

examples of drugs isolated from a natural source include paclitaxel (Taxol), an agent with antitumor activity derived from the Pacific yew tree (*Taxus baccata*) and employed in the treatment of metastatic carcinoma of the ovary; vincalkebostine, another antineoplastic drug, from *Vinca rosea*; and digoxin, a cardiac glycoside, from *Digitalis lanata*.

Throughout Europe during the late 18th century and the beginning of the 19th century, pharmacists like Pelletier and Sertürner were held in great esteem because of their intellect and technical abilities. They applied the art and the science of pharmacy to the preparation of drug products with the highest standards of purity, uniformity, and efficacy possible at that time. The extraction and isolation of active constituents from crude (unprocessed) botanical drugs led to the development of dosage forms of uniform strength containing singly effective therapeutic agents of natural origin. Many pharmacists of the period began to manufacture quality pharmaceutical products on a small but steadily increasing scale to meet the growing needs of their communities. Some of today's largest pharmaceutical research and manufacturing companies developed from these progressive prescription laboratories of two centuries ago.

Although many of the drugs indigenous to America and first used by the American Indians were adopted by the settlers, most drugs needed in this country before the 19th century were imported from Europe, either as the raw materials or as finished products. With the Revolutionary War, however, it became more difficult to import drugs, and the American pharmacist was stimulated to acquire the scientific and technologic expertise of his European contemporary. From this period until the Civil War, pharmaceutical manufacture was in its infancy in this country. A few of the pharmaceutical firms established during the early 1800s are still in operation. In 1821, the Philadelphia College of Pharmacy was established as the nation's first school of pharmacy. In 1820, the *United States Pharmacopeia* (USP) was created to aid in establishing standards for drugs in the United States.

DRUG STANDARDS

As the scientific basis for drugs and drug products developed, so did the need for uniform standards to ensure quality. This need led to the development and publication of monographs and reference books containing such standards to be used by those involved in the production of drugs and pharmaceutical products. Organized sets of monographs or books of these standards are called pharmacopeias or formularies.

The United States Pharmacopeia and the National Formulary

The term pharmacopeia comes from the Greek *pharmakon*, meaning drug, and *poiein*, meaning make, and the combination indicates any recipe or formula or other standards required to make or prepare a drug. The term was first used in 1580 in connection with a local book of drug standards in Bergamo, Italy. From that time on, countless city, state, and national pharmacopeias were published by various European pharmaceutical societies. As time passed, the value of a uniform set of national drug standards became apparent. In Great Britain, for example, three city pharmacopeias—the London, the Edinburgh, and the Dublin—were official until 1864, when they were replaced by the *British Pharmacopoeia* (BP).

In the United States, drug standards were first provided on a national basis in 1820, when the first USP was published. However, the need for drug standards was recognized in this country long before the first USP was published. For convenience and because of their familiarity with them, colonial physicians and apothecaries used the pharmacopeias and other references of their various homelands. The first American pharmacopeia was the so-called *Lititz Pharmacopeia*, published in 1778 at Lititz, Pennsylvania, for use by the Military Hospital of the United States Army. It was a 32-page booklet containing information on 84 internal and 16 external drugs and preparations.

During the last decade of the 18th century, several attempts were made by various