

RESPONSIBLE CONDUCT OF RESEARCH

please read and discuss during lunch

CASE STUDY #1

Jane is a very motivated and bright graduate student who is trying hard to synthesize a metabolically stable small molecule inhibitor of a newly identified brain enzyme. In a series of high profile publications, the enzyme has been shown to be 1000-fold overactive in a rare and fatal childhood disease. The field is convinced that if an inhibitory drug could be given to these young patients, a significant medical benefit could be realized.

Despite her perseverance, she meets with failure after failure. Every drug she makes is rapidly metabolized and thus shows no efficacy in her animal models. Finally, she goes to Dr. Jones, who is an internationally recognized investigator in drug metabolism in her department, and describes her problem. Dr. Jones is silent for a while and then says, "Don't fret. I'll have something for you to look at tomorrow." The following day when Jane arrives at the lab, she sees an unpublished manuscript on her desk with a post-it note from Dr. Jones that says: "Jane, read the methods and results sections of this paper. I think they might contain the solution to your problems. But don't tell anybody I gave you this. As soon as you are finished, return the paper to me."

The paper describes a synthetic design that seems exactly suited to solving Jane's problem. Sure enough and within a few days, Jane synthesized a potent metabolically stable inhibitor using the approach. The drug can now move forward into preclinical testing and ultimately into patients who could truly benefit from its utility. She gleefully reports all this to Dr. Jones and returns the paper. She can't help asking though, "Dr. Jones, I have searched the literature high and low to find a method to help me with my project and found absolutely nothing. Where did you get that manuscript?" to which Dr. Jones obliquely replies, "Oh, don't worry about that; I have many such manuscripts."

(Modified from a case study reported online)

DISCUSSION:

We have purposefully omitted the origins of the paper that Dr. Jones provided to Jane as therein lies the moral content of the dilemma. Students could consider each of these possibilities, and their implications in the responsible conduct of research.

CADE STUDY #2

Sally is a faculty member at a research university. Her basic research over 11 years eventually turns up a promising lead for a treatment for cerebral malaria, a major cause of epilepsy in the world. She founds the company "Malirax" to develop a drug that can be marketed for this purpose. Sally owns equity (stock) in Malirax. Sally is supervising Mark, a graduate student, who is working on another project in Sally's lab. When Mark learns about Sally's research on cerebral malaria and the potential to change the lives of millions in poor African countries, he approaches Sally and asks to switch his thesis project to cerebral malaria. What should Sally do? Both Sally and Mark want to help millions, but Sally has the chance to make millions if the research leads to a successful product. How should Sally deal with her responsibilities as Mark's mentor, given that she has a conflict of interest caused by her ownership stake in Malirax?

Fast forward. Mark does switch to malaria research. He works hard and accumulates a great deal of data but only publishes one paper since he started malaria research late in his graduate studies. Still, he feels he is ready to submit his dissertation given the importance of his one paper.

Moreover, he has an offer to work for Humongco, a large pharmaceutical company that has told Mark they want to initiate a program in cerebral malaria research because they see a huge market opportunity, given the promising results from Malirax, which has conducted trials but doesn't yet have a drug ready for the market. Sally tells Mark that she doesn't feel he is ready to submit his thesis and needs to publish several more papers.

Sally is friendly with Sheila, the chair of Mark's dissertation committee. At lunch, she tells Sheila in confidence that her research would stall if Mark graduates. Also, she is worried that if Mark joins Humongco, they will crush Malirax. Mark schedules a visit with Sheila to discuss submission of his dissertation. Sheila tells him that the dissertation committee won't permit him to graduate without several more publications.

DISCUSSION: What should Mark do? How should the conflict of the pharma company's interests and academic mission for training be handled?