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Secundum Artem

Current & Practical Compounding Information for the Pharmacist.

A HISTORY OF PHARMACEUTICAL COMPOUNDING

GOALS AND OBJECTIVES

Goal: To provide information on the history of pharmaceutical compounding and to present the development of compounding and quality standards for the profession.

Objectives: After reading and studying the article, the reader will be able to:

1. Discuss the sources of early medications used in civilization.
2. Describe the development of the apothecary practice.
3. List the various types of dosage forms prepared by the apothecary during selected time periods in history.
4. Explain the development of the U.S. Pharmacopeia and the current activities of the USP as related to pharmaceutical compounding.

INTRODUCTION

Kings, quacks, philosophers, priests, poisoners, dreamers, seers and scientific chemists have all helped to shape the fabric of pharmacy. Throughout history, pharmacy has been associated with magic, theology, alchemy, crimes, frauds, strange fancies, dogmas, delusions and the strictest science.

The art of selecting, extracting, preparing, and compounding medicines from vegetable, animal and mineral substances, i.e. pharmacy, is as ancient as man on the earth. Pharmacy's history parallels that of the history of civilization. As civilization began and grew, pharmacy was there in one form or another. Pharmacy became necessary as man desired to use whatever nature made available for protection from pain, disease, injury and death. Until the 20th century, pharmacy was all compounding; originally involving the use of water, leaves, etc. later, compounding included the extraction of substances from plants and animals, the preparation of minerals and then finally the blending of these different extracts from plants, animals, minerals and other materials together.

Much of the progress in ancient times resulted from observation and passing the information to others from generation to generation. Early practitioners and herbalists from among the primitive peoples would accumulate facts and experience and take advantage of their skills thus resulting in an easier life with less hard manual labor than their neighbors. This was supplemented with some mystery and the attempt to keep the practice within their own families. The "mystery" of the practice was promoted to minimize "outside" participants in the practice.

Before the days of priestcraft, the wise man or woman of the tribe whose knowledge of the healing qualities of plants had been gathered through experience or handed down by word of mouth was called upon to attend to the sick or wounded and prepare remedies. It was in the preparation of the medicinal materials that the art of the apothecary originated.

The art of the apothecary has always been associated with the mysterious, and its practitioners were believed to have connection with the world of spirits and thus performed as intermediaries between the seen and the unseen. The tribal apothecary was one to be feared, respected, trusted, sometimes mistrusted, worshiped, and revered, for it was through his potions that spiritual contact was made and upon which the cures or failures depended. Throughout history, the knowledge of drugs and their application to disease has always meant power.

The apothecary is listed in the Bible as one of the earliest trades or professions. As one reads through the Bible, it is evident that people experienced pain, disease, and suffering while using medicines of various types for healing and worship:

"And thou shalt make it an oil of holy ointment, an ointment compound after the art of the apothecary: it shall be an holy anointing oil." Exodus 30:25 [emphasis added]

There are many references to pharmacy in the Bible, including the following reference to the use of botanical specimens as medicine.

"And by the river upon the bank thereof, on this side and on that side, shall grow all trees for meat, whose leaf shall not fade, neither shall the fruit thereof be consumed: it shall bring

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forth new fruit according to his months, because their waters they issued out of the sanctuary: and the fruit thereof shall be for meat, and the leaf thereof for medicine." Ezekiel 47:12

In many cases, the medicines used were prepared either as topical ointments or products such as wines and plant extracts that were taken internally. The apothecary was noted for the mixing of perfumes, ointments, and some medicines, while the physician was noted for taking care of the sick. In some cases, the same individual performed both functions. The heritage of the compounding pharmacist is well documented throughout history as one involved in preparing products used for treatment of disease and for cosmetic purposes.

2000 BC

The Chinese Emperor Shen Nung investigated the medicinal value of hundreds of herbs, barks and roots. The following is a sample formula obtained from Sumerian documents:

"Pulverize the seed of the carpenter plant, the gum resin of the markasi plant, and thyme; dissolve it in beer; let the man drink."

Dosage forms prepared in this time period included medicated wines, draughts, mixtures, ointments, embrocations, cataplasms, enemas, poultices, plasters, lotions, infusions, decoctions and fumigations. Soon thereafter the herbal experts began to prepare their remedies in the form of infusions, decoctions, ointments, etc to make them more palatable or easier to apply.

