>
<td>Abilities of technological design</td>
<td>Students describe ways in which the principles and subject matter of other disciplines taught in the school are interrelated with those of music (e.g., language arts: issues to be considered in setting texts to music; mathematics: frequency ratios of intervals; sciences: the human hearing process and hazards to hearing; social studies: historical and social events and movements chronicled in or influenced by musical works)</td>
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Day 1 Overview

- Introductory activity to define proprietary, generic and counterfeit drugs. (10 minutes)
- Background reading on the Food and Drug Administration (10 minutes)
- Background reading and discussion of counterfeit drugs and their path to pharmacies. (10 minutes)
- Small group discussions about solutions from different perspectives. (15 minutes)
- Summarize – Effects of counterfeit drugs on the public and the economy. (5 minutes)

Review and Preview

At the start of the class ask students to review the definitions of patent and trademark from the first lesson. Then ask students to give some examples of patents and trademarks.

Introduction

Ask students if they have ever purchased or were given an item they were told was a particular brand name or designer name just to learn later that it was not. Ask them:

- How did they react?
- How did they feel?
- What did they do with the item?

What is Counterfeit?

The following activity will set the stage for students to define proprietary, generic, and counterfeit drugs and why it is important to know the difference.

1

Place the word “counterfeit” on the board. Ask students what comes to their mind when they see that word. Write their responses on the flipchart or board. Ask the students for a definition. Write their definition and leave it there for reference during the lesson.

2

Ask students if they can provide examples of types of counterfeit products. Some examples are handbags, CDs, sneakers, etc.

Students often come in contact with counterfeit goods—sometimes sold right on the streets in their communities. This strategy lays the foundation for understanding some of the concepts that are used in the next segment of the lesson.

3

1. Give students Handout 1: Definitions.
2. Ask for volunteers to read the definition of each.
3. Discuss the difference between proprietary, generic, and counterfeit drugs.
4. Once the students have an understanding of each, divide them into small groups of three to five.

5. Ask each group to select a recorder to write the groups ideas, and a reporter to present the groups responses.

6. Ask each group to come up with a list of examples of each definition using other items. Students should provide the proprietary item, its generic counterpart, and what they think would be a counterfeit of the item. Provide the students with an example. You can use food items such as candy or one of the examples in the table below:

<table>
<thead>
<tr>
<th>Proprietary</th>
<th>Sneakers</th>
<th>Drugs</th>
<th>Soda</th>
</tr>
</thead>
<tbody>
<tr>
<td>Handbags</td>
<td>Sneakers</td>
<td>Drugs</td>
<td>Soda</td>
</tr>
<tr>
<td>Louis Vuitton</td>
<td>Nike</td>
<td>Tylenol</td>
<td>Coca-Cola</td>
</tr>
<tr>
<td>Generic</td>
<td>Kmart</td>
<td>Acetaminophen</td>
<td>Any cola</td>
</tr>
<tr>
<td>Counterfeit</td>
<td>Handbag w/ Louis Vuitton monogram not made by Louis Vuitton</td>
<td>Sneakers w/ the Nike brand not made or sanctioned by Nike</td>
<td>Sugar pills labeled as Tylenol</td>
</tr>
</tbody>
</table>

Give students 10 minutes in their groups. Reconvene the class. Using the round robin strategy (described in the box below), ask each groups reporter to present one of the groups’ responses. Do this with each group until they have presented all of their ideas.

**Round Robin**

1. When small groups have completed their task and are ready to report, ask each group in turn to give one issue that they discussed. Continue around to each group, one at a time, until answers are exhausted.

2. This permits each group to share their work without the first group that is called on giving all the information.

3. It works well for generating a list. Have each student give one idea, in turn, and move around the room.

4. When doing problem-solving activities of a sensitive nature with a class, it is useful to have students write an opinion or idea on an index card without a name. The instructor then takes up all the cards and makes a list on the board or begins the discussion from the information on the cards.

**The U.S. Food and Drug Administration**

1

Tell students that the U.S. takes great measures to protect its citizens’ health and safety. The agency responsible for keeping our food and medications safe is the Food and Drug Administration. Distribute Handout 2 – U.S. Food and Drug Administration.

Ask for volunteers to read the handout out loud. Ask the students the following questions:

- What is the role of the FDA?
• What type of products does it monitor?
• What are some of the ways it ensures that our products are safe?
• Does the system always work?

2

Activity: FDA Scavenger Hunt
1. This can be done in class or given as a homework assignment. Tell students that you are going to send them on a cyber scavenger hunt to learn more about the FDA. Distribute Handout 3 – FDA Scavenger Hunt.
2. Have students share their answers.
3. Lead a discussion by asking the following question:
   Which branch of government does the FDA fall under? (executive branch)

3

The Rose Bud Story
Consider giving this reading to students as a homework assignment. Ask them to read the story and be prepared to discuss it.
1. Give each student a copy of Handout 4: The Rose Bud Story. Have students read the story out loud.
2. Clarify all of the facts of the story by asking:
   • Who was involved?
   • What happened?
   • What important facts are presented?
3. Now have students look at the story from the perspective of Rose, Mrs. Bud, and the Medicine Shack. Divide the class into groups by having students count off in threes.
4. Ask each group to briefly discuss what Rose, Mrs. Bud, and Medicine Shack could have done to protect Rose. Ask students to share their responses.
5. In the same groups, assign each group one of the following roles:
   • Group 1 – Doctors
   • Group 2 – Manufacturers
   • Group 3 – Patient/Family
6. Remind students to think back to the exercise where they came up with proprietary, generic and counterfeit items.
7. Ask each group to select a recorder to take notes and write responses for the group and a reporter to present their responses.
8. Distribute Handout 5: What Can Be Done? to students. Provide one sample response to each group:
**Doctor:** Tell patient to talk to doctor or pharmacist as soon as you think something isn’t right – it is their job to take these questions and concerns seriously.

**Manufacturer:** Make packages with hard-to-copy package seals that show tampering.

**Patient/Family:** Educate themselves by reading drug notices included with prescriptions and paying attention to side effect information.

Students should use the information they have learned from the handouts distributed earlier in the lesson. Give students 10 minutes to work together to discuss and formulate their responses. Reconvene the class and ask the reporters from each group to present the group’s responses.

**Summary/Debrief**

- Ask students to review by asking them the following questions:
  - What is counterfeit?
  - What is one characteristic of a counterfeit drug?
  - What could happen if someone takes a counterfeit drug?
  - What laws have been enacted to protect patients from counterfeit drugs?
  - What impact do counterfeit drugs have on the economy?
  - What other items that we use may be counterfeited?
Lesson 2: Forged, Fake and Phony Pharmaceuticals

Day 2 Overview

- Review and preview
- Discuss how laws are made
- Re-read and clarify facts of the Rose Bud Story
- Move students into groups and have them draft a law about counterfeit drugs

How are laws made?

1

Ask the following questions:

- Who governs your local community and makes its laws?
- Do you know any city laws?
  
  Examples: parking, zoning, gun regulations, fire codes, dog-leash laws, etc.
- Who makes state laws?
  
  The state legislature makes the laws with input from citizen groups and others.
- Who represents your city or district in the state legislature?
  
  If students don’t know, have them brainstorm ways of finding out this information. Possible sources to contact include the local newspaper, the local library, League of Women Voters, etc.
- What are the differences in local, state and federal laws?
  
  Local ordinances are regulations only for the city that the council governs. State laws apply to the whole state. Federal laws apply to all persons in the United States.

2

1. Distribute Handout 4—The Rose Bud Story. Have students re-read the story to themselves. Review and discuss the story as a class. Clarify the facts, what happened and who was involved.

2. Ask students to state the issues in this story. List all the issues raised in this discussion on a chalkboard or flip chart.

3. Have the community resource person comment on the list and discuss issues that were missed.

Drafting a law

1

Review the definitions of proprietary, generic, and counterfeit drugs with the students.
Distribute Handout 6: Drafting a Law. Review the handout and clarify. Tell students that they must use the rules to write a law about counterfeit drugs.

