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BESPOKE 'SCRIPTS

Compounding pharmacies are growing as a way to treat patients more individually

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BESPOKE 'SCRIPTS

Compounding pharmacies are growing as a way to treat patients more individually. Here's what you should know to work more effectively with them. By Lisa Schofield

Although it may seem “new” and “cutting-edge,” almost all prescriptions were compounded until mass drug manufacturing became the norm in the mid-20th century. The role of a pharmacist used to be one of a “mixologist” of ingredients, but has morphed more into dispensing any of a large number of drugs shipped in and prescribed by physicians.

According to the International Compounding Pharmacy Association (PCCA), compounding is making a strong comeback, thanks to “modern technology and innovative techniques and research.” More compounding pharmacies are cropping up, providing your patients and clients with a customized approach that considers strengths, flavors, dosage forms, and exclusion of certain ingredients that promote allergic reactions and sensitivities.

Michelle Violi, PharmD of the Women's International Pharmacy in Wisconsin and Arizona, observed that pharmacy com-

pounding has been an integral part of pharmacy and patient care since the beginning of medicine. “Before drug manufacturers were able to churn out countless identical tablets in one batch, each medication was compounded for a specific patient's needs by a pharmacist.”

She added that through time, increasing sophistication in compounding technology and research requires more education and skills to compound effectively; concurrently, many schools are “paring back their compounding curricula. However, compounding remains an important part of the health care system for patients and practitioners who prefer a tailored approach to medication use.”

And more physicians (both allopathic and naturopathic) are starting to add compounding into their practices. In his practice, Jacob Teitelbaum, MD, best-selling author and developer of the iPhone app “Cures A to Z,” asserted that he finds compounding pharmacies to be “invaluable” for patients who need bioidentical

hormones. Plus, they also typically provide excellent quality and very reasonable pricing structures. For example, he said, a month of bioidentical testosterone cream costs approximately \$30 from a compound pharmacy, versus upwards more than \$800 at a standard pharmacy.

Another example Dr. Teitelbaum likes is compounded topical pain creams that allow for seven different medications to be combined, reaching the same tissue levels in the affected area after two weeks of use as with oral medications, but with no side effects as blood levels are negligible. And for chronic sinusitis, an antifungal, antibacterial, and several other components can be combined in a sinusitis nasal spray. “These highly effective combinations are simply not available without compounding pharmacies,” he commented.

Evolution

Compounding pharmacies have expanded their ability to care for patients because of two main reasons, according to Omar

Allibhai, PharmD, RPh, FACA, compounding pharmacy fellow for Johnson Compounding & Wellness in Massachusetts. The first is the technological advances allowing for compounding pharmacies to supply medications more readily to patients. The second is the increased need for practitioners to provide a more holistic approach for their patients instead of using the one size fits all approach.

However, there have been a few hitches during the past 10 years. For example, Dr. Viola pointed out, in 2012, the New England Compounding Center (NECC) shipped more than 17,000 vials of contaminated injectable medications to health care facilities in 23 states. As a result, 64 people died and many more became ill. This was caused by a company licensed as a compounding pharmacy, but operating as a manufacturer, and prior to this incident, compounding pharmacies were regulated solely by their state boards of pharmacy.

The fallout, so to speak, was that additional Federal regulations—The Drug Quality and Security Act (DQSA)—became law on November 27, 2013, “Due to the actions of a few, the compounding industry is now faced with additional regulations, standards and guidance making it harder for pharmacists to incorporate compounding into their practice and meet the needs of patients for whom one-size-fits-all medications are not appropriate,” she commented.

Vera Parker, PharmD, nutrition and supplement specialist, Massachusetts-based Hopkinton Drug Inc. has also seen an increase in regulations. A decade ago, compound pharmacists could compound (create) and sell their own formulas over the counter to customers and patients. Now, customers who want those same formulas must have their doctors ask us directly how to prescribe them. “Our owner/president Dennis describes this as over-regulation, which he says, ‘interferes with patient care,’ she said.

