



**Jane Vail**  
**St. Louis, Missouri**

*In this first of a two-part series, the vision behind the creation of the McGuff companies is explored, an overview of corporate growth is provided, and two key staff members explain the reasons for their commitment to McGuff Compounding Pharmacy Services, Inc. (MCPS) and McGuff Pharmaceuticals, Inc. (MPI). In Part 2, the facilities, systems, services, and collaboration of the sister companies will be described, and Ron McGuff will comment on the advantages of coupling pharmaceutical compounding with manufacturing.*

Ronald M. McGuff is the founder and owner of a triad of medical and pharmaceutical companies unique in their collaboration and the level and types of service they provide. Twenty-six years ago, the first McGuff venture was established—McGuff Company, Inc., a wholesale distributor of medical supplies ranging from drugs to bandages. A subsidiary of that company, MCPS, opened for business in 1999 as a full-service compounding pharmacy with a specialty in sterile injectables. MCPS is certified to meet International Organization for Standardization (ISO) 9000:2000 standards for quality-systems management. The pharmacy was built in compliance with current good manufacturing practice standards to streamline the later development of a separate manufacturing facility. That concept was realized in 2002 with the establishment of MPI, a pharmaceutical manufacturing company licensed by the State of California, registered and inspected by the US Food and Drug Administration (FDA), and certified to meet ISO 9001:2000 standards for quality-systems management. MPI continues to demonstrate carefully controlled but consistent growth in the production of small-volume sterile injectables.

As sister companies, McGuff Company, MCPS, and MPI benefit from shared facilities, personnel, and quality-assurance systems, although distribution, compounding, and manufacturing functions are completely

# PROFILE

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## THE MCGUFF COMPANIES

separate. The three McGuff companies chronicle a remarkable pattern of growth and expansion fueled by Ron McGuff's personal priorities: astute planning, clinical excellence, quality assurance, customer satisfaction, and the loyalty of a carefully selected staff. William (Bill) Blair, PharmD, MBA, is the Vice President of Pharmacy Operations and the Director of Pharmacy for MCPS. "Since day one," he said, "Ron McGuff has been the driving force behind our success. He has always believed that the greatest assets we can offer to our customers are clinical knowledge and a willingness to help."

### **McGuff Company, Inc.:** **A Successful Venture Evolves**

The concept for the first in the McGuff series of successful business ventures arose from a need clarified by personal circumstance. While accompanying a family member to a number of medical treatments, Ron McGuff, who was then a sales representative for Procter & Gamble, Inc., identified the need for a better source of medical supplies for use in physicians' offices. Seizing that opportunity, he established McGuff Company, Inc., in 1979. Today, that parent company specializes in the wholesale distribution of more than 3,500 pharmaceutical and medical products. Customer bases across the country include (1) solo private-practice medical offices, (2) medical group practices, (3) physicians' office-based surgery centers, (4) complementary medicine practices, (5) freestanding ambulatory (urgent) care centers, and (6) pharmacies. Under the guidance of Alicia M. Johnston, Vice President of Operations, McGuff Company serves as a corporate center and provides centralized services (accounting; information technology; marketing; customer service cross-training and support; bookkeeping; compliance and process



# PROFILE

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## THE MCGUFF COMPANIES

audits; and human resource functions) for all three companies. That coordination eliminates redundancy, improves efficiency, and concentrates the focus of each McGuff company on its area of expertise.

### McGuff Compounding Pharmacy Services: The First Subsidiary

Twenty years after McGuff Company was established, another opportunity for corporate growth was identified. McGuff Company had been obtaining private-label sterile injectables from a contract manufacturing facility that closed temporarily. To provide an alternative source for his clients, Ron McGuff considered forming a partnership with various compounding pharmacies across the US, but none met his standards. He decided instead to build MCPS, his own compound-

ing facility, and he began to search for qualified staff to ensure the venture's success. Bill Blair was the answer to that quest. Blair had served as Pharmacy Director at the University of California, Irvine Medical Center until he retired. He then worked briefly for a health maintenance organization that had closed. The timing for both parties was perfect. "I joined MCPS at its inception," said Blair. "We started looking for a building to lease, and we found one about a mile from McGuff Company. From the very onset of our operation, we wanted to be the best. We built the compounding pharmacy to the highest standards from the ground up, with the goal of obtaining ISO certification. That effort was a tremendous amount of work and expense, but it was worth every minute and every dollar."