1552 BC (CIRCA)

The Papyrus Ebers was a single roll of yellow-brown papyrus about 12 inches wide and more than 22 yards long. It was wrapped in mummy cloths and packed in a metal case. The text is in black ink with the section headings, and weights and measures written in red ink. The Papyrus Ebers is a collection of about 800 prescriptions, mentioning 700 drugs. Two categories of personnel were involved; the gatherers and the preparers of drugs. In addition, there were the "chiefs of fabrication" or chief pharmacists. It was common for compounding to be done in large rooms.

Compounded medications during this time period included gargles, snuffs, inhalations, suppositories, fumigations, enemas, poultices, decoctions, infusions, pills, troches, lotions, ointments and plasters. Beer, milk, wine and honey were popular vehicles for drugs while honey and wax were used as binding agents. Also mentioned in the Papyrus Ebers are such botanic substances as acacia, castor bean (from which we express castor oil), and fennel along with apparent references to such minerals as iron oxide, sodium carbonate, sodium chloride, and sulfur. The following are sample prescriptions.

Rx Formula for the Stomach
Rx Formula for a Purge
Rx Formula for a Headache Remedy

It is interesting to note that 4 days was the common course of treatment and many formulas also contained 4 ingredients.

Also in the Papyrus, there are many formulas to draw blood from a wound, prevent immoderate crying of a child, to prevent the hair from turning gray, to make the hair grow, to rid the body of worms, to treat diabetes, applications for sore eyes, diarrhea, and a plaster to remove pains.

Common equipment described includes mortars, hand mills, sieves and balances.

600 BC (CIRCA)

Pythagoras' chief formula contribution was the invention of Acetum Scillae (vinegar of squill). Also, his Antidotum Pythagoras was popular.

460-370 BC

Hippocrates mentioned the preparation of fomentations, poultices, gargles, pessaries, pills, ointments, oils, cerates, collyria, lohochs, troches and inhalations. Drugs used included narcotics (juice of the poppy, henbane seeds and mandragora), the use of purgatives, sudorifics, emetics and enemas. The use of purgatives, emetics and enemas resulted from the Hippocratic theory that the first requirement of medical treatment is the purification of the body from illness-producing humors that are present in the body in excess.

100 AD

Dioscorides, a pharmacist-botanist, discusses the Egyptian origin of 80 vegetable drugs in his De materia medica libri quinque, which consists of five books. Book I contains aromatics, oils, ointments, trees; Book II lists living creatures, milk and dairy products, cereals and sharp herbs; Book III describes roots, juices, herbs; Book IV herbs and roots; and Book V vines and wines and metallic ores. He discussed purifying woolfat, making extracts by maceration followed by evaporation, expressing the juice from plants and concentrating it. He also knew the differences between medicinally used gums, such as acacia, tragacanth and others. He also described various storage containers, including the following narrative: "Vessels of brass will be suitable for eye-medicines and for liquids and for all that are compounded of vinegar or of liquid pitch or of Cedria, but fats and marrows ought to be put up in vessels of tin."

130-200 AD

Claudius Galen, a Greek pharmacist-physician who attained Roman citizenship, aimed to create a perfect system of physiology, pathology, and treatment. He formulated doctrines that were followed for 1500 years. Galen was one of the most prolific authors of his or any other era, having been credited with 500 treatises on medicine and some 250 others on subjects of philosophy, law, and grammar. His medical writings include descriptions of numerous drugs of natural origin with a profusion of drug formulas and methods of compounding. He originated so many preparations of vegetable drugs by mixing or melting the individual ingredients that the area of pharmaceutical preparations was once commonly referred to as "Galenic pharmacy"; the products have been known as "Galenicals". Many procedures originated by Galen are still used in today's compounding pharmacies. Perhaps the most famous of his formulas is one for a cold cream, called Galen's Cerate, which has similarities to some in use today.

700's

The arts and duties of the apothecary and the physician were separated by the Arabs in Baghdad late in the eighth century when the first privately owned drug stores were established. Common during this time was the compounding of syrups, confections, conserves, distilled waters and alcoholic liquids.

