



PROFILE

THE MCGUFF COMPANIES

This article represents Part 2 of a two-part series. Part 1 revealed the vision behind the creation of the McGuff companies, presented an overview of corporate growth, and provided an explanation by two key staff members for their commitment to McGuff Compounding Pharmacy Services, Inc. and McGuff Pharmaceuticals, Inc. Part 2 describes the facilities, systems, services, and collaboration of the sister companies and features comments by corporate founder and owner by Ron McGuff about the advantages of coupling pharmaceutical compounding with manufacturing.

Introduction

The unique relationship of the three McGuff companies was designed by owner Ron McGuff to ensure the success of each. McGuff Company, Inc., the first of the corporate triad, opened for business as a wholesale distributor of medical supplies in 1979. Established in 1999, McGuff Compounding Pharmacy Services, Inc. (MCPS), a full-service compounding pharmacy, was designed to specialize in formulating sterile injectables. Ron McGuff's long-term goal, however, was to expand the compounding pharmacy to include a manufacturing facility. That concept became reality in 2002 with the founding of McGuff Pharmaceuticals, Inc. (MPI), which produces sterile injectables for national and international distribution.

Although distribution, compounding, and manufacturing operations are separate entities, MCPS and MPI benefit from shared facilities, quality assurance systems, and, in some cases, staff members cross-trained to provide dual expertise when needed. McGuff Company, Inc. provides administrative oversight as well as centralized financial and human resource services for all three companies.

Perhaps just as unique as the cooperation among the McGuff triad is the core philosophy and overriding goals to which the companies are dedicated: (1) improving the patient's quality of life, (2) providing a complete range of medical and pharmaceutical supplies for physi-

cian customers, and (3) promoting staff education and advancement. Ron McGuff's management style encourages discussion and innovation. "I want to get everybody involved," he said. "All employees in each of our three companies should understand what their customers need, and I want to give credit to everyone—from the executive suite to the warehouse—who is involved with supplying those customers. I personally teach all sales and service representatives about our corporate philosophy. The work of every employee is important to our customers and essential to our progress."

That investment in staff education and promotion reaps a host of benefits. Many employees have migrated throughout the organization, within the same company or in a sister company, as their career advances. "Promoting from within generates well-being throughout the organization, understanding among departments, and employment longevity," said McGuff. "We want our people to stay with us as long as possible."

Innovative Services Boost Growth and Profits

The McGuff companies differ from many competitors in being driven by product categories. "We find out what the client needs and we supply it," said McGuff. "We work closely with our physician customers so that we understand their requirements and the problems they're having in their office, problems that we can resolve by working together. As a result, we've developed a number of very unique products, such as software that helps physicians understand and calculate osmolarity in a variety of regimens. We also found that many clinicians were mixing and administering intravenous solutions in their office, a task they often had not performed since medical school 20 or 25 years earlier. We helped them by developing a series of booklets on the basics of intravenous (IV) therapy and the technical aspects of preparing IV solutions. We're constantly asking our



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clients 'How can we help?' That approach has been very successful for us."

Ron McGuff's management style and corporate construct have proven sound and effective for more than two decades. The McGuff companies have exhibited steady growth, which in the last 12 months has approximated 30% for MCPS and 15% for McGuff Company, Inc. MPI has captured the market for its products, and an estimated annual growth rate of 5% to 10% should follow the approval of a recently submitted abbreviated new drug application. In addition, new preparations or products requested by prescribers are constantly under development at MCPS and MPI.

The First of Three: McGuff Company, Inc.

Corporate Profile

The McGuff Company, Inc. is a wholesale distributor of more than 3,500 pharmaceutical and medical

products to national and international clients, including traditional and complementary medical practices, office-based surgery facilities, ambulatory urgent care centers, and pharmacies. Among the products offered are disposable supplies for physician offices and examination rooms, diagnostic instruments, IV solutions and administration sets, oral nutritional supplements, pharmaceuticals (including injectable ascorbic acid and magnesium chloride manufactured by MPI), oral multivitamins and minerals, and software programs for physicians.

The Foundation for Success

Long before he established the first of his three companies, Ron McGuff had defined the values that would later ensure his business success. "Improving the health of individuals, both human and animal, has always been very important to me," he said. "I was



The McGuff Company
delivering low cost, quality
medical supplies
for **26** years





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in the Army before I began my career in business. Near the end of my tour of duty, I decided to enroll in a project that offered transitional jobs as preparation for the return to civilian life. Because I love animals, large and small, I volunteered at the veterinary clinic on the military post. The work that I did there clarified the difference in outcome that good health care provides. When I looked at a suffering patient brought in for treatment, I'd often find myself thinking, 'As bad as you are, this is the worst you will be; we're going to make you better.' Providing that type of intervention was very rewarding. The McGuff companies are based on a similar commitment of service. We want to offer our customers the highest quality supplies, compounded preparations, and pharmaceutical products, which ultimately benefits their patients."

