



Case Studies in Biodesign Ethics

Conflicting Allegiance

You are an expert in your special area of medicine and you are consultant/advisor to two of the leading companies working in your field. You are paid for your time by company A on an hourly basis (\$5,500 last year). Company B pays you a monthly retainer (\$1,000/month) and has given you options to buy 10,000 shares of their stock at a discounted price. You have helped both companies improve upon their existing products by making judgments on evolutionary changes they have shown you in their facility over the past 2 years. You have made suggestions for improvements but you are not sure you have "invented" anything in this activity. The consulting contracts you signed state that any intellectual property you develop as part of the contract belongs to the company. You have noted that the evolution of each company's product has resulted in them having some overlapping capabilities, and they are really becoming more and more similar from a functional and clinical standpoint. Company A is a little ahead of Company B in development and Company A's implementation has some advantage over Company B's user interface in your opinion.

Company A contacts you to say they feel their newly modified product is now ready for clinical testing and they ask you to carry out the clinical evaluation. They know that if they provide a "gift" to Stanford to remain under your control then you could do the work without them paying the indirect costs usually attached to a contract for the work. They ask if you are willing to accept such a gift from them with the tacit understanding that the funds will be used for their project, but also that there will be an overage to be used at your discretion. They have a finite amount allocated for the clinical trial so if they write a contract for the work with Stanford there will be much less money available (due to the indirect costs taken by Stanford) and you will either "break even" or potentially expend more than the amount available for the work. Several points come to mind after you finish this discussion with them:

- How important is it to you to be the first to try this new product?
- What are the restrictions on receiving funds as "gifts" to the University for your use?
- What will you need to disclose to Stanford about your relationship to the donor of the gift?
- Will you need to tell Company B that you are testing Company A's new product?
- How will Company B react to your testing of Company A's product?
- If you test Company A's product, can you also test Company B's product at the same or overlapping times?
- If you have to choose one company to work with, which will it be? What criteria shall you use to make this decision?
- Are there any proprietary aspects of either company's product that you have disclosed to the other company as part of your discussions?
- Would you need to get approval from the Conflict of Interest Committee to carry out this project (if it is purely from unrestricted University funds)?
- What will you include in a patient Consent form about your relationship to the Company? (If this study's sponsorship is "hidden" as a gift, you have not made clear to the School or IRB that the work is related to a company for which you are a paid consultant.)
- What will you include in a patient Consent form about your relationship to the Company if this study is sponsored by a contract with Company A?
- Others?