Arguably the most famous conflict of interest case in medicine is the gene therapy trail that lead to the death of a 18 y.o. research subject, Jesse Gelsinger. Please read an article by R. Wilson in the American Journal of law and medicine, 2010. This article provides a detailed legal account of the events surrounding death of a research subject in a clinical trial and contributing conflict of interest of Dr. James Wilson, no relation to the author of the legal article. It is a legal reading, so do not focus on unknown terms too much, just get the main message. This article reads as a detective story, and it is very carefully dissecting all steps of the trail.

After almost a decade since Jesse’s death, Dr. J.Wislon published his paper in Molecular genetics and Metabolism about Lessons learned from gene therapy trail. He was legally required to do so. He addresses all steps very carefully as well.

Please submit  APA style paper that address Use both sources to answer these questions. Paper has to be at least two pages long, not including references, 12 pt font, single space, 1-inch margins. There will points deducted from submissions that do not conform to these requirements.

1.      What was the rationale for this particular trail? Briefly address the biological mechanism of the OTC deficiency and animal findings that lead to the trail.

2.      Who was sponsor of the trail?  Was the sponsor information revealed in the consent form that Jesse signed? Notice any conflict of interest there.

3.      What is step I of clinical trial? What was the design of the trail? What are possible risks of stair-step trail?

4.      Was the principle “first do no harm” obeyed in the experimental design and choice of research subjects for the study? Consider risk- benefit ratio for Jesse.

5.      Did the IRB sufficiently address trail risks? Give examples.

6.      How would Dr. Wilson personally benefit if the trail succeeds? If financial conflict would have been avoided, in the opinion of the authors would the outcome of the trail be different?  Were scientist primarily motivated with money? What other incentives for conflict exist?

7.      What deviations from the approved protocol exist? List those that you noticed. Is it allowed to change consent form “in a real time” as the trail progressed without prior IRB approval?

8.      Was the death of experimental animals properly disclosed in the consent form? Offer your own wording.

9.      Jesse had borderline elevated serum ammonia at the start of the trail. What does elevated serum ammonia means? How is ammonia toxic?

10.  What were particular mistakes in the clinical trail protocol that lead to Jesse’s death?

11.  What was the role of Penn’s Conflict of Interest standing committee? What limitations were placed on Dr. Wilson? How did it affect decision-making for Jesse?

.Was Jesse’s death preventable? How? What particular mistakes were made during the course of the trail

13.  What is an example of a significant financial relationship?

14.  In your view, is total avoidance of conflict of interest beneficial? Is it realistic under real world circumstances?