Acute business acumen supports that commitment to quality. In his early career, McGuff worked as a sales representative for Procter & Gamble, Inc., but he always had a strong desire to own and operate his own company. While accompanying his father (a retired pharmaceutical sales representative) to a series of medical treatments, Ron identified a business niche: the need for a better supplier of medical products for physician offices. He developed a pro forma financial plan and decided to go into business. In 1979, he established McGuff Company, Inc., to provide every type of medical office supply that physician clients requested, and he hired his father as his first employee.

As the customer's needs changed, so did the products offered by McGuff Company, Inc., and the venture proved successful. "At first we provided a full range of disposable medical office products," said McGuff, "and we specialized in large- and small-volume parenterals ranging from vaccines to vitamin B12. Over the years, we've increased our number of products to cover the needs of an expanded audience. Our focus for

the future is to add additional product lines so that we can always answer the demands of our clients."

MCPS: The Second Venture

Corporate Profile

MCPS is a full-service compounding pharmacy that offers all types of dosage forms (injectables, ointments, creams, capsules, Pluronic lecithin organogel [PLO] formulations, troches, solutions, suspensions, nasal sprays, and suppositories). The pharmacy specializes in the preparation of sterile injectables. The facilities, some of which are shared with MPI, consist of a core of cleanrooms surrounded by offices, laboratories, and a warehouse. Class 100 cleanroom filling areas are located within Class 10,000 cleanrooms that are enclosed by Class 100,000 cleanroom production areas.

Management, Methods, and Values

Early in the strategic planning of MCPS, a decision was made to achieve International Organization for Standardization (ISO) 9000:2000 certification, a goal that was realized. ISO certification ensures that the pharmacy's design, development, and production meet international quality standards, and independent third-party inspectors evaluate and certify MCPS annually. MCPS is licensed by the State of California to compound sterile injectables and has obtained non-resident pharmacy licenses in all states that require the licensing of pharmacies. Providing the highest quality compounds is the primary focus. Every lot of injectables is tested for foreign matter, endotoxins, container integrity, and sterility before it is released. At the time of this writing, potency testing was conducted via sampling, but soon the potency of all lots will be evaluated as testing protocols are created, reviewed, and approved by the staff of the Quality Sys-



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tems Department.

Perhaps most unusual is the relationship that MCPS has established with the US Food and Drug Administration (FDA). When MPI is inspected, the FDA also inspects the pharmacy facility and reviews its operations and procedures. “We have an open-door, open-book policy with the FDA and all the regulatory agencies that oversee our operation,” said McGuff. “We look forward to working with them because they offer us an objective assessment of what we do. They let us know what needs improvement. As a result, we are continually improving the preparations and services that we provide for our clients.”

Personalized service is also a cornerstone of MCPS operations. “We don’t advertise the fact that we can prepare formulation A or formulation B; that’s not what we’re about,” said McGuff. “Instead, it’s our goal to supply each physician client and his or her patients with exactly what they need when they need it.” To tabulate the degree of customer satisfaction, MCPS conducts an annual client survey, the results of which are communicated to staff members and customers via the company newsletter. The information from that survey serves as a barometer of business success and is essential in enabling MCPS to adapt to the customers’ ever-changing demands.

A Closer Look at Sterile Compounding

At MCPS, injectables are compounded inside cleanrooms with separate air-handling systems that exhaust outside the facility to eliminate airborne crossover contamination. Sterile filling takes place in certified Class 100 areas within the cleanroom core. Solutions are filtered through appropriate 0.2- μ m filters immediately before aseptic filling by certified pharmacy technicians. To displace the air in the vial headspace, a layer of sterile nitrogen gas is infused into the sterile vials, which

are then closed by a sterile stopper before they are transported through a pass-through to be crimped. Preparations that can withstand terminal sterilization are processed through a temperature-mapped and validated autoclave. After aseptic filling, sample vials are tested for leaks in an evacuated chamber.

Each sterile preparation is inspected for foreign matter and overall package integrity by qualified technicians, after which a final label is affixed. The vials are then packaged in boxes. Before advancing from one step to the next, however, a pharmacist reviews the preparation and the compounding record to verify that each process has been completed correctly.

