

## Green Fluorescent Protein Dilemmas 1

### Testing and Placebos

Anytime a company tests a new use of a particular protein it is taking a huge risk. We will pretend that GFP could be a cure for stomach cancer (it's not, this is just a simulation).

Our simulated company, ProteinFind, will spend over \$100 million dollars in testing over about 10 years, but the potential for curing stomach cancer and making a profit is good. Right now there is enough money in the bank to pay the employees at ProteinFind for a few more years, but ProteinFind urgently needs a product so it can survive beyond that.

Before your protein is tested on humans, you must first test it on rats or mice with stomach cancer. You must determine if these animals are cured and, if so, how much of your protein it takes to do it. You also need to find out about possible side effects or problems that your protein may cause.

In order to determine if your protein really works you must use a control, or placebo. A placebo can be any inert substance, like water, which has no medicinal value, but can be administered in the exact same way as the molecule you are testing. The U.S. Food and Drug Administration (FDA), will examine ProteinFind's experiments to determine if your protein is safe and actually cures stomach cancer without negative side effects. The FDA also requires that you test all drugs on two species of animals, before you conduct human studies. If you do not comply with these FDA regulations, you will lose millions of dollars in wasted research.

One of ProteinFind's technicians has injected 1, 2 or 3 drops of your purified protein into rats with stomach cancer. She has also similarly tested the placebo on another set of animals. After a time, she has counted the number of stomach tumors still left in the animals. Examine her observations shown in the table below and answer the questions that follow.

Sample tested	# of drops	# of tumors found
Green protein	1	11
Green protein	2	7
Green protein	3	1
Placebo	1	14
Placebo	2	17
Placebo	3	13

1. Based on the results above, does it appear that the green protein controls stomach cancer?

Explain your answer.

2. What amounts of our protein would you now recommend to be tested on larger animals like monkeys or humans?

3. Having heard about your testing, animal activists from People for the Ethical Treatment of Animals (PETA) are in ProteinFind's lobby while others are sending faxes and letters requesting that you find alternatives to animal testing. Because some individuals feel so strongly about treating animals humanely, they are threatening to boycott all of your future

products. Bad publicity could keep potential investors away and threaten additional research. What would you say or do to help these activists with their concerns and mend this explosive situation?

4. Consider the following groups and how their opinions might influence your efforts to get your green protein to the market.

a. FDA

b. Ramon and the other stomach cancer victims

c. The activists from PETA

d. The employees of ProteinFind

## Green Fluorescent Protein Dilemmas 2

Currently ProteinFlnd has 50 employees and \$40 million in the bank. Since your protein has not completed all the FDA-required testing, your protein cannot be marketed yet, so you have no income. During the first two years of testing, you used over \$16 million. Examine the table below to help you decide how much ProteinFlnd will need to charge customers once you market this cancer-curing protein.

### Estimated expenses for ProteinFlnd: Years 1 through 6

Year	Number of employees	Estimated expenses (millions \$)	Testing and commercialization events
1	50	8	Rodent testing w/placebo
2	50	8	Monkey testing w/placebo
3	70	11	Submit animal testing results to FDA and start Human testing: Phase I—identify side effects in healthy humans
4	85	13	Human testing: Phase II—determine if protein works, best dose, and side effects are tolerable to actual cancer patients
5	100	45	Human testing: Phase III—many stomach cancer patients involved and if successful, send in Product License Application (PLA) to FDA
6	100	18	FDA Approval? If yes, ProteinFlnd will continue to spend \$18 yearly to produce and market the protein.

Assume that it costs ProteinFlnd \$400 (per treatment) to manufacture the drug. The selling price of the medicine determines how many people can afford the treatment. After FDA approval the market might look like this:

Type of cancer treated	Number of patients who can afford treatment	If cost of treatment is
<b>Stomach cancer</b>	10,000	\$2000
(Medicare will not cover above \$1000 per treatment)	30,000	\$1000
	60,000	\$600
<b>Lung cancer</b>	6,000	\$2000
(Medicare will cover, if priced \$500 or less, since it is currently paying \$500 for a competing treatment)	15,000	\$1000
	300,000	\$500

Questions:

- Which type of cancer, lung or stomach, will receive the most financial support from Medicare?
- Which type of cancer, lung or stomach, will enable ProteinFlnd to make the largest profit? Explain your answer.
- If ProteinFlnd were to market the green protein for both types of cancer, at what price should the company sell the medication: the same price for both, or different prices? Explain your answer.