1240

In Europe, pharmacy remained a function of medicine until the increasing variety of drugs and the growing complexity of compounding demanded specialists who could devote full attention to the art. In Europe, pharmacy was separated from medicine after exposure to the Arabian influence. This occurred when German Emperor Frederick II regulated the practice of pharmacy within that part of his kingdom called the Two Sicilies. His edict separating the two professions acknowledged that pharmacy required special knowledge, skill, initiative, and responsibility if adequate care to the medical needs of the people was to be guaranteed. Pharmacists were obligated by oath to prepare reliable drugs of uniform quality according to their art. Any exploitation of the patient through business relations between the pharmacist and the physician was strictly forbidden. It was during this time period that public pharmacies began to appear in Europe.

1498

The first pharmacopeia, the Nuovo Receptario, originally written in Italian, was published in 1498 and became the legal standard for Florence, Italy. It was given official status and was to be followed by all apothecaries.

1540

Perhaps no person in history exercised such a revolutionary influence on pharmacy and medicine as did Aureolus Philippus Theophrastus Bombastus von Hohenheim, a Swiss physician and chemist who called himself Paracelsus. He influenced the transformation of pharmacy from a profession based primarily on botanic science to one based on chemical science. Some of his chemical observations were astounding for his time and for their anticipation of later discoveries. He believed it was possible to prepare a specific medicinal agent to combat each specific disease and introduced a host of chemical substances to internal therapy. He was instrumental in preparing many alcoholic tinctures and extracts, essences and quintessences.

1617

In London, the apothecaries were grouped with the Grocers Guild in this time period. Due to their uniqueness, the apothecaries were separated from the Grocers Guild in 1617 by a charter granted by Francis Bacon, Attorney General, later Lord Chancellor of England. This was done under protest by the Grocers Guild who enjoyed the apothecaries as subordinate partners. This newly formed group was known as the "Master, Wardens and Society of the Art and Mystery of the Apothecaries of the City of London", which was the first organization of pharmacists in the Anglo-Saxon world. The Grocers Guild ultimately received a subsidy payment from the apothecaries to relieve their financial loss resulting from the apothecaries' secession from the Guild. Later in 1665, the apothecaries strengthened their position as medical practitioners in the public's eye by remaining at their posts during the Great Plague in London during which most of the physicians fled from the city.

17th Century in the U.S.

For the most part, the roles of the apothecary and the physician were co-mingled. Many native herbs were used because of their long-time use by the Native Americans.

In 1602, the first cargo of New England's exports consisting of the bark and the pith of the sassafras tree was loaded for England. Also, Sir Walter Raleigh returned from the vicinity of Cape Fear loaded with timber, sassafras, china root, benjamin, sarsaparilla, cassia lignea and a "strong bark". In the colonies, the exportation of sassafras, Virginia snake root and ginseng was of considerable economic significance.

In 1640, John Winthrop, first governor of Massachusetts, made available imported drugs and those derived from plants native to New England according to the "art and mystery" of the apothecary, for his citizens. He compounded using ingredients such as saltpeter, preparations of antimony and mercury, tartar, copperas, white vitriol, sulfur and iron, red coral, powdered ivory, rosin, some vegetable drugs and several Galenics. Winthrop was one of the first to do actual pharmaceutical compounding in the U.S.

1662

During Sir Walter Raleigh's imprisonment in the Tower during the early part of the reign of James I, he was allowed a room fitted up with a laboratory where, among other things, he developed a formula for his Great Cordial, which the Queen Anne of Denmark was convinced had saved her life. The actual composition of the Great Cordial is unknown, but the following formula was given in an English Court on September 20, 1662 for Sir Walter Raleigh's Great Cordial.

The cordial consists of forty roots, seeds, herbs, etc., macerated in spirit of wine and distilled. With the distillate were combined bezoar stones, pearls, coral, deer's horn, amber, musk, antimony, various earths, sugar and much besides.

1711

Dr. Daniel Turner, a surgeon, developed a cerate named after him and interesting comments are recorded related to his product, as follows in part:

"As I have had ample experience of this cerate, I may be allow'd, I hope, to judge of its singular properties and good effects in all cutaneous ulcerations and excoriations either from scalding, burning, or fretting of the said parts by means of salt, acrid, or sharp humours; upon which accounts, not straining a tittle beyond its deserved euology, I am bold to affirm it will do more in all these superficial hurts of the body than either.....and do wish that the Apothecaries would keep it made up in their shops, to deliver, at a suitable price, to indigent or poor people, instead of their ridiculous Locatellus's Balsam, and other improper medicines which they call for ignorantly to heal their skin-deep maladies...."