Ultimately, the preparation and compounding record are examined by an independent pharmacist who reviews the entire process before releasing the lot to the Quality Systems Department. There, personnel who are also independent of the pharmacy place the lot under lock and key in quarantine while they independently review the preparation and its compounding records. The lot remains quarantined until completion of testing for endotoxins, sterility, and potency. The pharmacist in charge performs a final review of the compounding record of lots that meet specifications and authorizes the release of those preparations. Quality Systems personnel then release the physical product from quarantine, update all information technology systems, and remove retained samples of all sterile preparations. To expand the range of potency testing, MCPS has recently invested in a complete chemistry laboratory that provides high-pressure liquid chromatography, total organic carbon analysis, and other relevant analytical methods.

Although the preparation of sterile injectables is an MCPS specialty, the development of novel compounds is also a priority. “The number of new preparations that we offer is increasing as a result of



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prescriber demand,” said Larry Woodhouse, PharmD, Director of Product and Business Development at the McGuff companies, “and we’re now providing compounds for clinicians in a growing number of medical specialties.”

The Third Venture: MPI Expands Services and Increases Profits

Corporate Profile

Since it opened for business in 2002, MPI has demonstrated steady growth in the manufacture of small-volume parenterals. Licensed by the State of California and registered and inspected by the FDA, MPI is certified to meet ISO 9001:2000 standards for quality systems management. Ascor L 500 (Ascorbic Acid Injection USP), which is prepared from corn-sourced raw materials; Ascor L NC, an alternative ascorbic acid injection extracted from beet or cassava; and magnesium chloride injection are the products currently manufactured, and new product development is also under way.

Compounding and Manufacturing Yield Multiple Benefits

The expansion from compounding pharmacy to pharmaceutical manufacturing was a key feature of Ron McGuff’s original business plan. “I love the technical aspects of both compounding and manufacturing,” he said. “We chose to develop sterile compounding, which is the most heavily regulated aspect of compounding pharmacy, into the type of manufacturing that we wanted to provide. I’ve always been interested in offering unique products on a scale larger than that afforded by traditional compounding pharmacies.” The opportunity to expand compounding into manufacturing developed in 1998. Steris Laboratories, Inc., which supplied McGuff Company with several drugs, was closed by the FDA. “Steris was manufacturing several unique injectables that could not be obtained elsewhere,” said McGuff, “and when an FDA injunction closed that company quickly, we suddenly lost our source for those medications.

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The enactment of the 1997 Food and Drug Administration Modernization Act, in which section 503A clarifies the compounding regulatory environment, plus the loss of several very important drugs from the marketplace, led us into compounding pharmacy—and the additional goal of manufacturing.”

Investigational New Drug Studies

Compounding and manufacturing have proven useful in investigational new drug (IND) studies, and both MCPS and MPI have been selected to participate in several clinical trials. “Our IND work is very exciting for us because it moves medicine forward,” said Ron McGuff. “We are now involved in the development of a number of innovative medicines and the clinical studies that validate them. Most of our current IND studies are confidential because of trade relationships, but some can be discussed. For example, we’re currently participating with several clinics in a multi-center trial of a drug that enables high-risk pregnancies to be carried to term. In addition, MCPS is involved in an ongoing study conducted by the University of California, Los Angeles, in which the effect of intravenous magnesium administered to stroke patients during ambulance transport to the hospital is being evaluated.”

The study type and the product distribution dictate which McGuff company will participate in an IND trial. “If we ship a preparation to a single location under the supervision of one researcher, MCPS would be involved,” said Larry Woodhouse. “If we ship a product to multiple locations, however, we’d use MPI.”

Corporate Cooperation

Ensures Success

“The benefits of having a compounding pharmacy co-located with a pharmaceutical manufacturing company cannot be overstated,” said Ron McGuff. “The key to running a successful pharmacy is to control all aspects of the envi-

ronment in which the pharmacy operates. Early in our planning, we decided that ISO certification would be the backbone of that control. Having the manufacturing company with its separate review of quality control on site allows MCPS to operate within that same type of carefully monitored environment. The expertise from manufacturing improves the pharmacy, and the expertise of the pharmacists improves manufacturing.”

Larry Woodhouse agrees. “The McGuff companies have a symbiotic relationship in which we all benefit from each other, both managerially and in providing our clients with the preparations and products they require,” he said. “Over more than two decades, the McGuff Company built a reputation of excellence and had an established book of business. When Ron chose to build a compounding pharmacy and a manufacturing facility, we had access to those clients, and we knew their needs. We were able to leverage each new company on the base established by the preceding venture. That’s of great benefit to us, and it enables us to provide a continual supply of medications and products for our clients.”

“The growth of MPI will ensure the future of its sister companies, because manufacturing presents opportunities for growth that compounding does not,” concluded McGuff. “In all three companies, however, our mission is the same. By understanding what we do best, we can focus on our customers, and by tracking and measuring quality, we can ensure the integrity of our products, preparations, and services.”

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