Bringing a Drug to Market

As your teacher has described, medications sold in pharmacies must pass a series of important tests. Drug approval is a rather lengthy process that verifies the effectiveness and safety of a drug, while detecting any potential side effects. In this activity, you will have the opportunity to design a pharmaceutical drug with a specific effect in the human body and develop a hypothesis to explain its mode of action. Then, you will need to develop an experiment to test your hypothesis and the efficacy of your molecule in a mock pre-clinical trial. You will then present your findings to the rest of the class using a presentation method of your choice (Prezzi, PowerPoint, or other).

Activity 1: Choice of a drug and its role in the body

Like all pharmaceuticals, your molecule must have one or more effects that will positively influence your health. For example, painkillers such as analgesics (Advil™, Aspirin™) work by diminishing the sensation of pain and blocking the chemical signal of pain to the brain, while anticoagulants prevent clotting in blood vessels. In short, for a drug to work it must have a precise action on one or more systems of the body (blood system, nervous system, musculoskeletal system, respiratory system, etc.)

Your first task is to choose what effect your drug will have on the human body. The following questions will help you identify important information that should be included in your presentation. Be creative in the effect of your molecule! Some examples of drug effects include:

- A drug that increases muscle strength
- A drug that improves concentration for long periods of time
- A drug that improves vision in the dark

To help you make a choice, research some of the different human body systems and choose an attribute or function that you would like to improve or eliminate, or a disease affecting one of these systems that could be treated with a drug.

Body system choices: digestive, blood, nervous, muscular, skeletal, lymphatic/immune, urinary, respiratory, one of the five senses, etc.

1- What is the function of your medication? ________________________________

______________________________________________________________________

______________________________________________________________________

2- On which body system will it have an effect? ________________________________
3- Using the Internet as a research tool, explain the mechanism of action that your molecule will have on the targeted system. Knowing the mechanism of action will help you explain why the drug will have its intended effect on the body. Ask your teacher for help as necessary. Summarize your findings in the space below.

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**Activity 2: Protocol for pre-clinical trials**

From your teacher’s presentation, you now know that once a promising drug molecule has been made and tested in a laboratory, the next step is to verify its efficacy in a pre-clinical trial using animals, usually mice.

To do this, researchers measure certain attributes of two groups of mice. One group will be receiving doses of the drug, while the second group (the *control group*) will be receiving a *placebo*, a fake treatment that doesn’t contain any drug molecules. By comparing the two groups of mice, researchers are able to see if the drug has any therapeutic effect, and then decide if the drug is promising enough to move on to human clinical trials. Scientists must develop their protocols very carefully to ensure that the right attributes are being measured – for example, muscle strength, rate of reaction, or amount of red blood cells in the blood.

4- Choose two measurable attributes in both the test and control groups of mice, and explain the method you will use to obtain a measurement of this attribute (e.g. search for hidden food in a
maze; withdraw a blood sample for analysis; etc.). Then, describe how your measurements will be analyzed between the two groups (e.g. compare times taken to retrieve hidden food; blood glucose levels following meals; etc.), and how the test could show evidence of a therapeutic effect.

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Activity 3: Presentation of your drug and protocol

You must now present a proposal for a pre-clinical trial for your drug. Use the guidelines below to help develop your presentation. Each slide should have images, graphics, or photos to illustrate the information that you have found.

Slide 1: The health issue or human ability to be addressed
What ability, disease, or health issue does your drug target? What made you decide to pursue it? What benefits will the person taking the medication have?

Slide 2: System to be treated
How does the organ or system on which your drug acts function naturally?

Slide 3: Drug’s desired effect on the targeted system
On which function of the targeted system does your drug act? What is its mechanism of action? How will interactions on the molecular level lead to observable effects? Be specific in your explanations.

Slide 4: Pre-clinical experiments
What experiments will you use on your two groups of mice (test & control) to demonstrate the efficacy of your drug? What tools or objects will you use in order to carry out this strategy? Explain the details of your experiments and provide a rationale for choosing these particular experiments.

Slide 5: First attribute to analyze
What attribute will you analyze in this experiment? Why do you think this test is important in order to demonstrate the efficacy of your molecule? How will you measure or quantify the data that you get? How will you interpret the results of this experiment?

Slide 6: Second attribute to analyze
What attribute will you analyze in this experiment? Why do you think this test is important in order to demonstrate the efficacy of your molecule? How will you measure or quantify the data that you get? How will you interpret the results of this experiment?

Slide 7: Feasibility and societal impact
In your opinion, why should the drug that you have proposed be approved? What are the possible positive effects that your drug could have on health for both individuals and society at large? What are some of the possible negative effects?