Dr. Allibhai agreed, observing that there have been numerous changes in the health care industry in the last few years resulting in increased regulation on both the prescribing and dispensing side of medicine. These increased regulations have curtailed naturopathic prescribing formula, prescribing and dispensing requirements and have also reduced insurance reimbursement, the latter itself resulting in limited access for patients to obtain the care that they may need. “It is important that patients advocate for their needs, to ensure that these vital therapies can

remain available for them in the future,” he urged.

In Dr. Parker’s similar view, the more restrictive regulations on compounding have definitely hurt compounding pharmacies’ business and created barriers to patient care. “Naturopaths who used to simply refer patients for an OTC (over-the-counter) compound now have to learn how to prescribe compounded medication, and compounding pharmacists need to be careful in how they provide this information to avoid going outside their own scope of practice,” she admonished. For example, compounding pharmacies can’t provide pharmacy-specific prescription forms for naturopaths to sign off on compounded medication.

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—Vera Parker, PharmD, Hopkinton Drug Inc.

As a practitioner, Dr. Teitelbaum stated that the increasing, “and generally counterproductive,” regulatory burdens are certainly hampering these pharmacies, and are also threatening to health and well-being of Americans. For example, he said, regulations that prohibit out-of-state shipping unless the pharmacy registers in all 50 states serve to prevent smaller compounding pharmacies from making specialty items. In addition, illegalizing intravenous colchicine “has resulted in horrific suffering for countless people with low back pain, and who failed back pain surgery,” he said. “This was done because it was labeled incorrectly, resulting in several overdose fatalities.” When an incident like

this occurs from standard medication, use of that medication is not eliminated entirely—manufacturing and use safety guidelines are simply increased.

Despite more restrictive regulations on compounding, it appears that clear understanding of what it is remains somewhat elusive for many physicians and patients alike. Continued educational efforts would likely increase motivation on both sides to try compound pharmacy therapies.

There are a few obstacles that need to be overcome to accelerate education. According to Dr. Allibhai, there is a large deviation in practitioners’ understanding and motivation to turn to compounding versus conventional dietary supplement and/or pharmaceutical modalities. He assigned this disparity to “the practitioners’ needs and their knowledge bases.” For example, some practices can indeed fulfill most of their patients’ needs with conventional modalities and use compounding to complement when deemed most appropriate. But, conversely, he noted, there are those patients who may need non-mainstream therapies.

And there’s another “great divide,” observed by Dr. Parker—that between allopathic physicians and functional medicine practitioners. Most of the former are unaware of what compounding is and how it may benefit their patients. The latter (including naturopaths) are more aware and are more likely to write compound prescriptions.

American consumers (patients) are much more empowered than ever to inform their physicians not only what their ailments are, but what they want and how they want to go about fixing them—many self-educate via the internet and other media outlets. And, they are much more aware and informed about dietary supplements. Therefore, said Dr. Parker, “the biggest factor driving a patient to seek compounded medication is an unmet need; the majority of our compound prescription business comes from patients who have poorly understood chronic conditions that do not respond well to conventional therapy.”

As with dietary supplements, breakthroughs in research occur in compounding, and studies are continual. Dr. Parker related that she looks to placebo-controlled, randomized, double-blind human studies where the subjects have a relevant condition, preferring results of these studies over animal or *in-vitro* studies. Study population size is also important. “I am very skeptical in studies of under 20 patients, and greater than 100 patients is more interesting,” she commented.



BESPOKE 'SCRIPTS

Examples of recent studies that Dr. Allibhai said he finds intriguing include new research showing that high doses of biotin (vitamin B-7) may benefit people with multiple sclerosis.

Another major advancement he pointed to is the use of low-dose Naltrexone; while the FDA (U.S. Food and Drug Administration) has approved Naltrexone for alcohol and opioid dependence, an increase in published studies show benefit of low-dose Naltrexone to help in numerous disorders by facilitating immunomodulation.

As practitioners, you know that each patient/client is unique and presents a distinctive health profile. There are certain questions or approaches you can use to facilitate working with compound phar-

macies to ensure most appropriate and efficacious solutions.


