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FORCE



Oakdell Pharmacy's Jeff Carson, tailor-made to help

By Chris Linville

As a father, Jeff Carson wants to ensure that his children are healthy. As a pharmacist, he has the same goal for his patients. And when his newborn son had an extended stay in a hospital neonatal care unit, Carson's belief in the power of pharmacy compounding was only strengthened.

PHOTOGRAPHY BY: BRYAN SPARKS

"Compounding, and pediatric compounding in particular, is one of the things that really drives me," says Carson, chief of staff of Oakdell Pharmacy Inc., in San Antonio. "And the reason it does is because of my second child and what he went through when he was born. I know from experience the struggles that young parents have with these little babies. And we just don't have medications for them. So they get an enormous amount of medications compounded."

So when Carson talks about the potentially life-saving benefits of compounding, it hits close to home.

"I take it personally because I saw those children," he says. "It's not their fault that they were born either

with those conditions or prematurely. They have no say in what is happening to them."

Fortunately, Carson's son Ryan, now 5, is doing fine, and the same could be said for the pharmacy founded in 1969 by his father John, NCPA president in 2000–2001. The business has four locations in San Antonio, with the largest providing retail items along with nursing home and home infusion pharmacies. Oakdell has 11 pharmacists on staff and more than 50 total employees.

Carson says that compounding accounts for approximately 15 percent of Oakdell's \$15 million in annual sales, but contributes upward of 45 percent of its gross profits.

COMPOUNDING AROUND THE WORLD

By Loyd V. Allen, Jr. PhD, RPh

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Patient-specific medications are prepared by pharmacists around the world according to many different compounding regulations and standards and in many different forms. This issue of the International Journal of Pharmaceutical Compounding features articles from numerous compounding pharmacists in various countries. Because topics were suggested, many of those authors discussed similar subjects. The questions they addressed include:

1. Is compounding permitted in your country?
2. Who regulates compounding in your country?
3. What are some of the difficulties that you have with regulatory agencies in regards to compounding?
4. What are you allowed to compound?
5. What are you not allowed to compound?
6. How would you describe your compounding pharmacy?
7. Which unique equipment do you frequently use in compounding?
8. Can you compound or manufacture large quantities to provide to other pharmacies?
9. How do you assign beyond-use dates or expiration dates to your compounded preparations?
10. What do you think is unique about the way in which compounding is performed in your country?
11. Does compounding require additional special training, or do all pharmacists in your country have the ability to compound?

12. Are you allowed to compound nonprescription medications?
13. What are some of the dosage forms that you prepare?
14. Which nonsterile and sterile dosage forms do you compound?
15. Which therapeutic categories do you compound?
16. What other information would you like to share with compounding pharmacists around the world about compounding in your country?

This fall, the International Society of Pharmaceutical Compounding in Madrid will join with the National Community Pharmacists Association at its Annual Convention in Tampa, Florida, which will include presentations from pharmacists around the world on the topic titled "Compounding Around the World." The language of these presentations will be English. A similar program was held in Brazil last year with great attendance and excellent presentations. It is amazing what can be learned during these sessions; information that can be applied so effectively to other pharmacies is willingly shared. It's also very enlightening and enjoyable to visit with pharmacists from other countries and to learn about the health care and regulatory systems within which they work.

Start your plans now to attend the Compounding Around the World meeting in Tampa this fall; it will be well worth your time.

Loyd V. Allen, Jr., PhD, RPh, is editor-in-chief of the International Journal of Pharmaceutical Compounding.

“That’s an incredible number,” he says. “It demonstrates the difference between dispensing a compound prescription and a traditional prescription.”

Winding Path to Pharmacy

As the son of a successful pharmacy owner, it would seem natural that Carson would take a straight path into the profession. Well, not exactly.

“I tried real hard in college to escape it,” he says with a laugh. Carson tried his hand at architectural engineering, geology, and marine biology (which remains a passion). “I thought I was going to work at Sea World.”

However, the road eventually led him back to pharmacy. So, naturally he must have worked with his father as he went through school, right?

“Actually, not a lick,” Carson says. “I’m the odd-ball. All my classmates were working in pharmacies, but I worked at a pet store, I did professional aquarium design, I did construction and installation in people’s homes. I had a good time doing that. It was a good learning experience and good life experience.”

Eventually pharmacy won out. Carson received his pharmacy degree from the University of Texas in December 1996, and went to work full time with his father. At the time Oakdell was not doing much compounding (less than one prescription per day). Carson says that expanding the pharmacy’s compounding base was an opportunity, and in his opinion, almost an obligation, as not all patients can be treated with standard medications.

“There are some patients that can only be helped through the skills of compounding,” he says. “I quickly realized that in the current environment, outside of compounding, that you can’t always help all of your patients, which was frustrating.”

Carson continues, “When I started getting into compounding I realized that was the vehicle through which you can help those patients that were falling through the cracks. So the more I went into compounding, the more I was able to solve medication-related problems. Not only is it very empowering, but it generated a whole new level of job satisfaction for me.”

Sterile Specialization

Oakdell specializes in several aspects of the compounding arena, including bio-identical hormone



replacement therapy and pain management. Carson says that sterile compounding, which can cover a wide variety of applications, is becoming a larger part of its offerings.

Carson says that sterile compounding has excellent potential, as he sees it as an underappreciated market.

“There are so few people who have the knowledge to not only do basic sterile compounding, but also anything advanced,” he says.

Carson explains that sterile compounding was almost the exclusive domain of hospitals. But in recent years the regulatory environment has changed. That includes US Pharmacopoeia (USP) Chapter 797. Enacted on Jan., 1, 2004, its intent is to set forth the procedural and practical standards for safe compounding of sterile preparations. In recent years, some hospitals have been phasing out sterile compounding, with the private sector picking much of it up.