Post the **Steps for Writing Your Law transparency/poster** and give these instructions:

1. Place students in small groups of three to five to write a law about the manufacturing, sale, and/or transport of counterfeit drugs.
2. Ask each group to select a recorder and a reporter.
3. Give the groups adequate time to complete their laws. The community resource person and the teacher should circulate to assist each group.
4. When the groups are finished, have each group reporter read their law aloud.
5. After each group has read their law aloud, students may ask other groups questions. Students also can critique the laws. Lead the discussion in a way that highlights the questions for discussion on the **Drafting a Law handout**. Keep the discussion supportive of each group’s work.
6. Ask each group the following questions:
   - What is the purpose of the law?
   - Is the law clear or vague?
   - Is it understandable or is it confusing?
   - Is the law enforceable?
7. After each group has reported, additional questions for class discussion could include:
   - How do the draft laws agree? How do they differ?
   - Did you discuss how to enforce your decisions?
   - Did you discuss what penalties to impose?
   - What types of penalties will be most effective?
   - How do the draft laws give notice to the community?
   - Why is this an intellectual property issue?
   - Are there any other ways to handle this problem?
8. Ask the community resource person to comment on the students’ laws.
9. For the final discussion, have the resource person share the federal law and your state’s law on counterfeit drugs. Ask the students the following question:
   - How are your laws similar to the federal laws? Your state’s law? How are they different?
   - What is the process for filing a complaint? (Both state response and federal response)
Handout 1 – Definitions

Proprietary drug (brand name)
According to the Food and Drug Administration (FDA) U.S. law defines brand name drugs as:

   A drug marketed under a proprietary trademark-protected name (can be produced and sold only by the company holding the patent).

Generic drug
According to the Food and Drug Administration (FDA) U.S. law defines generic drugs as:

   A drug product that is comparable to a brand/reference listed drug product in dosage form, strength, route of administration, quality and performance characteristics, and intended use.

Counterfeit drug
According to the Food and Drug Administration (FDA) U.S. law defines counterfeit drugs as:

   Those sold under a product name without proper authorization. Counterfeiting can apply to both brand name and generic products, where the identity of the source is deliberately and fraudulently mislabeled in a way that suggests that it is the authentic approved product.
   Counterfeit products may include products without the active ingredient, with an insufficient quantity of the active ingredient, with the wrong active ingredient, or with fake packaging.
The U.S. Food and Drug Administration is the federal agency responsible for ensuring that foods are safe, wholesome and sanitary; human and veterinary drugs, biological products, and medical devices are safe and effective; cosmetics are safe; and electronic products that emit radiation are safe. FDA also ensures that these products are honestly, accurately and informatively represented to the public.

What does the FDA do?
- promotes and protects the public health by helping safe and effective products reach the market in a timely way
- monitors products for continued safety after they are in use
- helps the public get the accurate, science-based information needed to improve health

Product Areas Regulated by the FDA:
- safe wholesome sanitary food
- safe and effective medicines, biologics, and medical devices
- safe consumer and medical radiation products
- safe and effective animal drugs
- safe cosmetics
- truthful and informative labels

Enforcement:
When a problem arises, the FDA can take a number of actions to protect the public health.
- works with the manufacturer to correct the problem voluntarily.
- asks the manufacturer to recall a product
- has federal marshals seize products if a voluntary recall is not done
- detains imports at the port of entry until problems are corrected
- can ask the courts to issue injunctions or prosecute those that deliberately violate the law
Handout 3 – FDA Scavenger Hunt

How much do you know about the FDA? By the end of this hunt, you will know a lot more! To start the hunt, you’ll need to go to the FDA web site at www.fda.gov then to About FDA then to More About FDA.

1. What is the name and title of the person in charge of the FDA?
   Hint: Commissioner’s Corner

2. Name four categories of products that the FDA regulates.
   Hint: What We Do

3. Name four categories of products that the FDA does not regulate.
   Hint: What We Do

4. The FDA is an agency of the Department of Health and Human Service. Organization of the FDA consists of nine centers. Name four of the centers.
   Hint: How We Are Organized

5. When did the FDA start?
   Hint: Our History/FDA History/History of FDA

6. How do you report an emergency problem with an FDA-regulated product?
   Hint: Contact Us

7. Where is the FDA headquarters?
   Hint: Our Locations
How much do you know about the FDA? By the end of this hunt, you will know a lot more! To start the hunt, you’ll need to go to the FDA web site at www.fda.gov then to About FDA then to More About FDA.

1. **What is the name and title of the person in charge of the FDA?**
   
   **Hint:** Commissioner’s Corner
   
   Andrew C. von Eschenbach, M.D.