1729

Christopher Marshall, an Irish immigrant, established his community apothecary shop in Philadelphia which later was managed by his granddaughter Elizabeth, America's first woman pharmacist. Later, his son and others established one of the first large scale drug manufacturing companies in the U.S.

1752

America's first hospital pharmacy was established in Philadephia; the first hospital pharmacist was Jonathan Roberts. Many pharmacists of this era not only compounded but actually "manufactured" drugs.

18th Century in the U.S.

Although many of the drugs indigenous to America and first used by the Native Americans were adopted by the settlers, the vast majority of drugs needed in this country before the 19th century were imported from Europe, either as raw material or as finished pharmaceutical products. With the Revolutionary War, however, it became more difficult to import drugs, and the American pharmacist was motivated to acquire the scientific and technologic expertise of his European contemporary. From this period until the Civil War, pharmaceutical manufacturing was in its infancy in this country. A few of the pharmaceutical firms established during the early 1800s were the forerunners of some of the large pharmaceutical companies of today.

18th Century in Europe

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 that were of the highest standards possible at that time regarding purity, uniformity, and efficacy. The extraction and isolation of active constituents from crude (unprocessed) botanic drugs led to the development of dosage forms of uniform strength containing singly effective therapeutic agents of natural origin. Much of their research work and manufacturing was done in the backrooms of their pharmacies.

Many pharmacists of the period began to manufacture quality pharmaceutical products on a small but steadily increasing scale to meet the growing drug needs of their communities.

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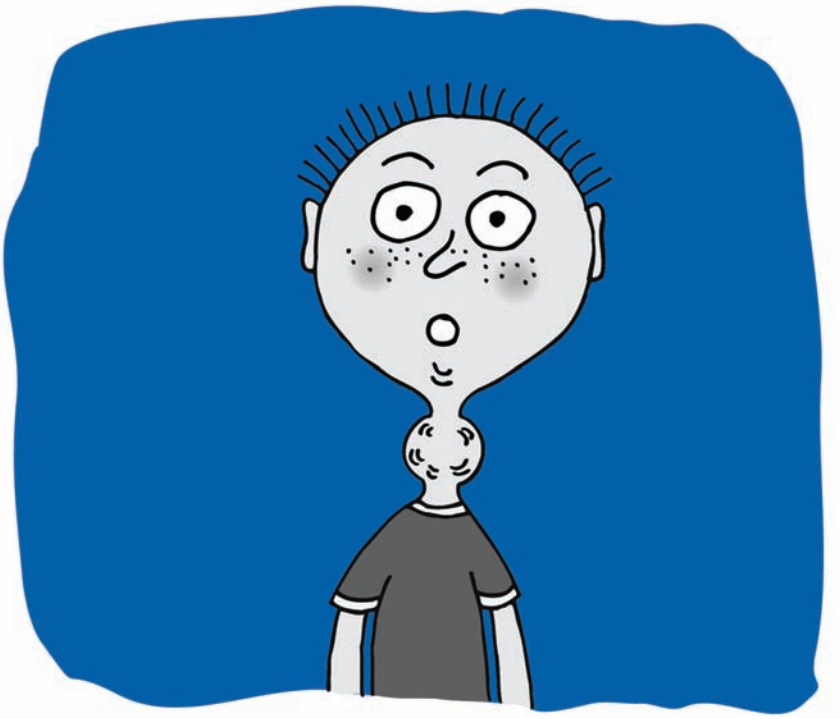

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1815

Seidlitz is a small town in northern Bohemia close to where the Seidlitz spring was found in 1724. The spring reportedly contained "sulphate of magnesia and some sulphate of soda". At one time magnesium sulfate was obtained commercially from this spring. There have been many theories on the actual development of Seidlitz Powders but a patent was issued in 1815 for "the combination of a neutral salt or powder which possesses all the properties of the medicinal spring in Germany under the name of Seidlitz powders."

19th Century

To promote standardization of formulas and medical ingredients, the U.S. Pharmacopeia was established in 1820. Later, in 1888, the National Formulary of Unofficial Drugs was first published. A sample formula in early National Formulas included Acetum Aromaticaum.

Also during the 18th and 19th centuries, the Native Americans had developed an extensive list of medications that varied somewhat from tribe to tribe. The information concerning their use was passed from generation to generation and included many herbal preparations. Drugs used by the Native Americans included black cohosh, bloodroot, cascara sagrada, ginseng, jimson weed, mandrake, peyote, pleurisy root, poke root, pumpkin, seneca snakeroot, slippery elm, staghorn sumac, tobacco, virignia snakeroot, white pine, wild licorice, wintergreen, witch hazel and yerba santa.

Industrial Revolution

The second half of the 19th century brought great and far-reaching changes. The United States was now under the full impact of the industrial revolution. The steam engine, which used water power to turn mills that powdered crude botanic drugs, was replaced by the gas, diesel or electric motor. New machinery was substituted for the old whenever possible, and often machinery from other industries was adapted to the special needs of pharmaceutical manufacturing. Mixers from the baking industry, centrifugal machines from the laundry industry, and sugarcoating pans from the candy industry were a few examples of the type of improvisations made. Production increased rapidly, but the new industry had to wait for the scientific revolution before it could claim newer and better drugs for mankind. A synergism was needed between science and the advancing technology.

By 1880, the industrial manufacture of chemicals and pharmaceutical products had become well established in this country, and the pharmacist was relying heavily on commercial sources for drug supply. Synthetic organic chemistry began to have its influence on drug therapy. The isolation of some active constituents of plant drugs had led to knowledge of their chemical structure. From this arose methods of synthetically duplicating the same structures, as well as manipulating molecular structure to produce organic chemicals yet undiscovered in nature. This new source of drugs-synthetic organic chemistry-welcomed the turn into the 20th century.

Moving into the 20th century, the majority of drugs were still compounded but the industrial revolution that was occurring was removing from pharmacy the age-old function of making drug products. Between the 1920s and the 1960s, “compounding” was swept away as a central function with which pharmacy was closely identified by both patients and pharmacists. In the 1930s, about 75% of prescriptions were compounded, by the 1950s only 26%, by 1962 only 3 to 4 percent, and by 1973 approximately 1% or less. Disappearance of compounded medications along with the impact of the industrial revolution had a great impact on pharmacy practice. Associated with these changes was the influence of third party payers and the necessity to dispense larger numbers of prescriptions in shorter periods of time along with the discovery of effective medications and the mass promotion of trade-named products.

The concept of pharmacist responsibilities for dispensing safe and effective health information and health products began to move during the late 1960s from an auxiliary service to a primary goal.

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 utilized by those involved in the production of drugs and pharmaceutical products.

History of the United States Pharmacopeia (USP) and compounding

After the appearance of the first USP (USP I), published in 1820, the art and science of both pharmacy and medicine changed remarkably. The USP of 1820 reflected the fact that the apothecary of that day was competent at collecting and identifying botanic drugs and preparing from them the mixtures and preparations required by the physician. The individual pharmacist seemed fulfilled as he/she applied his/her total art to the creation of elegant pharmaceutical preparations from crude botanic materials. It was a time that would never be seen again because of the impending upsurge in technologic capabilities and the steady development of the basic sciences, particularly synthetic organic chemistry.

The purpose of the first USP was to set standards for drug products that were prescribed by physicians and prepared (compounded) by pharmacists. The USP was used primarily by pharmacists and provided for standardization of products, mostly from natural sources, that were compounded into prescriptions throughout the 1800s and first half of the 1900s.

In the 1900s, the entry of the pharmaceutical industry resulted in large scale production of pharmaceuticals with greater uniformity and production efficiency. As new drugs were developed and chemical synthesis became a major source of new drug products, there was a shift in the pharmaceutical industry towards synthesis, rather than primarily extraction of drugs from natural sources. The USP began incorporating standards for these newer synthetic drugs rather than just methods of extraction, preparation and standardization of natural products.

As the pharmaceutical industry expanded, the purpose of the U.S. Pharmacopeia changed from that of setting standards for pharmacist-practitioners to that of setting standards for manufactured drug products for use by industry. The compounding formulations slowly gave way to manufacturing formulations and bulk drug substance monographs and the content of the USP became less useful for pharmacists and more useful by industrial personnel.