One of the biggest difficulties for new patients coming to a compounding pharmacy is not knowing what to expect, related Dr. Parker. She advised that practitioners who send patients to a compounding pharmacy should become familiar with the pharmacy's usual procedures, including whether they take insurance, and their usual turnaround time for compounded medication.

"Practitioners should find out whether the patient can easily travel to the location of a compounding pharmacy, whether they can afford to pay for a compound, and whether the pharmacy can reach them on the phone," she said. "At our pharmacy, we know certain prescribers who always want us to call their patients first before initiating work on a compound (for instance, to answer the patient's questions and provide pricing information). Communication and sharing of expectations are very important."

Dr. Allibhai emphasized that, just like patients/clients, "compounding pharmacies come in multiple different shapes and sizes." It is important for a practitioner to ask their pharmacy what they do for qual-

ity assurance, do they hold any accreditations, and what they do to ensure that their staff's knowledge base is evolving with the times.

When it comes to working with patients, he advised, find out what their health goals are, if they are they looking to just maintain their reasonably healthy status, or do they want to work towards optimizing their lifestyle. "It is also important to find out from their patients if they have any special considerations when it comes to taking medications. Would it be beneficial for them to receive their medications gluten free, lactose free, preservative and dye free...? All of this information should also be available to the pharmacy, so they can collaborate with the practitioner to maximize the therapy goals."

Overall, these questions and the ability of compounding pharmacies to customize ingestible health solutions will greatly increase likelihood of compliance, and thus, attaining the specific health goals. 

■ Compounding is making a strong comeback, fueled by improving technology and innovative techniques and research.

■ Compounding remains an important part of the health care system for patients and practitioners who prefer a tailored approach to medication use.

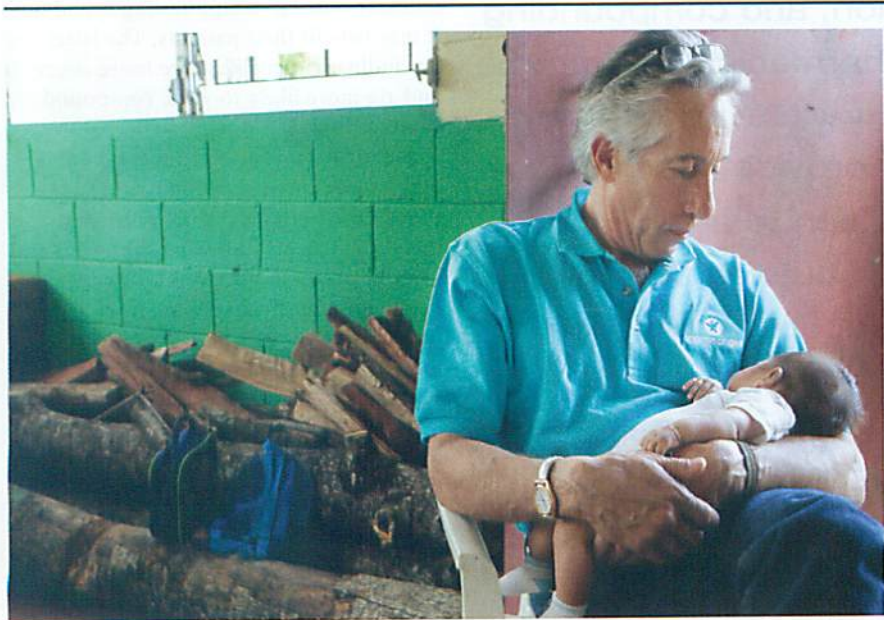
■ A month of bioidentical testosterone cream costs approximately \$30 from a compound pharmacy, versus upwards over \$800 at a standard pharmacy.

■ A decade ago, compound pharmacists could compound (create) and sell their own formulas over the counter to customers and patients. Now, customers who want those same formulas must have their doctors ask us directly how to prescribe them.

■ It is important that patients advocate for their needs, to ensure that these vital therapies can remain available for them in the future.

■ The biggest factor driving a patient to seek compounded medication is an unmet need.

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