Illustrative Cases of Financial Conflicts of Interest

1. Professor Smith has developed a promising new drug for acne. He sets up a small company with himself as Scientific Director and major stockholder to produce the drug and test it in humans. He applies for and receives an NIH grant for a phase 1/phase 2 clinical trial at UCSF. What are Professor Smith’s obligations under current conflict of interest guidelines?

Answer: Since this UCSF project is federally supported, it falls under federal regulations in which the threshold for declaring a potential conflict of interest is $10,000/year in income and/or >5% equity interest in an entity that is related to the research. Clearly this company of Professor Smith is related to the research, and Professor Smith has a greater than 5% equity interest (he would have to disclose the exact percent). Therefore, Professor Smith is obligated to submit a financial disclosure form to the Chancellors Advisory Committee on Conflict of Interest (COIAC). Because this research is federally funded, the COIAC is required to review the case and has the option to 1) approve the research despite the financial interest involved 2) approve the research and recommend ways to manage the financial interest (for example, requiring that the financial interest be declared in publications that emanate from the research) or 3) deny the research funding.

2. Pfizer is developing a new drug for baldness. Pfizer contacts Professor Jones who is an expert in hair follicle cycling. Pfizer contracts with Professor Jones to perform studies with this new drug in the hairless mouse. While this study is in progress, Pfizer invites Dr. Jones to meet with its scientific staff and other consultants to discuss new lines of research in psoriasis. They offer a $2000 honorarium plus travel expenses. What are Professor Jones’ obligations under current conflict of interest guidelines?

Answer: Since this project is not federally sponsored, state regulations apply. Since Professor Jones will be receiving more than $500 in income (i.e., the $2000 honorarium) from Pfizer during the period of the grant, she needs to fill out a state mandated form declaring this financial interest. Because this research project does not involve human subjects the COIAC is required to review it. The COIAC has the option to 1) approve the research despite the financial interest involved, 2) approve the research and recommend ways to manage the financial interest (e.g., declaring it in publications that emanate from the research), or 3) deny the research funding.
3. Merck is competing with Pfizer re developing a new drug for male pattern baldness. They too enroll Professor Jones’ help, but in this case to participate in a phase I/II trial which Merck is sponsoring and in which their product is being tested. The trial is launched. During the trial Merck asks Professor Jones to speak at several CME courses which they sponsor. Professor Jones will receive $2000 per talk plus travel expenses. What are Professor Jones’ obligations under current conflict of interest guidelines?

Answer: Since this project is not federally sponsored, state regulations apply. Since this research involves human subjects, additional UCSF regulations apply. Because the income (the honoraria) exceeds the $500 threshold, state regulations require that the financial interest be declared. Furthermore, current UCSF policy stipulates that “Faculty who have, or participate in, a privately sponsored clinical study shall not concurrently receive any compensation from the sponsor, including honoraria and consulting fees, during the course of the study. In addition, they shall not have any investment in, or serve in a decision making capacity (such as service on the Board of Directors or management committee), or be an officer or employee of the company sponsoring the study.” Therefore, Dr. Jones may not accept the honoraria from Merck to give these talks during the course of the investigation. The COIAC has no discretion in this case. These rules do not apply to the period before or after the study.

4. Professor Ray serves as consultant for the Robert Wood Johnson Foundation, and is paid $1000 plus travel expenses for each meeting with the Foundation Board. In response to an identified area of interest by the Foundation she submits a proposal to determine whether the French paradox regarding the potential health benefits of red wine also applies to the beer drinking Dodgers fan. This study is funded. During the study the RWJ Board continues to meet with its consultants. What are Professor Jones’ obligations under current conflict of interest guidelines?

Answer: As in cases #2 and #3, this situation falls under state regulations. The UCSF-specific policy does not apply because RWJ is a foundation and not a private sponsor. Since Professor Ray will be receiving more than $500 in income (i.e., the $1000 honorarium) from RWJ during the period of the grant, she needs to fill out a state mandated form declaring this financial interest. The COIAC is required to review it. The COIAC has the option to 1) approve the research despite the financial interest involved, 2) approve the research and recommend ways to manage the financial interest (e.g., declaring it in publications that emanate from the research, or 3) deny the research funding.