Case study

The Food and Drug Administration: An Overview The Food and Drug Administration (FDA) is the main body responsible for the creation of new drugs, clinical research, and setting standards and safety concerning food and drug legalities (Hertzman, 3). The US Food and Drug Administration is responsible for the safety of more than a trillion dollars worth of products each year, or approximately 25% of the US economy (Hertzman, 4). The FDA's mission focuses mainly on speeding innovations to make medicines more effective, safer and more affordable, and helping the public to obtain accurate, scientific, and evidence-based information (Hertz, 4). One of the issues that capture the attention of the public is the drug approval process done by FDA. A patient might not understand why a particular medication may not be available in his/her country. For instance, a 46-year old woman who purchased an over-the-counter weight loss medicine in South America cannot buy the similar medication in US. Your health teaching as a care provider is to inform them of the role of FDA and the process underlying the issue. The FDA restricts and regulates imported medications to address safety of individuals. In addition to this regulation and unavailability of some drugs is the time it takes for a drug approval. The time it takes from a drug approval starting from the drug discovery to the FDA's Inspectional Background and Data is 22 months duration of waiting (Hertzman, 9). Aside from FDA's restriction in the drug approval process, a comprehensive risk assessment is performed to determine safety and efficacy of a certain drug to human subjects. In line with this are phases of clinical development and are categorized in Phase I to Phase III (Madzarevic, 49). Supposed a patient presents to a primary care practice with a letter from a local drug research center asking them to consider participation in a phase III clinical trial, the

primary care provider should provide accurate, detailed, and specific information about phase III. Patient must be made aware that it includes pivotal studies and will determine the most of the safety and efficacy data gathered in phase II. Since it is the most important and centralize among phases, patient will participate together with hundreds to thousands of subjects per trial. We must also inform them that it is a comparative study and it can either be controlled or uncontrolled (Madzarevic, 50). Primary care provider must discuss with the patient that the duration of the study is long term and will last from weeks to months and must ensure that all communicated information are well-understood. As a student who will eventually play an active role in prescribing medication, knowledge and participation about FDA and drug issues is a must. The greatest bulk of the public’s concern centralized on the difference between the generic and branded medications especially with regards to cost. According to Walmart. Com, branded medications cost $4 for a 30-day supply while generic drugs cost $10 for a 90-day supply of medications. Therefore, a 90-day supply of medication will cost $12 and is $2 more expensive than the generic medications. Students must get acquainted with the wide variety of generic drugs that are available to patients at a fraction of the cost of brand name drugs. To sum it up, the Food and Drug Administration serves as a regulatory body. Clinical development of drugs as well as time approval requires a scientific basis and a long duration of time. Clinical studies or trials need to follow a series of protocols and patient participating in the study must be kept well-informed. The FDA and the pharmaceutical market also provide a wide range of choices by citing price difference between generic and brand name medications. Works Cited Hertzman, Marc, and Lawrence Adler.

Clinical Trials in Psychopharmacology: A Better Brain. 2nd ed. Chichester, John Wiley & Sons Ltd., 2010. p. 1-30. Madzarevic, Vera Mihajlovic. Clinical Trials Audit Preparation: A Guide for Good Clinical Practice. New Jersey, John Wiley & Sons Ltd., 2010. p. 47-55. Walmart. " Retail Prescription Program Drug List." Walmart. Save Money. Live Better. 8 February 2011. Wal-Mart Stores, Inc. 19 May 2011. Retrieved from http://i. walmartimages. com/i/if/hmp/fusion/customer_list. pdf