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## Week 5: Pharmacology

### Module 5: FDA Approval Process

#### Lesson: Who Decides If a Drug is Safe?

| Lesson Overview                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
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| <p>Students explore how drugs are tested and reviewed before they are available to the public. They use evidence from the module to understand why the FDA approval process happens in stages and how each stage helps reduce risk. By the end of the lesson, students apply evidence to explain why each stage of the FDA approval process is necessary for protecting public health.</p> |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Learning Targets                                                                                                                                                                                                                                                                                                                                                                           | Vocabulary                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <p>Describe the steps of drug testing in order.</p> <p>Explain what each step is testing (safety or effectiveness).</p> <p>Use evidence to explain why testing steps should not be skipped.</p>                                                                                                                                                                                            | <p><b>FDA</b><br/>organization that reviews and regulates drugs to protect public health</p> <p><b>Clinical Trials</b><br/>testing drugs in stages before they are approved</p> <p><b>Safety</b><br/>whether a drug causes harm</p> <p><b>Effectiveness</b><br/>whether a drug works as intended</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Materials                                                                                                                                                                                                                                                                                                                                                                                  | Instructional Notes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <p>Module</p> <p>Student response sheets</p> <p>Whiteboard or chart paper</p>                                                                                                                                                                                                                                                                                                              | <p>Students investigate how scientists and the FDA identify risks before medications reach the public. The lesson shifts student thinking from responding to medication problems to understanding how those problems can be prevented through testing and review. Many students believe that if a medicine seems promising, it should be available immediately. Others may assume that if a medicine works for a few people, it is ready for everyone. Through the module, students learn that different testing stages answer different questions about safety, dosage, effectiveness, side effects, and long-term outcomes.</p> <p>The key conceptual shift is understanding that each stage of drug testing serves a specific purpose. Students move from viewing approval as a single event to understanding it as a process designed to reduce risk and protect people.</p> |



## Learning Experience

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| 8<br>min  | Opening | <p>Display and read the scenario: “A rare disease is spreading across the country. Thousands of people are getting sick, including children and teenagers. After research, a scientist announces that her team may have found a medicine that could help. News stations begin calling it a breakthrough treatment. Families are hopeful. Social media is full of people asking why the medicine is not already available. The scientist explains that the medicine has not finished testing yet. Some people argue that patients should receive the medicine right away. Others believe more testing is needed first. Before people can use the medicine, what should happen?”</p> <p>Display the following options:</p> <p><b>Option A</b></p> <ul style="list-style-type: none"><li>• Use the medicine right away.</li></ul> <p><b>Option B Complete All of the Following:</b></p> <ul style="list-style-type: none"><li>• Test on animals.</li><li>• Test on a small group of people.</li><li>• Test on many people.</li><li>• Using evidence make a decision about public use.</li></ul> <p>Ask students:<br/>“Which option would you choose and why?”</p> <p>Then ask:<br/>“If testing is important, which testing step would be the most dangerous to skip? Explain your reasoning.”</p> <p>Allow discussion without confirming answers. Explain that students will investigate the actual process used to determine whether medicines are ready for public use.</p> <p><b>Students:</b></p> <ul style="list-style-type: none"><li>• Choose Option A or Option B independently.</li><li>• Compare choices with a partner.</li><li>• Revise thinking if needed.</li><li>• Explain their reasoning.</li><li>• Record an initial prediction.</li></ul> <p><b>Sentence Frame:</b><br/>“I would choose _____ because _____.”</p> |
| 15<br>min | Module  | <p><b>Focus:</b><br/>Students gather evidence about how drugs move through the FDA approval process and how each stage helps protect people.</p> <p><b>Guiding Questions:</b></p> <ul style="list-style-type: none"><li>• What is each step trying to find out?</li><li>• How does each step protect people?</li><li>• Why are multiple stages necessary before a drug reaches the public?</li></ul> <p><b>Quick Checks:</b></p> <ul style="list-style-type: none"><li>• “Is this step focused on safety, effectiveness, or both?”</li><li>• “Why might scientists test a small group before a larger group?”</li></ul> <p><b>Sentence Frame:</b><br/>“This step checks _____ because _____.”</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |



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| 15 min | Application | <p>Tell students: “Imagine that one stage of the FDA approval process suddenly disappeared. Scientists can still test medications using all of the other stages, but one phase is completely removed. Your job is to determine what information would be lost and why that missing phase matters. You will use evidence from the module to investigate what scientists learn during each phase and what could happen if that information was never collected.”</p> <p>Assign each group one phase:</p> <ul style="list-style-type: none"><li>• Phase 1</li><li>• Phase 2</li><li>• Phase 3</li><li>• FDA Review</li><li>• Post-Market Monitoring</li></ul> <p>Display the evidence chart and leave it visible throughout the activity.</p> <p><b>Teacher Reference and Student Slide</b></p> <p><b>What Do Scientists Learn During Each Phase?</b></p> <p><b>PHASE 1</b></p> <ul style="list-style-type: none"><li>• 20–80 volunteers participate in testing.</li><li>• Scientists study the safety of the drug.</li><li>• Scientists determine appropriate dosage levels.</li><li>• Scientists identify serious side effects.</li></ul> <p><b>Main Question:</b></p> <p>“Is this drug safe enough to continue testing in people?”</p> <p><b>PHASE 2</b></p> <ul style="list-style-type: none"><li>• Patients with the disease or condition receive the drug.</li><li>• Scientists collect data on how well the drug performs.</li><li>• Scientists continue monitoring safety.</li><li>• Scientists may compare results to other drugs or placebos.</li></ul> <p><b>Main Question:</b></p> <p>“Does the drug help people with the condition?”</p> <p><b>PHASE 3</b></p> <ul style="list-style-type: none"><li>• Even more people participate in testing.</li><li>• Scientists continue monitoring side effects.</li><li>• Scientists look for long-term effects that may not have appeared earlier.</li></ul> <p><b>Main Question:</b></p> <p>“What happens when many more people use the drug?”</p> <p><b>FDA REVIEW</b></p> <ul style="list-style-type: none"><li>• FDA experts review the drug’s safety and reliability.</li><li>• The FDA reviews drug labeling.</li><li>• The FDA inspects manufacturing facilities.</li><li>• The FDA decides whether the drug should be approved.</li></ul> <p><b>Main Question:</b></p> <p>“Does all of the evidence support approval?”</p> <p><b>POST-MARKET MONITORING</b></p> <ul style="list-style-type: none"><li>• The FDA continues studying the drug after approval.</li><li>• Scientists monitor how the drug affects people over time.</li><li>• Rare or unexpected effects can still be identified.</li></ul> <p><b>Main Question:</b></p> <p>“What are we still learning after the drug reaches the public?”</p> |
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|       |                    | <p><b>Step 1: Investigate the Missing Phase</b><br/>Groups discuss: What information is collected during this phase? What important question does this phase answer? What information would scientists lose if this phase disappeared?</p> <p><b>Step 2: Complete the Challenge Statement</b><br/>Groups complete: "Without _____, scientists would not know _____. This could lead to _____. Therefore, this phase helps protect people by _____. Students must support their reasoning with evidence from the module.</p> <p><b>Step 3: Share Out</b><br/>Each group delivers a brief 30-second report.<br/><b>Presentation Frame:</b><br/>"Our missing phase was _____. This phase helps scientists learn _____. Without it, scientists would not know _____. This could increase the risk of _____."</p> <p><b>Step 4: Individual Exit Challenge</b><br/>Students respond independently: "Which phase would be the most dangerous to remove from the FDA approval process and why?" Students must use evidence from the module and one idea from class discussion.<br/><b>Sentence Frame:</b><br/>"I think _____ would be the most dangerous phase to remove because _____."</p> |
| 2 min | Reflection         | "How has your thinking changed about why medicines go through multiple testing stages before reaching the public?"                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| 2 min | Career Connections | The FDA works with physicians, chemists, pharmacologists, and other scientists to evaluate medications before they reach consumers. During the approval process, different phases gather different kinds of evidence about safety, dosage, effectiveness, side effects, and long-term outcomes. Even after a drug reaches pharmacy shelves, the FDA continues monitoring its effects. Understanding why each stage exists helps students recognize how scientific evidence is used to reduce risk and protect public health.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |