Process of Drug Approval

Gaining FDA approval for a new drug is expensive and time consuming. Here are the different stages of getting approval for a new drug:

- **Phase I study:** The safety of the drug is tested with a small (20–100) group of volunteers.
- **Phase II:** The drug is tested for effectiveness in randomized trials involving a larger (100–300) group of subjects. This phase often has subjects randomly assigned to either a treatment group or a placebo group.
- **Phase III:** The goal is to better understand the effectiveness of the drug as well as its adverse reactions. This phase typically involves 1,000–3,000 subjects, and it might require several years of testing.

Lisa Gibbs wrote in *Money* magazine that "the (drug) industry points out that for every 5,000 treatments tested, only 5 make it to clinical trials and only 1 ends up in drugstores." Total cost estimates vary from a low of $40 million to as much as $1.5 billion.

Errors in Hypothesis Tests

When testing a null hypothesis, we arrive at a conclusion of rejecting it or failing to reject it. Such conclusions are sometimes correct and sometimes wrong (even if we apply all procedures correctly). Table 8-4 summarizes the two different types of errors that can be made, along with the two different types of correct decisions. We distinguish between the two types of errors by calling them type I and type II errors.

- **Type I error:** The mistake of rejecting the null hypothesis when it is actually true. The symbol α (alpha) is used to represent the probability of a type I error.
- **Type II error:** The mistake of failing to reject the null hypothesis when it is actually false. The symbol β (beta) is used to represent the probability of a type II error.

MEMORY HINT Because it is difficult to remember which error is type I and which is type II, we recommend this mnemonic device: Remember "routine for fun," and using only the consonants from those words (**RouTiNe FoR FuN**), we can easily remember that a type I error is RTN: Reject True Null (hypothesis), and a type II error is FRFN: Fail to Reject a False Null (hypothesis).

Notation

α (alpha) = probability of a type I error (the probability of rejecting the null hypothesis when it is true)

β (beta) = probability of a type II error (the probability of failing to reject a null hypothesis when it is false)

Table 8-4 Type I and Type II Errors

		True State of Nature	
		The null hypothesis is true	The null hypothesis is false
Decision	We decide to reject the null hypothesis	Type I error (rejecting a true null hypothesis) $P(\text{type I error}) = \alpha$	Correct decision
	We fail to reject the null hypothesis	Correct decision	Type II error (failing to reject a false null hypothesis) $P(\text{type II error}) = \beta$

Example 2 Identifying Type I and Type II Errors

Consider the claim that a method of gender selection increases the likelihood of a baby girl, so that the probability of a baby girl is $p > 0.5$. Here are the null and alternative hypotheses:

$$H_0: p = 0.5$$

$$H_1: p > 0.5 \text{ (original claim that is addressed in the final conclusion)}$$

Identify the following: **a.** Type I error; **b.** Type II error.