

tuberculosis, or pregnancy. They can replenish a body deficient in antibodies, vitamins, hormones, electrolytes, protein, enzymes, or blood. Drugs can prevent pregnancy, assist fertility, and sustain life itself.

Certainly, the vast array of effective medicinal agents available today is one of our greatest scientific accomplishments. It is difficult to conceive our civilization devoid of these remarkable and beneficial agents. Through their use, many of the diseases that have plagued humans throughout history, such as smallpox and poliomyelitis, are now virtually extinct. Illnesses such as diabetes, hypertension, and mental depression are effectively controlled with modern drugs. Today's surgical procedures would be virtually impossible without the benefit of anesthetics, analgesics, antibiotics, blood transfusions, and intravenous fluids.

New drugs may be derived from plant or animal sources, as by-products of microbial growth, or through chemical synthesis, molecular modification, or biotechnology. Computer libraries and data banks of chemical compounds and sophisticated methods of screening for potential biologic activity assist drug discovery.

The process of drug discovery and development is complex. It entails the collective contributions of many scientific specialists, including organic, physical, and analytical chemists; biochemists; molecular biologists; bacteriologists; physiologists; pharmacologists; toxicologists; hematologists; immunologists; endocrinologists; pathologists; biostatisticians; pharmaceutical scientists; clinical pharmacists; physicians; and many others.

After a potential new drug substance is discovered and undergoes definitive chemical and physical characterization, a great deal of biologic information must be gathered. The basic pharmacology, or the nature and mechanism of action of the drug on the biologic system, must be determined including toxicologic features. The drug's site and rate of absorption, its pattern of distribution and concentration within the body, its duration of action, and the method and rate of its elimination or excretion must be studied.

Information on the drug's metabolic degradation and the activity of any of its metabolites must be obtained. A comprehensive study of the short-term and long-term effects of the drug on various body cells, tissues, and organs must be made. Highly specific information, such as the effect of the drug on the fetus of a pregnant animal or its ability to pass to a nursing baby through the breast milk of its mother, may be obtained. Many a promising new drug has been abandoned because of its potential to cause excessive or hazardous adverse effects.

The most effective routes of administration (e.g., oral, rectal, parenteral, topical) must be determined, and guidelines for the dosages recommended for persons of varying ages (e.g., neonates, children, adults, the elderly), weights, and states of illness have to be established. It has been said that the only difference between a drug and a poison is the dose. To facilitate administration of the drug by the selected routes, appropriate dosage forms, such as tablets, capsules, injections, suppositories, ointments, aerosols, and others, are formulated and prepared. Each of these dosage units is designed to contain a specified quantity of medication for ease and accuracy of dosage administration. These dosage forms are highly sophisticated delivery systems. Their design, development, production, and use are the product of application of the pharmaceutical sciences—the blending of the basic, applied, and clinical sciences with pharmaceutical technology.

Each particular pharmaceutical product is a formulation unique unto itself. In addition to the active therapeutic ingredients, a pharmaceutical formulation contains a number of nontherapeutic or pharmaceutical ingredients. It is through their use that a formulation achieves its unique composition and characteristic physical appearance. Pharmaceutical ingredients include such materials as fillers, thickeners, solvents, suspending agents, tablet coatings and disintegrants, penetration enhancers, stabilizing agents, antimicrobial preservatives, flavors, colorants, and sweeteners.

To ensure the stability of a drug in a formulation and the continued effectiveness of