2. **Name four categories of products that the FDA regulates.**
   
   **Hint:** What We Do
   
   Biologics, cosmetics, drugs, foods, medical devices, radiation-emitting electronic products, veterinary products

3. **Name four categories of products that the FDA does not regulate.**
   
   **Hint:** What We Do
   
   Advertising, alcohol, consumer products, drugs of abuse, health insurance, meat and poultry, pesticides, restaurants and grocery stores, water

4. **The FDA is an agency of the Department of Health and Human Service. Organization of the FDA consists of nine centers. Name four of the centers.**
   
   **Hint:** How We Are Organized
   
   • Center for Biologics Evaluation and Research (CBER)
   • Center for Drug Evaluation and Research (CDER)
   • Center for Veterinary Medicine (CVM)
   • Office of Chief Counsel
   • Office of Regulatory Affairs (ORA)
   • Center for Devices and Radiological Health (CDRH)
   • Center for Food Safety and Applied Nutrition (CFSAN)
   • National Center for Toxicological Research (NCTR)
   • Office of the Commissioner (OC)

5. **When did the FDA start?**
   
   **Hint:** Our History/FDA History/History of FDA
   
   The modern era of the FDA dates to 1906 with the passage of the Federal Food and Drugs Act; this added regulatory functions to the agency's scientific mission.
6. **How do you report an emergency problem with an FDA-regulated product?**
   Hint: Contact Us
   
   Contact the district office consumer complaint coordinator for your geographic area. If the problem involves meat or poultry, which are regulated by the U.S. Department of Agriculture, call the USDA hotline at 1-800-535-4555.

7. **Where is the FDA headquarters?**
   Hint: Our Locations
   
   5600 Fishers Lane, Rockville, MD 20857
Handout 4 – The Rose Bud Story

Rose Bud had a rare condition called Idontwantadothis. Patients with this condition are required to take a medication called Thiswillhelp. Rose was prescribed Thiswillhelp by her doctor two years ago. Her mom fills the prescription every three months. Thiswillhelp has some minor side effects such as sleepiness and nausea. Rose has gotten use to these side effects.

Rose’s mom filled a new prescription yesterday at her regular pharmacy, the Medicine Shack. Rose took her medication as usual. A few days later, Rose started feeling strange. She told her mom she was really dizzy and couldn’t sleep. Her mom told her it was probably a side effect of the medicine and not to worry.

A week later, Mrs. Bud received a phone call from a Medicine Shack worker who warned her that the pharmacy had distributed at least one bogus batch of Thiswillhelp, which sells for roughly $500 per dose. The Buds put two and two together and finally realized why Rose was experiencing so much dizziness and sleeplessness after taking her medication. The medication they were administering to her was counterfeit.

Thiswillhelp is a drug used to treat Idontwantadothis, which is a disease that occurs when the brain doesn’t produce enough oxygen. Thiswillhelp is sold using the brand names Ican and Youwill.

Ican and Youwill are made by their manufacturers in different strengths. The drug is a liquid that comes in a vial, and must be refrigerated to remain effective. The vials of full strength product contain 40,000 units/mL. Another commonly-sold dose strength is 2,000 units/mL, which is 1/20th the strength of the full strength product.

For drugs that originate in the U.S., typically the real drug is made by the manufacturer, who sells it to one of three large distributors of drugs in the U.S., who then resell the drugs to smaller regional distributors. The drugs that leave the three large distributors are generally not adulterated. However, after the three major distributors have passed the drugs on to the smaller regional distributors, they become difficult to track. Most counterfeit drugs of U.S. origin are introduced into the supply chain by small counterfeiters.

Counterfeit drugs can also be imported into the U.S. If a counterfeit drug was made to look like the genuine drug, if the counterfeit drug is not detected by U.S. Customs and seized at the border, it may be inadvertently sold alongside other genuine drugs using the normal distribution channels.
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Handout 5 – What Can Be Done?

Doctor
You have written your patient a prescription for Thiswillhelp to treat idontwantadothis. You have read in the Journal of the American Medical Association about the counterfeit Thiswillhelp on the market.

1. What would you tell patients to pay attention to when buying prescription drugs?
2. What would you tell the patient to do to protect against the dangers of counterfeit medicines?
3. What kind of educational materials could you provide and to whom?

Manufacturer
Your company has been informed by the Medicine Shack that several patients received counterfeit medication resembling your most prescribed drug Thiswillhelp.

1. How would you change the way you operate with manufacturing facilities in foreign countries?
2. What could you do to help prevent counterfeit drugs from being able to confuse doctors, pharmacists and patients into believing they are real?
3. What kind of educational materials could you provide and to whom?

Patient/Family
You have been experiencing a side effect from your prescription medication that is different than what the doctor warned you about.

