

2) (25 pts) On April 12, 1955, after a series of clinical trials on 1.8 million Elementary School children (the largest clinical trial in history), it was announced that the “killed-virus” or Inactivated Polio Vaccine developed by Dr. Jonas Salk was, “safe, potent and efficient” in combating the most feared illness of the 20<sup>th</sup> Century. During the 1952 epidemic, for example, 57,800 cases of polio were reported in the United States alone. In anticipation of this announcement, six pharmaceutical companies were given contracts by the Federal Government to produce 9 million doses of the vaccine for immediate use, and with the intent of inoculating 57 million people by years end.

Within two weeks of the vaccine’s initial use, it was determined that Cutter Laboratories in Berkeley, California (one of the 6 companies under contract) produced a batch of the vaccine that contained a live strain of the polio virus causing 260 cases of polio and 10 deaths. These cases were traced to one batch of the vaccine consisting of about 250,000 doses.

In 1957, in an effort to improve upon the killed Salk vaccine, Dr. Albert Sabin began testing a live, oral form of vaccine in which the infectious part of the virus was inactivated (attenuated). The “volunteers” in Dr. Sabin’s first tests upon human beings with live virus vaccine were 25 initiates (teenagers) of the Federal Reformatory at Chillicothe, Ohio, and in one newspaper report at the time, the following description of the tests appeared, "...is being tested on children in a California institution for the feeble-minded after having undergone long trials on animals."

This “live” Polio vaccine became available for use in 1963 and because of its effectiveness, is the preferred choice around the world today. Polio was considered eradicated in the Americas in 1994, although in the United States, during the period 1980-1990, an average of 8 cases per year occurred due to the vaccination itself.

List some of the ethical and societal impact issues associated with the discovery and use of Polio vaccines in the United States.

- a) Discuss the ethical issues from the various moral and ethical theories listed in Question 1 above, **but only for those that might apply to these issues**. How might this history effect the development and use of vaccines today (e.g. the flu vaccine, an AIDS vaccine, etc.).
- b) How would you characterize the risk of contracting polio in the United States before the use of the various polio vaccines (1952) and after (1980s)?
- c) How does this whole episode shed light on the current risk analysis paradigm? Do the benefits outweigh the risks? Why?

Note: In 1952, the population in the United States was 158 million. Today, the population is just under 300 million.

- a) **(8)** Discuss the ethical issues from the various moral and ethical theories listed in Question 1 above, **but only for those that might apply to these issues**. How might this history effect the development and use of vaccines today (e.g. the flu vaccine, an AIDS vaccine, etc.).
- i) **(5)** All of the theories listed in question 1 probably could be addressed within the context of this problem to some degree. However, due to time constraints full credit for this part was given for addressing any **3** of the theories. I assumed that the theories were formally defined in question 1, so the focus here is on the application of each theory to the problem. The response here should be clear as to the knowledge of the theory and how it is applied: i.e., A Kantian would oppose this type of testing because here people are being used as a means to an end. Furthermore, people were test subjects without being informed as to the risks involved.
- ii) **(3)** Some mention of current vaccination testing based on the information provided for this problem is required. Specific examples can be used or just a discussion of the issue.

Aside: For this case of vaccine testing, the utilitarian approach was utilized, and in essence, “trumped” Kantian idea of using people as a means to an end, as well as an approach involving rights ethics, where informed consent would be addressed.

b) (8) How would you characterize the risk of contracting polio in the United States before the use of the various polio vaccines (1952) and after (1980s)?

i) (2) Risk was defined in class:

- What could go wrong?
- How likely is it to happen?
- What are the consequences?

Short answers to these questions are sufficient: *What could go wrong? A person contracts polio.* Alternatively, calculations were acceptable, but they were not required, nor are they sufficient. These calculations need to be explained.

ii) (3) Before the use of vaccines...use the above discussion to explain risk before the use of vaccines.

iii) (3) After the use of vaccines...use the above discussion to explain risk after the use of vaccines.

Just stating that the risk was greater before the use of vaccines is not sufficient; the response needs to include some application of the definition of risk and how someone approaches these types of problems.

- c) **(8)** How does this whole episode shed light on the current risk analysis paradigm? Do the benefits outweigh the risks? Why?
- i) **(2)** A paradigm is a framework within which we shape our worldview. The current risk assessment paradigm is based upon utilitarianism, which usually results in a cost/benefit analysis.
  - ii) **(3)** Shedding light on the risk analysis paradigm basically should have included a short discussion of any drawbacks or strengths of risk analysis. The interpretation for this part is very broad, and any opinion is acceptable as long as it pertains to risk analysis in general.
  - iii) **(3)** Here, too, a discussion of benefits and risks should be addressed. Either answer is acceptable as long as the argument is logical. However, a conclusion should be stated.
- d) **(1)** Essay quality: Due to time considerations, neatness was not a factor in the grade. Grammar was not a factor either because English is not everyone's first language. The essay though, should be logical, and show some progression of thought, as well as the attempt to apply ethical theories and critical thinking to a practical problem.