During the middle part of the 20th century, pharmaceutical compounding became less important as the pharmaceutical industry was providing many different dosage forms for most of the drugs available, including oral solids, oral liquids, parenterals, topicals, suppositories, etc. During this time period, most of the prescriptions that were compounded were topicals/dermatologicals and oral liquids for pediatric administration.

During the 1960s and 1970s, intravenous admixture services were incorporated into hospital pharmacy departments from nursing services so this aspect of compounding was increasing; however, it primarily consisted of manipulating commercially available dosage forms. Also during this time period, the USP and NF, which were used as required textbooks and reference books in many colleges of pharmacy, were removed from the curriculum as their content no longer reflected significant

material that was used in pharmacy practice; even though much of the content continued to set standards of practice for dispensing pharmacy.

In the 1980s and 1990s, the number of compounded prescriptions began increasing, due in part to home healthcare, total parenteral nutrition, hospice care (pain management) and the fact that many pharmaceutical manufacturers began decreasing the dosage forms offered for drug products on the market (Since 1975, over 6,000 products have been discontinued and removed from the marketplace by manufacturers). Also, as new drug products are introduced on the market, only limited dosage forms are introduced, primarily oral solids and/or injectables. This has resulted in a great increase in the number of prescriptions requiring compounding, especially pediatric oral liquids. In addition, many physicians are prescribing therapeutic agents or alternate dosage forms that are not commercially available and which must be compounded. Also, because some individuals may have sensitivities to an excipient in a commercial product, these preparations must be individually compounded.

Also during this time period, a number of new startup companies began providing bulk drug substances in small quantities for purchase by compounding pharmacies. Prior to this, small quantities of many drugs were not reasonably available and individual pharmacies would not purchase large quantities of an individual bulk drug substance. Examples of contemporary compounded prescriptions of the 1990s and early 2000s are as follows:

Rx Topical Fentanyl in a Pluronic Lecithin Organogel
Rx Fentanyl, bupivacaine and Baclofen Intrathecal Injection
Rx Adult Peripheral Parenteral Nutrition Solution

USP Contemporary Role

The USP became involved in pharmacy compounding again as a result of resolutions passed at the United States Pharmacopeia conventions in the 1980s and 1990s. Especially in the 1990s and during the 2000-2002 time period, the compounding efforts of the USP in the area of pharmaceutical compounding has been significant. One difficulty, is that the information in the form of monographs, chapters and formulations, is published in the USP/NF; however, most pharmacists are not really aware of its importance and utility.

With all the political, professional and scientific activities related to pharmaceutical compounding in the past five years, it is evident that the USP/NF will probably play a major role in setting the standards for the practice; this is supported by the following.

When the Food and Drug Administration Modernization Act of 1997 (FDAMA97) was enacted, it specifically referred to the General Chapter on Pharmacy Compounding <795> and the standards described. The FDA determined that sterile products compounding was in this category of "Difficult to Compound Drugs" and was going to require that they be compounded using the USP General Chapter (formerly <1206> and now <797> as the standard. In addition, other chapters have been prepared specifically as a result of the compounding initiative, as well as specific compounding monographs for preparations.

Pharmacists are the only health professionals formally trained in the art and science of compounding medications. Consequently, they are expected to possess the knowledge and skills necessary to compound extemporaneous preparations. In 1995, the percentage of compounded prescriptions was estimated to be approximately 11% of all prescriptions dispensed, a five- to tenfold increase in the percentage of such prescriptions dispensed in the 1970s and 1980s. It is evident that the need for individualized drug therapy for patients has been realized, resulting in patient-specific prescriptions and the compounding of medications that are not commercially available. This number includes compounding done in all practice sites in pharmacy.

Compounding Today

Prescription compounding is a rapidly growing component of pharmacy practice. This change can be attributed to a number of factors, including individualized patient therapy, lack of commercially available products, home health care, intravenous admixture programs, total parenteral nutrition programs, and problem solving for the physician and patient to enhance compliance with a specific therapeutic regimen. Pharmacists are creative and have the ability to formulate patient-specific preparations that enhance pharmaceutical care.

Pharmacy is united in the sense that pharmacists have a responsibility to serve their patients and to compound an appropriately prescribed product in the course of their professional practice. It is the responsibility of pharmacists to compound quality medications to meet the specific needs of patients. Pharmacists are therefore ultimately responsible for the integrity of the finished product prepared by them or by those under their immediate supervision.

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