# PROFILE

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## THE MCGUFF COMPANIES

Today, MCPS is a full-service compounding pharmacy that counts among its clients physicians, patients, and research institutions conducting investigational new drug clinical trials. An example of efforts made by MCPS to provide solutions to their customers' needs is the development of flexible osmolarity software in response to the many physician queries about the osmolarity and sodium content of intravenous solutions (see Figure 1). Among MCPS specialties are preparing sterile injectables, and all categories of dosage forms (injectables, ointments and creams, capsules, gels, troches, solutions, suspensions, nasal sprays, vaginal creams, suppositories, etc.). The company does not offer compounded veterinary preparations.

### **McGuff Pharmaceuticals, Inc.: Manufacturing Offers New Range of Products and Services**

The combined financial success of McGuff Company and MCPS enabled the funding of a manufacturing venture, and the third McGuff company was established in 2002. A manufacturing facility for sterile injectables, MPI was built in compliance with state, federal, and ISO requirements. At the time of this writing, MPI produces three products for commercial distribution: (1) Ascorbic Acid Injection USP (Ascor L 500) from corn-sourced raw materials; (2) an alternative ascorbic acid injection (Ascor L NC), which is extracted from cassava; and (3) magnesium chloride injection. MPI products are distributed nationally and internationally, and new product development is under way.

Although MCPS and MPI share facilities and staff expertise, functional overlap is never permitted. MCPS compounding processes and prescription dispensing are kept separate from and independent of MPI production processes and products. "Our personnel cross lines," Bill Blair explained, "although manufacturing and pharmacy

operations are kept completely separate." Regulation of the two companies also differs. Although MPI is subject to FDA inspection, MCPS is reviewed by the state board of pharmacy.

MCPS and MPI have always maintained a very positive relationship with the FDA. Early in the planning stages for each of the new companies, management sought and received FDA input and guidance to ensure compliance with federal regulations. "We have always worked closely with FDA staff," said Blair. "Rather than being uncomfortable with their interest, we welcome their ongoing inspections and their efforts to protect the public health. We want to learn from them, and we're always interested in identifying areas that need improvement. We supply the FDA with as much information as we can, and we have carefully documented procedures for doing so."

The McGuff family of companies today is based on a well-integrated management structure led by Ron McGuff, President and CEO. The three Vice Presidents of Operations are Alicia Johnston, McGuff Company, Inc.; Damon P. Jones, MBA, CQE, McGuff Pharmaceuticals, Inc.; and William Blair, PharmD, MBA, McGuff Compounding Pharmacy Services, Inc. Rounding out the management team are Lawrence Woodhouse, PharmD, Director of Product and Business Development; and Doug Tran, PharmD, Manager of Product Development.

Each of these key staff members was attracted by Ron McGuff's vision for his companies, his overall plan, and his emphasis on quality and service. When Damon Jones decided to join the McGuff team he had worked 15 years for Medtronic, Inc., a medical devices company, and had his own successful business as a consultant on regulatory affairs and quality systems. One of his clients was McGuff Company,



# PROFILE

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## THE MCGUFF COMPANIES

Inc. When Ron McGuff offered him a job with an opportunity for professional growth, Jones decided to accept. “Ron had clearly defined his goals. He had an excellent vision of what he wanted his companies to be,” said Jones. “Our approach to key issues matched very well. In the pharmaceutical industry, which is extremely regulated, there are many barriers to entry. Ron had considered those barriers and had developed a plan to expand from medical products distribution into compounding pharmacy and then into pharmaceutical manufacturing. His approach was novel and very logical. Instead of needing millions of dollars of capital up front to start a pharmaceutical manufacturing business, he knew how to leverage his existing business to build a compounding pharmacy from scratch. The plan he developed enabled him to meet the needs of his current customers while his new compounding business was being established. His ultimate goal was to offer his clients the very best in medical equipment, compounded medications, and generic commercially available pharmaceuticals from a licensed manufacturing group.”