1. What kind of questions could you ask and of whom before taking prescription medications?
2. What kind of things could you look for to protect yourself from counterfeit drugs?
3. How could you educate yourself about the medications you are taking?
Handout 6 – Drafting a Law

Date:
Committee Members:

Our Law:

Rules for Laws:
- A law must be clear and easy to understand.
- People must be able to do what the law says.
- It must not conflict with another law.
- It must be enforceable.
- There should be a penalty for breaking the law.
- It must be posted or explained to people. This means giving notice.

Questions for Discussion:
1. What is the purpose of the law?
2. Is the law clear or is it too vague?
3. Is it understandable or is it confusing?
4. Is it enforceable?
Transparency/Poster 1 – Steps for Writing Your Law

1. Select a recorder to take notes. Select a reporter to announce your law to the rest of the class.

2. Agree on one sentence that states the purpose of your law.

3. You may use up to eight sentences to write your law.

4. When the law is completed, review the list of issues to be certain each is covered.

5. Write the law on the handout.

6. Answer the questions on the bottom of your handout. Does your law meet the requirements of a good law?
Guidelines for Using Resource People

Community resource people can be used to:

- Make the lessons come alive by sharing firsthand experiences
- Answer questions about the lesson
- Provide technical assistance in implementing activities such as mock dispositional hearings.
- Serve as positive adult role models

Careful planning is required to make the involvement of a community resource person as meaningful and valuable as possible. Attention should be given to the following considerations:

1. Topics covered by community resource people should be relevant to the lesson and scheduled to fit appropriately within the sequence of activities.
2. The resource person’s presentation should include participation from young people. Lecture-style presentations are typically less effective.
3. Visitors should present a balanced picture of the topic, including a variety of perspectives.
4. Before a visit by a community resource person, young people should be informed of the planned visit and have time to think of questions that they would like to ask. It may be useful to have students write down their questions before the visit.

Making Arrangements

1. Visit or call the resource person.
   - Introduce yourself and give a brief summary of the lesson, what you are studying, why you want them to participate, and what follow-up activities are planned.
   - Let the resource person know:
     - Date and time of participation.
     - Length of class period.
     - Age and approximate grade level of students.
     - Lesson objectives, topics you will cover, or questions you want answered. (Provide the resource person with a copy of the lesson.)
     - How you expect the resource person to participate (e.g., mock dispositional hearings).
       - Location, parking, and where the resource person should report.

2. A proper introduction of the resource person is extremely important. A brief statement concerning the resource person’s background and expertise helps to prepare young people for the experience and makes the resource person aware of the importance of the visit.

3. Use interactive strategies. Use a strategy that is related to the resource person’s area of expertise. Keep the information relevant to the young peoples' lives and avoid jargon.
4. The resource person is *not* responsible for classroom management. It is important that the teacher participate in the lesson. This approach models adult cooperation, which can be as important as the substance of the lesson.

5. Have resource people help prepare for, enact, and debrief mock exercises. Young people can play the roles of judge, attorney, or witness.

6. Frequently, the resource person has another commitment to keep. It is best to end the presentation within the time scheduled unless the resource person clearly indicates otherwise. Some resource people will offer to meet with the students who may still have questions.

7. Most resource people are not trained presenters. It is sometimes necessary for the teacher to give directions to the resource person by using appropriate questions or other clues to help the resource person more effectively communicate the information desired.

8. Allow sufficient time to summarize the lesson and thank the resource person.

**Debrief the Visit**

1. What were the major points made by the resource person?
2. How did the group react to the resource person and the issues he/she presented?
3. Do the students think the resource person helped them learn about the topic?
4. Ask participants if the resource person had any particular biases.
5. If a resource person is an advocate of a particular viewpoint, it is important to introduce other viewpoints/perspectives in the debriefing discussion.

**Follow-up**

1. Thank-you letters from students really please resource people, help improve writing skills, and encourage resource people to respond to similar requests. The teacher should also send a thank you note to the resource person.
2. A thank-you letter to the resource person’s supervisor will be appreciated by both the resource person and his/her supervisor and will also help encourage future visits.
3. Consider inviting resource people with different viewpoints to do follow-up visits on the same topic.

**Tips for the Community Resource Person**

Tips for the resource person are listed on the next page. Photocopy the page for the resource person with the lesson when you confirm the date and location of the class.