NATIONAL CENTER FOR CASE STUDY TEACHING IN SCIENCE

Is That Pill You're Taking Safe?

A Case Study About the Drug Development Process

by

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Sally couldn't believe that the trial was finally going to begin. She had been waiting for this for years. She hadn't even been sure she would make it to the trial. Her heart had been giving her trouble—and it was all their fault! As Sally sat waiting for the trial to begin, she thought "Why was that drug on the market? Aren't we the most cautious nation in the world? Don't we require strict testing of drugs before they go on sale?" Her husband Fred was by her side.

"Oh, Fred, if only I didn't take that diet drug Fen-phen! We wouldn't be in this trouble, I'm sure of it!"

"But, Sally, at least we can make them pay for your suffering. Your problems have to be caused by those drugs. The company had to know about the problems—and they did nothing about it!"

But Sally had been sick to death of being fat. She had been fat all her life. She was teased as a child and never had any dates in high school. The doctor had said Fen-phen wouldn't solve all of her problems and that it had some side effects, but that it should help her lose weight. So she decided to go ahead and take it anyway. And she did lose 30 pounds. But that was before the heart problems started. Now she was about 50 pounds overweight and on medication for cardiac valvular disease—and she wasn't sure she would be able to dance at her daughter's wedding next year.

Sally and Fred had sued the makers of dexfenfluramine (the "fen" in Fen-phen) for marketing the drug. They had been joined in their suit by Anne and Joe. Joe was about 75 pounds overweight. He had been diagnosed with a heart murmur after he had been on Fen-phen for five months. He had no overt health problems. Anne was 150 pounds overweight and had developed pulmonary hypertension after being on Fen-phen for two months. She had had to quite her job and go on disability.

Instructions

1. The case will be set up as a trial. You may be asked to be part of the jury, defense (drug company), or the prosecution (Sally).

Disclaimer: The story and characters presented in this case study are fictitious. The case itself is based on data reported in the literature and the media—data that are available for public scrutiny and comment. There is no intent to "find fault" or present an opinion pro or con. Judgement is in the domain of the scientific community. Every effort has been made to present the scientific considerations concisely and accurately. Any errors should be attributed to the author Janis Hammer and not the original investigators.

2. You will work in the groups assigned at the beginning of the semester.
3. Within each group there will be an expert witness in the following areas:
   - history of the drug approval process
   - thalidomide as an example of the approval process
   - drug development process – from discovery through animal testing (e.g., high throughput screening, toxicity, reproduction, GLP's)
   - drug approval process—human testing (e.g., INDA, clinical trials, GCP's, GMP's)
   - Fen-phen (what is it, indications for use, problems encountered, studies performed)
   - pulmonary hypertension and cardiac valvular disease (what are they and how do they relate to Fen-phen?)
4. You may use any sources available to you (books, journals, web). Do not forget the research librarians! They can be a big help if you are having difficulty finding information. (Note, a good place to start: http://www.fda.gov)
5. Pretrial hearing (date to be announced, this will take at least two class periods):
   - You must be prepared to present the information for which you are the expert to the class during the pretrial hearing. Charts, graphs, pictures, or an outline to summarize your information is helpful.
   - Each group will be asked to present their information on one of the topics listed above. After each topic, other groups may add additional information or ask questions. This is the time to ask questions if you don't understand something! This is to provide information only. *Do not* state your opinion.
6. At this time assignments will be made. One group will be assigned to designate someone (or two) to play the part of Sally, Anne, and Joe. One or two groups will be assigned to be the jury and the remaining groups will be divided between the defense and the prosecution. As a group you must decide how you are going to use the information gathered to present your side of the story.
7. At the time of the trial (to be announced—may run over into the next class):
   - The instructor will be the judge.
   - The prosecution will go first. Present your case against the drug company using the information presented earlier. Be as specific as possible. This should take approximately 15 minutes.
   - The company will now have 15 minutes to defend their product. Again, use the information provided earlier and be as specific as possible.
   - The prosecution will have 5 minutes to ask questions of Sally, Anne, and/or Joe (if more than one student is assigned a character, they will confer before answering the question so that only one answer is given) or the "experts," followed by 5 minutes for the defense.
   - The prosecution will have 5 minutes to rebut and close, followed by 5 minutes for the defense.
   - The jury will then meet to make their final decision and justify it. The decision and justification will be presented in the first 5 minutes of the next class.
   - Final questions/answers period, regarding trial and information provided.
8. Two class periods later, a summary of the case study (one to two pages) from your assigned perspective (defense, prosecution, or jury) is due. The summary should include a list of references for your "expert" topic. The jury's decision will be announced at that time. We will wrap it up with a final discussion/ thoughts about the case.