Module 3:
The Drug Approval Process

Learning Goals

1. Describe five distinct FDA mandates regarding prescription drugs.
2. Identify controversies related to three recent FDA laws concerning prescription drugs.
3. Identify the five phases of the FDA drug approval process and define the key objective of each.
4. Discuss three limitations of clinical trials in establishing whether psychotropic drugs are efficacious to treat a given psychiatric condition.
5. Discuss three limitations of clinical trials in establishing whether psychotropic drugs are safe to treat a given psychiatric condition.
6. Assess conflicts of interest created by pharmaceutical companies' funding of clinical research.
7. State consequences of inadequate post-marketing surveillance of new drugs.
8. Learn to report suspected adverse drug reactions to the FDA using MedWatch.
9. Articulate the need for skepticism and vigilance concerning findings from clinical trials of new drugs.

Questions for Practice, Supervision and Administration

1. Your client, currently taking an anticonvulsant and an antipsychotic drug prescribed for a diagnosis of bipolar disorder I, has not been doing very well. You hear from her physician that a brand new antipsychotic has recently been approved by the FDA for the treatment of bipolar disorder I and perhaps it should be tried with your client. Based on the information and analysis presented in this module, what questions about the approval process of this drug would you want answered before you discussed with your client her options and were able to provide her with your fair estimate of the known risks and benefits of this new product?
2. The pain medication Vioxx was removed from the market after 932 deaths were reported to the FDA as possibly related to its use. On the other hand, the atypical antipsychotics clozapine (3,277 deaths reported between 1998-2005), Risperdal (1, 093 deaths reported between 1998-2005), and Zyprexa (1,007 deaths reported between 1998-2005) are still

on the market—despite most of their prescriptions being off-label, many young children are taking them, and taxpayers are footing the bill for most prescriptions via state insurance programs such as Medicaid. Why do you think different standards are being applied?

3. Obtain the latest label for the antipsychotic olanzapine (Zyprexa, Zyprexa Zydis, or Zyprexa IntraMuscular) directly from the FDA website or the Internet (as of this writing, it is dated 2006). Review the sections entitled "Carcinogenesis, Mutagenesis, and Impairment of Fertility" and "Pregnancy." Summarize them as if you were presenting this information to one of your female clients currently taking olanzapine.
4. In the medium or long-term, who might benefit if you report your client's adverse drug reaction to the FDA using MedWatch?