Industrial Pharmacy Residency Program

The Faculty of Pharmacy of the University of Toronto, along with the companies participating in the Industrial Pharmacy Residency Program (AltiMed, Apotex Inc., AstraZeneca, Baxter Corporation, Eli Lilly Canada Inc., ESI Canada, Genpharm Inc., GlaxoSmithKline, Hoffmann-La Roche Ltd., and Nycomed Amersham Canada Ltd.) are pleased to announce that the following Industrial Pharmacy Residents have completed the program:

Cynthia Leung
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Ethics and Pharmacogenomic Research

I read Mary Ensom's editorial[1] discussing the implications of pharmacogenomics research with interest. I agree that the results of such research will provide tools to help personalize drug therapy and that pharmacists will need to be able to apply this knowledge in their care of patients. In this context, it may be helpful for pharmacists to be aware of the hotly debated issues that surround genetic research and its application. Knowledge of these controversies and of ongoing educational efforts and policy development will help pharmacists to understand the process of genetic research and to improve their ability to discuss the research and its outcomes with colleagues and patients.

As a member of a research ethics board, I was very excited when projects that included a genetic research component began to cross my desk for review. The possibilities seemed fantastic, and it was tempting to rush forward with approval without first examining the implications for research subjects. A research ethics board, however, is entrusted with the responsibility to ensure that the welfare and rights of research subjects are in no way compromised and that these subjects make their decisions to participate in the research in a fully informed manner. To protect the welfare of research subjects, researchers are asked by the research ethics board to describe potential harm to the subjects. The problem with genetic research is that potential harm is poorly understood.

Most harm could arise from the possibility of linking, in the research records, biological material to the person from whom it was taken and thereby revealing clinically relevant information about the individual and his or her family. The risks associated with such linkage and revelation of information include loss of confidentiality of the information and possible psychological and socioeconomic impacts on the research subject and his or her family. Receiving information about susceptibility to a genetic disease may cause anxiety, identify a need for additional tests, and necessitate access to genetic counselling. Knowledge of this information could limit the availability of medical services or insurance for the subjects and could lead to discrimination, stigmatization, or even ostracism. Blood relationships and information that affects family planning could be revealed, and family conflict created.

The research ethics board requires researchers to conduct an informed consent process so that subjects fully understand the research, the implications of their decision to participate, and their rights within the project. In early projects reviewed by our research ethics board, these aspects of informed consent were difficult to understand, as the consent for the use of biological materials was either included as a small section of a consent form for a clinical trial or was added as a separate consent form, without an accompanying research protocol specifically for the genetic material. The goal of the research, how long the samples might be kept and what they would be used for, whether or not they could be linked to the individual from whom they came—all of these aspects were unclear.

Several groups have now developed guidelines for obtaining consent related to use of biological materials.