

SCI 331: THE THALIDOMIDE TRAGEDY: LESSONS FOR DRUG SAFETY AND REGULATION- ASSIGNMENT 1- A CASE STUDY (TOTAL PTS 100)

QUESTIONS FROM THE ARTICLE

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Answer all questions in complete sentences. Type in your answers in MS words. Save the work in PDF format.

Submit the document in the proper dropbox.

1. What made the developers of the drug thalidomide claim the drug was completely safe for everyone? (5pts)

- The Thalidomide drug was discovered in 1954 by a German pharmaceutical firm leading to the approval and monitoring system of the United States Food and Drug Administration. In 1957 the German market advertised their product as an “completely safe” over-the counter remedy drug for everyone.

2. Name the conditions for which the drug thalidomide was used? (5pts)

- Thalidomide was prescribed to prevent sleeplessness during the post-war era; it was marketed for tranquilizers and sleeping pills. Dr. William McBride recommended the drug to his pregnant patients to alleviate morning sickness. Thalidomide was also prescribed as an depression medication treat chronic pain.

3. What was the most adverse drug reaction of thalidomide reported by doctors in 1961? (5 pts)

- In 1961, Dr. William McBride began to associate the drug with the severe birth defects within the babies he delivered. 161 babies were reported adversely affected by the thalidomide which concluded to many countries banding the use of the previously sold drug.

4. Describe the condition of phocomelia? (5 pts)

- Phocomelia is a side of the drug thalidomide, resulting in the shortening or absence of limbs.

5. Who prevented the drug’s approval within the United States? What were the THREE ethical reason(s) behind the decision? (10 pts)

- FDA inspector Frances Kelsey prevented the approval of thalidomide because of the lack of reliable data, no system for clinical trials, and minimum compliance of tracking the data.

6. By passing the Kefauver-Harris Drug Amendments Act in 1962, legislators tightened restrictions surrounding the surveillance and approval process for drugs to be sold in the U.S. What were the requirements of this Act? (10 pts)

- Drug approval can take between eight and twelve years, involving animal testing and tightly regulated human clinical trials.

7. Currently, thalidomide is FDA-approved for **two** uses today. What are they? (10 pts)

- Thalidomide is FDA-approved for **two** uses today—the treatment of inflammation associated with Hansen’s disease (leprosy) and as a chemotherapeutic agent for patients with multiple myeloma, purposes for which it was originally prescribed off-label.

8. What is S.T.E.P.S. program? What is their function? (10 pts)

- System for Thalidomide Education and Prescribing Safety. The S.T.E.P.S. program, designed by to educates all patients who receive thalidomide about potential risks associated with the drug.

Questions from outside

9. Describe three ways by which patients can be educated about a drug? (10 pts)

- Counseled about the risk, benefits, and safe administration of the drug from their physician.

10. Thalidomide has also been associated with a higher occurrence blood clots. How can this be monitored? (10 pts)

- The specific blood test used to measure the time it takes for blood to clot is called a prothrombin time test, or protime (PT)

11. Thalidomide is considered a double-edged sword. Why? (10 pts)

- Thalidomide was prescribed to prevent sleeplessness and morning sickness that resulted into congenital disabilities, high occurrence of blood clots, nerve and blood disorders.

12. What ethical issues could have been addressed in early 1960s so phocomelia could have been prevented? (10 pts)

- The issue of humanity and honesty should have been addressed to prevent the numerous cases of birth defects.