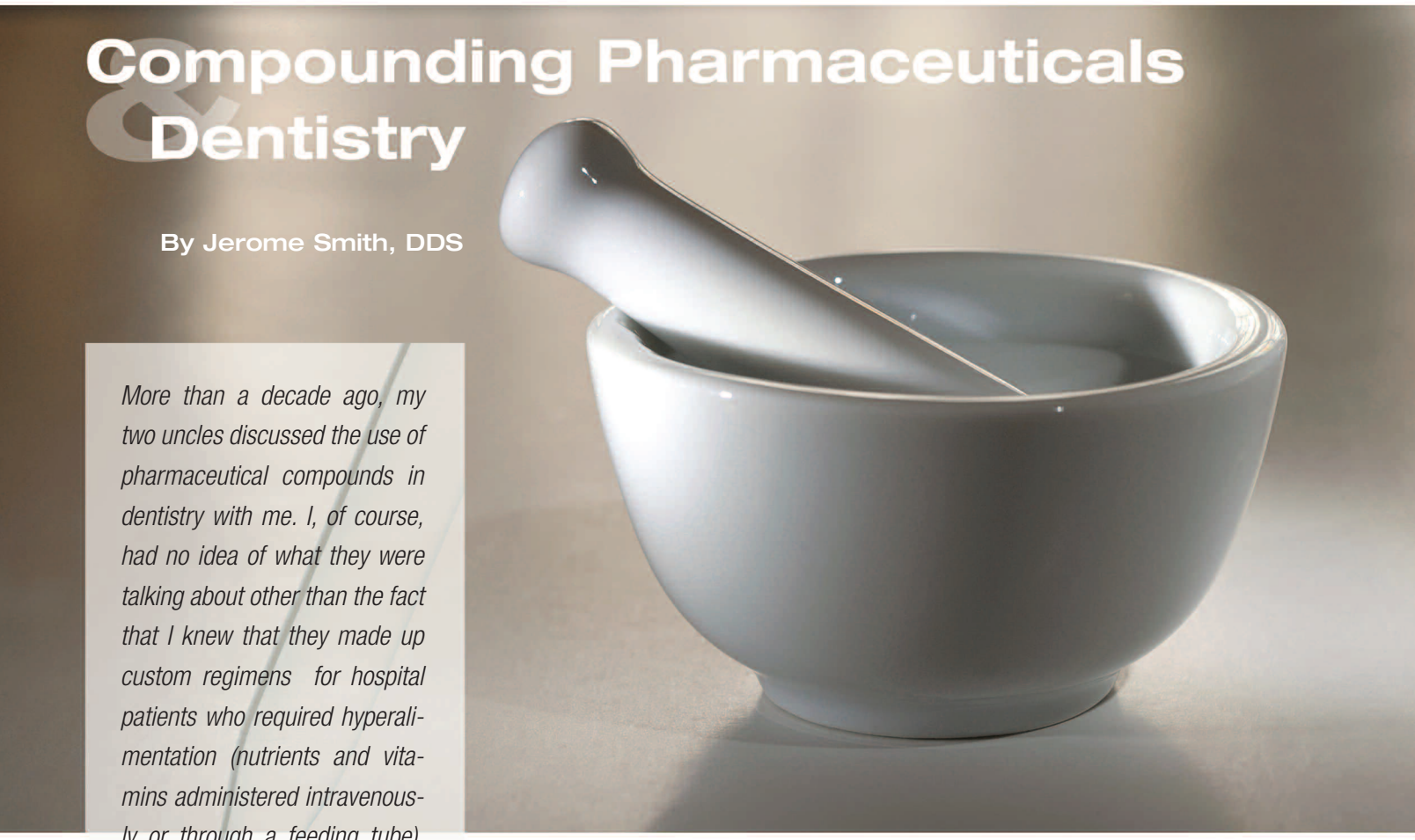
# Compounding Pharmaceuticals & Dentistry

By Jerome Smith, DDS



*More than a decade ago, my two uncles discussed the use of pharmaceutical compounds in dentistry with me. I, of course, had no idea of what they were talking about other than the fact that I knew that they made up custom regimens for hospital patients who required hyperalimentation (nutrients and vitamins administered intravenously or through a feeding tube). They had also invented an ingenious device known the "rectal rocket" for treatment of hemorrhoids for which they'd become somewhat famous in their circle of American compounding pharmacists.*

## The Community Pharmacy History

Custom compounding is nothing new in the pharmacy world. In fact before the advent of the multi-billion dollar drug companies, pharmacists were compounders by definition. It has been estimated that a "broad knowledge of compounding" was still essential for 80 percent of the prescriptions dispensed in the 1920s. Although pharmacists increasingly relied on chemicals purchased from the manufacturer to make up prescriptions, there still remained much to be done secundum artem.

