

<https://ori.hhs.gov/case-one-age-old-conflicts>

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The screenshot shows the ORI website header with the U.S. Department of Health & Human Services logo and the ORI logo. The navigation bar includes links for Home, About ORI, News & Events, Research Misconduct, RCR Resources, Programs, Policies & Regulations, and Assurance Program. The main content area is titled 'Case One: Age-Old Conflicts' and includes a breadcrumb trail 'Home » Case One: Age-Old Conflicts'. Below the title is the subtitle 'RCR Casebook: Conflicts of Interest' and a 'Table of Contents | Previous | Next' link. A sidebar on the right contains links to 'Misconduct Case Summaries', 'Newsletter', 'Follow Us on Twitter', 'PHS Administrative Action Bulletin Board', and 'Annual Report System'.

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 his research group at a very good Midwestern school in the US has successfully isolated a handful of 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 has to 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 potential patent? Discussion Questions for the Facilitator

- 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?
- Does Dr. Bill have a conflict of commitment? How does this concept differ from the concept of a conflict of interest?
- 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? Does the company have to report their compensation to Dr. Bill?
- 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?
- Are faculty sometimes allowed to serve as outside consultants? If the school has a policy on faculty consultation activities, might that affect their rights in this situation?
- Is collaboration between academia and industry a good thing? What are the pros and cons?
- Has Dr. Bill done anything "wrong" in this scenario? Has the company?
- What special issues might arise for the postdoctoral fellow whose stipend is paid through a gift from a company, such as in this case?
- Should this research be subjected to peer review through publication, or is the push to help humanity better served by allowing the company to continue along these research lines without the added competition that publication would certainly bring?
- Does the NIH have any IP/patent rights in this scenario? In any scenario?
- Debate Question: Must we avoid all conflicts of interest, or can some be managed? *