## Green Fluorescent Protein Dilemmas 3

Student Presentations:

Here are some real-life dilemmas which you may encounter while bringing a new medicine to market. You and your team will select one dilemma to research and develop a well-rounded solution that considers these four main viewpoints:

- a. FDA
- b. Patient Advocacy Groups—Cancer Patients, American Cancer Society
- c. Social Conscience Groups—Sierra Club, PETA, National Resource Defense Council of Concerned Scientists, etc.
- d. ProteinFind Employees

Dilemma 1

During preclinical testing, in year 2, PETA protesters become concerned about the use of monkeys in testing. ProteinFind tries to get the FDA to waive the requirement, but FDA refuses (why?) and the whole process gets bogged down. ProteinFind calls a group meeting attended by all four groups, including cancer patients who are desperate to break the impasse and get things moving again. Devise a way to resolve the issue and get your protein to market as soon as possible.

Dilemma 2

During Phase II human testing, doctors refuse to use a placebo treatment on their patients. These doctors believe that the green protein can cure cancer, so why should half their patients receive a placebo and therefore be allowed to die? Determine a way to convince the doctors to get your protein tested properly so the FDA will allow ProteinFind to market the cure.

Dilemma 3

Year 6 is half gone. The Phase III results were very good and the company is waiting for FDA approval. But the FDA calls for a public meeting, to which the PETA activists are invited. The FDA is concerned about possible long-term side effects of the drug on reproduction, since none of the information gathered in the trials has addressed that issue. This would involve doing more studies using monkeys. Come up with a compromise strategy to deal with this new issue and still get the medicinal protein to market quickly.

Dilemma 4

In year 7, ProteinFind starts selling your cure for stomach cancer. Using the financial data provided in Dilemmas 2, decide on a pricing policy. Note that if you take in less than your annual expense of \$18 million, you will either need to lay off employees or go out of business. Come up with a way to keep ProteinFind competitive and financially stable without losing employees or its ability to make and sell its products.

Dilemma 5

Imagine that a new study in year 8 at ProteinFind shows that your green protein can also cure lung cancer. There is a huge market for this product, if only Medicare will reimburse hospitals for the treatment. But Medicare will only pay if you promise to charge patients \$500 (or less). You are already charging more than that for the same medicine to treat stomach cancer patients. What can you do to keep your stomach cancer patients and still receive the benefits of financial support from Medicare?

Dilemma 6

In year 9, a patent is issued to an obscure scientist in Massachusetts for the same cancer-curing protein. Apparently, he had been studying this protein independently. He now has the legal right to demand payment from ProteinFind. He asks for \$20 million. What can you offer this scientist in order to avoid going out of business?

Dilemma 7

Most cancer patients are unable to pay more than \$40 for the use of the cancer-curing protein that costs ProteinFind \$400 to produce. Assume you decide to provide your product to these patients below cost. Six months later, a thriving black market for your drug appears in Los Angeles—at reduced prices! What do you do now?

Dilemma 8

Apparently, your green protein may also help prevent or control a rare skin disorder called Splotchy Skin. This disease affects approximately 250-300 individuals worldwide. Should ProteinFind determine if the green protein also cures Splotch Skin so that these unfortunate people no longer have to hide themselves from their neighbors? If ProteinFind takes on this study it must follow all of the FDA testing requirements and spend an additional \$12 million to verify if the green protein can safely treat this condition. Explain your answer.

Creating Your Presentation:

To create an outline for your presentation analyze one of the eight dilemmas, and describe the controversies or problems created by it. Then design two possible questions and answers. In each case, identify the viewpoint of the person asking the question:

- a. FDA
- b. Patient Advocacy Groups
- c. Social Conscience Groups
- d. ProteinFind Employees

Dilemma _____	Your response
What is the controversy?	

Question 1	Possible answer
(Viewpoint a, b, c, or d?)	

Question 2	Possible answer
(Viewpoint a, b, c, or d?)	