The 19th century did not see the end of the art of compounding, but the art did give way, however grudgingly, to new technology. They spread their own plasters, prepared pills (of aloes and myrrh or quinine and opium, for example), prepared powders of all kinds, and made up confections, conserves, medicated waters and perfumes. They put up tinctures (of laudanum, paregoric, and colchicum) in five gallon demijohns. And they frequently combined several medicines into single dosages, which today would normally be written and dispensed as separate prescriptions. Furthermore, they were often called upon to provide first aid and medicines for such common ailments as burns, frostbite, colic, flesh wounds, poisoning, constipation and diarrhea. In addition to maintaining a prescription laboratory, pharmacists usually carried the disliked but necessary patent and proprietary remedies along with herbs and locally popular nostrums of their own compounding.

## The Declining Art of the Apothecary

Industrialization had an impact on every aspect of the activity of the pharmacist. First, it led to the creation of new drugs; drugs that the individual pharmacist's own resources could not produce. Second, many drugs that the individual pharma-

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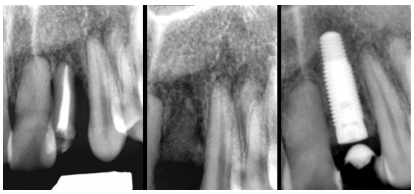
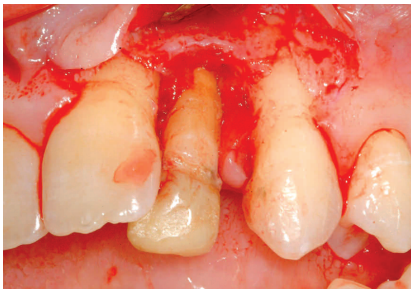


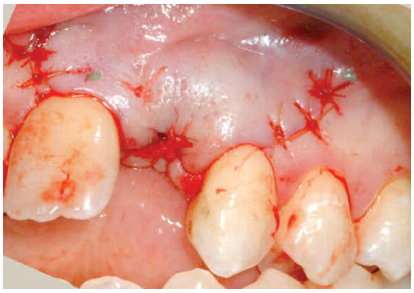
*1. Pre-operative x-ray. 2. Post-op x-ray showing extraction site grafted. 3. Implant placed several months later.*

*Pre-operative photograph.*



*Full flap elevation for full exposure of the defect as well as removal of the tooth.*

*Defect to be grafted.*



*After grafting and suturing.*

cist was able to produce could be manufactured more economically, and in superior quality, by industry. Third, the industry assumed responsibility traditionally vested in the pharmacist for the quality of the medication. The plethora of proprietary medicines, widely and often blatantly advertised, deprived the pharmacist of a market for private specialties; it forced the pharmacist to become a vendor of questionable merchandise; and it opened the way to much broader competition from merchants, grocers and pitchmen than the pharmacist had previously encountered.[4]

## Modern Compounding Pharmacists

Custom compounding pharmacies are on the rise. Physicians, veterinarians, dentists, medical institutions and patients are realizing, more than ever, the importance of tailoring an individual's medications to specifically meet his or her needs. A majority of the pharmacists who are going back to compounding are doing so for the love of the science and interest in the patients well-being. Being able to be in the role of a problem solver opens the doors to creativity and genius that the medical industry has been eagerly adopting for the last decade.[3]

Compounding allows pharmacists the opportunity to use new technology to mix ingredients that are accepted as safe and effective. Compounded products are generally tailor-made to fit the needs of the individual. They are for patients who fall through the cracks of traditional medications and need special help. About two percent of all prescriptions written in the United States are compounded prescriptions. *The International Journal of Pharmaceutical Compounding Vol. 7 No. 5 September/ October 2003* states, "Overall, compounded preparations are generally agreed to be a useful element in the therapeutic armamentarium of the practitioner. This is particularly true in an era of discontinuations and shortages of manufactured drugs, and it has also become increasingly important as a means of tailoring the dose of a drug to an individual patient. Together, federal and state officials, the USP, practitioners, consumers, and many others can create an environment whereby patients can receive well compounded preparations that contribute to their health and well-being."[2]

## My Experiences with Compounded Pharmaceuticals

My uncles first informed me about the use of chlorohexidine gluconate in Europe and its effectiveness in the prevention of bacterial plaque accumulation. Subsequently, we began using this compounded rinse for our periodontal patients long before "Peridex" became a dental household name. This intrigued me quite a bit. Later they introduced me to Betamethasone Rinse (0.025%) for treatment of muccositis associated with everything from oral surgery post-op pain management to a vital agent for patients undergoing chemotherapy and/or head and neck radiation. Negatan (polysulfonic acid) for topical treatment of recurrent apthous stomatitis was another effective remedy that seemed far superior to anything I'd ever run across in my early years of practice. To this day we keep an inventory of vials of Negatan in the office for patients with this common affliction. Later on, they were able to compound TAC alternative gel as a pre-injection topical anesthetic, which has become a standard in thousands of dental offices throughout the United States and beyond. Tricaine Blue is another similar and familiar topical anesthetic which has also become very popular on the Dentaltown discussion boards.

