

Homework from Lectures 21 and 22 (Chapters 14 and 15)

Questions 1-4 are from the text book (5 pts)

1. Contrast the rate of diffusion of the following two innovations: vitamin C to prevent scurvy in sailors, and laparoscopic cholecystectomy.

2. You have developed a new type gold nanoparticle to improve a physician's ability to detect cancer at the earliest possible stages. Many internet based health food stores sell solutions of identical gold nanoparticles to "lift your body's performance, and fight off germs, viruses, bacteria, allergens, pathogens and pollution". Yet, it will be several years before you can begin clinical trials to determine whether this same nanoparticle can improve early cancer detection.

http://alchemistsworkshop.com/_wsn/page8.html

a. Describe the current differences in FDA regulation of this particle when it is used as a dietary supplement vs as a drug.

b. Briefly summarize the history of government regulation of drugs in the US, noting the year of major changes in legislation and the primary changes in regulation associated with these laws.

3. Consider the differences in regulation of drugs and dietary supplements.

a. If I wish to market a new drug to treat pancreatic cancer, am I obligated to provide scientific data to the FDA indicating that it is safe and/or effective before I can sell it?

b. The following is an actual internet ad for an herbal supplement. If you were employed by the FDA to monitor and investigate these ads please indicate statements you see that may not follow legal guidelines in the United States. Explain why you chose each of your selections. If you did not identify anything, explain why.

There's a new nutritional supplement available for people suffering from [Type 2 diabetes](#). It's called Rejuvenator, marketed by Lafayette Miracle Solutions. It contains two key ingredients – green tea and [cinnamon](#). The first thing to realize is that nutritional supplements can very successfully control sugar in diabetics. Both green tea and cinnamon are well-known to help control blood sugar [for people who] have such wild blood sugar swings (and potentially don't need as much insulin either). Also, the other benefits documented from taking both green tea and cinnamon. Green tea is noted for its effects, as well as its ability to aid in weight-loss, which is something that diabetics are typically struggle with.

4. Consider a new implantable device that does not have any reasonably similar products already in the market.

a. What class of device would the FDA consider this product?

b. Would this device need a 501(k) or PMA approval process?

c. Based on your answer to part b, describe the remaining steps needed to carry this product through to the market?

Current Events: Pick one assignment (5 pts)

Find a newspaper article or NPR clip related to the recent events in poisoned toothpaste and/or medicine that was made in a different country. How did the FDA react – were there any criticisms of how they handled things? Please include a 200 word summary (or less) that adequately describes the problem as portrayed in the article or clip, and describes some of those criticisms (with references).

Next, in less than 100 words, describe two reforms the FDA could implement in order to prevent something like this from happening in the future.

OR

Find a newspaper article or NPR clip related to either the Vioxx or Ephedra ban. How did the FDA handle the ban – were there any criticisms of how they handled things? Please include a 200 word summary (or less) that adequately describes the problem as portrayed in the article or clip, and describes some of those criticisms (with references).

Next, in less than 100 words, describe two reforms the FDA could implement in order to prevent something like this from happening in the future.

Note: Please include a copy of the article, or copy of the link to the clip.