Jones currently oversees the operation of MPI, and his primary responsibility involves ensuring that the company’s commercial products meet customers’ needs. “MPI is unique,” he said, “because its affiliation with the compounding pharmacy provides a steady stream of feedback about clients’ rapidly changing demands. Patients and physicians are constantly calling the pharmacy to fill prescriptions, and if there’s a new indication for drug use, an unmet need, or a new theory about an effective treatment, we’ll know about it immediately. That’s a real advantage, because we can respond on target with research, development, and (ultimately) manufacturing to answer those demands.”

Jones is also charged with developing new and generic products in anticipation of future needs. Much of his time is spent planning the production cycles for es-

tablished products and determining the infrastructure needed to further progress. “With success comes growth, and with growth comes greater capacity,” he explained, “and we are evaluating ways of using our existing capabilities to increase the capacity of MPI. In our 3 years of operation, we have tripled the size of our physical facility. At this point, our short-term goals involve expanding our commercial offerings, and our vision for long-term growth is to continue the expansion of our compounding and manufacturing businesses and to participate more in new-drug development.”

The plan for directing the continuing growth of the McGuff Companies is in place, but what, we asked Damon Jones, will ensure its success? “The answer,” he said, “is an incredibly bright and dedicated staff of individuals who are very motivated to contribute to their company’s future. We have a great team. That dedication is due in large part to the company philosophy of appreciating each employee’s efforts. In every area from the warehouse to the corporate suites, our staff members are given the opportunity to succeed, and they are rewarded for their success,” he said. “We try to promote a very interactive working environment. Everyone who works for us is provided with broad exposure to many different areas of pharmacy and pharmaceutical manufacturing. Our employees welcome that opportunity. They are never bored, and they are always expanding their professional horizons. It’s clear that Ron really cares about his staff, and that commitment is repaid many times over in performance excellence.”

What does the future hold for the triad of McGuff companies? Objectives for McGuff Company, Inc., include expanding existing lines of quality medical and pharmaceutical products to meet customer’ ever-changing needs. Long and short-term



# PROFILE

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## THE MCGUFF COMPANIES

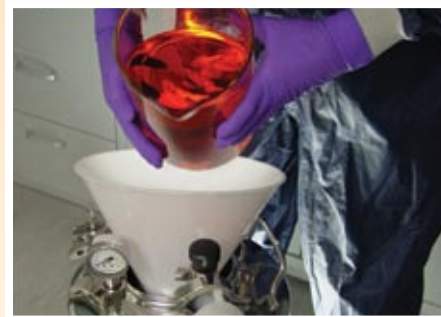
goals for MCPS involve (1) providing quality preparation and excellent customer service, (2) employing the most qualified personnel and providing for their well-being, (3) working with individual physicians and their affiliated institutions to improve patient outcomes, and (4) developing and maintaining an excellent reputation with all regulatory agencies so that competent, conservative input can be provided to legislative and regulatory processes.

New options for MPI also abound. “MPI was developed to serve the needs of Mc/guff Company customers, and we’re filling that niche,” said Jones. “As we expand, we’ll open other markets. For example, we are now working with several group purchasing organizations, such as Broadlane (San Francisco, California). We’ve just inked a 3-year agreement to include our products in the catalogue that Broadlane offers to its physician members who benefit from a negotiated best-price-in-volume. We’d like to introduce one or two new products lines per year, and eventually we’ll need a new facility. Our top priorities, however, remain the same – to produce the highest quality products for our customers and to ensure that no item or service offered is ever unavailable.”

The McGuff companies, then, have built a reputation of excellence based on product integrity and responsiveness to clients’ needs. “We are first and foremost devoted to ensuring the quality of our preparations and products and to supporting the best possible patient care,” said Damon Jones. “If we meet those goals, we believe that success will follow. And it has.”



Air pressure is maintained in our production core so that air flows from critical areas to less critical areas.



All compounding (not to be confused with aseptic filling) occurs in special rooms with independent air handling systems to prevent cross contamination.



Aseptic filling room