

RESPONSIBLE CONDUCT OF RESEARCH

please read and discuss during lunch

CASE STUDY #1

Dr. Bobby Bill was an undergraduate in the lab of one of the first researchers to successfully demonstrate the existence of a “longevity gene” in *c. elegans*, and since then his passion has been the search for the expression of genes uniquely present in genetic variants of organisms that live significantly longer than the mean. He has turned the attention of his NIH-funded lab to drosophila as a model organism and has successfully isolated new genes that are highly expressed in fruit flies that live significantly longer than typical.

Dr. Bill was contacted by a large pharmaceutical company, also interested in longevity, to be a professional consultant. Initially, they were interested in establishing a drosophila colony that would include an aged population, and asked Dr. Bill’s help in the husbandry of the aged fruit flies. They invited Dr. Bill to their corporate research labs about three times a year, each time paying his travel and a \$2,000 honorarium. However, the relationship has evolved and now Dr. Bill is serving a role more like a scientific collaborator than a consultant. He has now been asked to serve on their Scientific Advisory Board and as compensation will be getting some shares in the company stock currently worth about \$12,000. Furthermore, they have “gifted” \$180,000 to his lab to cover a postdoctoral fellow for three years to work on a few collaborative projects. Dr. Bill now spends about 15% of his effort on the collaboration and 60% of his effort on his NIH project. The remainder of his time is spent on teaching and committee service. The trips to the company have increased, and sometimes Dr. Bill must get other faculty members to cover his lectures because of his travel schedule.

At a recent research meeting at the company, Dr. Bill and the Board could clearly see a potentially patentable product emerging from their joint line of inquiry. This product, which stimulates expression of the longevity genes, has the potential of providing a therapy to slow the onset of aging in humans, which is extremely exciting and could be quite lucrative. However, the Scientific Advisory Board would need to decide whether or not to publish their findings, and how to protect the intellectual property rights emerging from this research. The Board asks which parties need to be represented legally as the push to commercialize the product moves forward: Dr. Bill, his postdoctoral fellow, his institution? Dr. Bill feels that, while his research group contributed to the success of the project, direct experiments related to the product were not performed by any NIH-funded personnel. And, he has spent much effort at night and on weekends on the company’s project. Therefore, he feels that it is fair that his intellectual property (IP) interests be represented, but not necessarily the school’s interests. Dr. Bill feels as though, since he fulfilled his teaching, service, and research efforts at the school during this time period, all additional efforts he may have made were on his own behalf. Further, Dr. Bill feels that since the postdoctoral fellow was getting his training on this project, he has not really earned any additional benefit for his participation in the project.

- How should Dr. Bill answer the Board’s questions about who should be listed on the patent?
- Does Dr. Bill have either a perceived or real conflict of interest in participating in this project? At what point in this scenario did that happen?
- Under NIH Financial Conflict of Interest (FCOI) guidelines, must he report any or all of his travel reimbursements, stocks or direct payments from the company?
- When should IP/patent rights be discussed and determined in a collaborative project? By what mechanism does that occur at academic institutions?
- In your opinion, does the school have any IP/patent rights? Why might this be important to the school?
- Is collaboration between academia and industry a good thing? What are the pros and cons?
 - What special issues might arise for the postdoctoral fellow whose stipend is paid through a gift from a company, such as in this case?

Debate Question: Must we avoid all conflicts of interest, or can some be managed?

CASE STUDY #2

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 1,000-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. Consider each of these possibilities and their implications in the responsible conduct of research.