In addition, the use of topical Ketoflex Gel for temporomandibular disorder (TMD) management greatly reduced the need for non-steroidal anti-inflammatory drugs (NSAIDs) and narcotics in treatment and management for patients with this condition. Most recently, a compound known as Fusion was developed by Boudreaux's Compounding Pharmacy as a "bone binder" for use in socket grafting, periodontal grafting, etc., to simplify these procedures as well as to yield a "bone putty" when this binder is used in combination with the dentist's particulate graft of

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*Final photographs taken with a provisional crown in place ready for the final crown impression.*

choice. In other words, Fusion can be used with particulate freeze-dried bone (mineralized or demineralized), autogenous bone, bovine bone, and other resorbable and non-resorbable products that are on the market today. It is compounded with Gentamycin (antibiotic) and other unique mixing fashions that allows for complete asepsis. This product "stays put" when placed and eliminates the former problems associated with grafting materials "leaking out" of a grafted area often as a result of post-op bleeding.

## Some frequently asked questions about compounding:

**Why don't dental companies manufacture and market these helpful items?**

A lot of the products have been out so long that they are unable to be patented. Some are natural and cannot be patented. For the most part, compounding allows us to help the physician immediately.

**How are these compounds treated by the FDA? Are there any risks to the dentist if the patient has a negative reaction?**

The FDA has stated that compounded prescriptions are ethical and legal as long as they are prescribed by a licensed practitioner for a patient and are compounded by a licensed pharmacist. Compounding is accepted and used in the medical community everyday. It has precedent as standard of care for many years. The Federal Food, Drug and Cosmetic Act (FDCA) recognizes the USP-NF as the official "compendia" of the United States.[1]

The Food, Drug and Cosmetic Act of 1932 protects pharmacies and pharmacists and allows them to compound medication for physicians' requests.

Please refer to the following article for more information.

http://www.usp.org/pdf/EN/healthcareInfo/applicationPharmacy.pdf

**Where can we find a good compounding pharmacy?**

The International Academy of Compounding Pharmacists (IACP) maintains a referral service on its Web site: www.iacprx.org. It can also be reached by telephone at 800-927-4227.

**Are these pharmacies regulated in some way?**

Compounding pharmacies are regulated by State Boards of Pharmacy. They are required to follow United States Pharmacopeia Guidelines (USP) chapters 795 for compounding and 797 for sterile compounding. These are federal guidelines adopted and enforced by state boards of pharmacy.

**Compounded pharmaceuticals that we use in our practice include:**

**TAC alternative gel topical anesthetic** for pre-injection as well as before using the diode laser for tissue troughing, tissue removal, gingivoplasty and implant exposures.

**Cotton Mouth Lollipop** for treatment of xerostomia

**Miracle mouthwash** for alleviation of symptoms associated with muccositis (e.g. radiation burns and thrush)

**Antifungal lollipops** for treatment of thrush

**Various dry socket preparations**

- **Amitriptyline and Clonazepam trouches** for "burning mouth syndrome"
- **Fusion** as a bone binder for creation of a bone putty for intraoral bone grafting. ■

*References*

*1. Code of Federal Regulations, Title 21 U.S.C. § 321 (j).*

*2. International Journal of Pharmaceutical Compounding Vol. 7 No. 5 September/October 2003*

*3. Pharmacy an Illustrated History, David L. Cowen and William H. Helfand, published by Harry N Abrams, Inc., New York. – ISBN 0-8109-1498*

*4. Application of USP-NF Standards to Pharmacy Compounding, Gail Bormel, RPh, JD; Joseph G. Valentino, JD; and Roger L. Williams, MD, United States Pharmacopeial Convention, Inc., Rockville, Maryland*

### Author's Bio

**Jerome Smith, DDS,** a graduate of the University of Louisiana at Lafayette and the Louisiana State University School of Dentistry, has been practicing dentistry in Lafayette since 1980. His practice is devoted to dental implants. In addition to practicing general dentistry, Dr. Smith has worked with numerous dentists and specialists throughout Louisiana, and has lectured on the subject of dental implantology throughout the United States.