“Now there’s a network of pharmacies around the country with the skills, facilities, expertise, and technology to do sterile compounding,” Carson says. “Physicians are also recognizing that it is a viable treatment option as well.”

Carson says that military hospitals from around the country have been calling Oakdell, seeking sterile compound medications. Wounded Iraq war veterans are among those treated with Oakdell’s medications, which certainly is a source of pride for Carson.

Oakdell’s longstanding reputation in the local health care community, largely built by his father, was enhanced when it stepped up to fill a void when a local hospital needed a specific medication. A product called 17 Alpha hydroxy-progesterone helps prevent miscarriage for at-risk mothers. It’s a progesterone shot given once a week or once every two weeks, based on the patient’s status.

Unfortunately, Carson says that the manufacturer stopped making the product due to low market share, and needless to say, ob-gyn's in the area were concerned. Carson says that Oakdell, in consultation with the Professional Compounding Centers of America (PCCA), began compounding the medication, which eased anxieties to a certain extent. However, while retail pharmacies such as Oakdell were allowed to make and distribute the product, hospital pharmacies were prohibited from purchasing and providing it. Soon, frustrated practitioners began calling the Texas State Board of Pharmacy to seek help in remedying the situation. The good news for Oakdell and the hospitals is a state law that took effect on Jan. 1 allowing retail pharmacies to provide compounded medications for hospital pharmacies.

"That's been tremendous," Carson says. "Now we have an opportunity to provide sterile products and other things to hospitals that are in need, and ultimately to those patients that are in need. Before, it

was extremely challenging, and frustrating to patients. Now, hospitals will call us and we can deliver to them. It's much better situation."

Maximizing Opportunities

About eight years ago, Carson came across a group of pain physicians. At the time, the physicians were in the initial phase of a patient therapy which entailed using implantable intrathecal pain pumps, which are basically miniature I.V. devices implanted in the buttocks, from which a catheter runs up the spine and inserts into the intrathecal space in the spinal column. The pump is controlled wirelessly by a physician, and drugs are slowly infused directly on the patient's spinal cord, providing more targeted and quicker relief, with fewer side effects compared to other medications such as morphine.

"At the time they approached us because there were only two medications being manufactured for use in

OAKDELL LAUNCHING BHRT STUDY

In what he describes as "the most ambitious thing I've undertaken," Jeff Carson, RPh, and Oakdell Pharmacy in San Antonio are about to embark on a research project focusing on bio-identical hormone replacement therapy (BHRT).

"I'm very excited about this," says Carson. "We're going to do it with real life patients receiving compounded hormones. We're going to try and organize compounding pharmacists from around the country to get involved with the research that we're going to be doing. We have some pretty lofty goals. We want to try and get as close to 50,000 patients as possible. We've got a good plan, good authors in place, good scientists that are going to be working with us, and we look forward to the outcomes."

Carson says the goal is to have as diverse a patient population as possible to get the best results.

"We want to answer some questions," he says. "A lot of us, myself included, feel very strongly about bio-identical hormones, and that they are the best treatment option available out there right now. But there are a lot of answers that we're missing to a lot of questions that are being asked. So instead of just going on gut instinct and opinion, our goal is to get out there and provide some scientific answers."

Carson is hoping to raise \$500,000 in funding for the next two years, which will constitute the bulk of

the study. So far about \$250,000 has been raised. He says the research will be ongoing.

"We'll decide as we go along how long we want to continue it," Carson says. "It will also depend on funding. But we should be able to obtain enough seed money to maintain the project somewhat indefinitely."

Carson is hoping to recruit compounding pharmacists, who in turn would sponsor as many as five patients to be in the study. The pharmacists would help conduct the research and monitor their patients. Carson says the study is going to be too large for only a few people to undertake, "So we want patients from all over the United States, with pharmacists being involved and helping fund the project by sponsoring a couple of patients."

Carson says the project is not limited to a specific number of participants.

"If we recruit 100,000 patients, we can handle that many," he says. "We just have a target of 50,000 patients. It's entry level research, certainly not complex, but it's going to answer some real basic questions, and with numbers and longevity, we should be able to demonstrate some real good data to help answer the questions: is it safe, and how does it compare with other treatments? Regardless of the outcome, we're going to learn something. And when you learn something, it helps you treat patients better."— C.L.

that pump,” Carson says. “They have to be compounded because they haven’t found a way to manufacture it yet. So we began providing a tailored and customized regimen of drugs combined together to be implanted in these pumps. Now we’ve got about 600–700 patients implanted with these pumps at any one time.”

After about five years of working with Oakdell, the physicians said they were planning to construct a new medical complex, and invited them to build a pharmacy within it.

“We certainly saw a good opportunity, and after about three years of planning and construction we opened up.”

The 2,500-square-foot facility, which debuted in March 2007, is a crown jewel for the company, and Carson doesn’t disagree. “We’re rather proud of it,” he says.

In designing the pharmacy, Carson focused on two primary groups: chronic patients and hormone replacement therapy patients.

“We wanted to design a pharmacy to serve them the best way that we could,” he says. “I would say that most patients that come to us that are in pain or have hormone imbalances are not happy people. They don’t feel real good. At least not yet. And things don’t get better when they go into a busy, chaotic pharmacy like a typical chain, and they have to wait an hour and a half, and phones are ringing, and people are standing around. It really adds to the patient’s discomfort.”

Along those lines, Carson says he tells rotating pharmacy students that getting the right medication to the right patient at the right dose is only 50 percent of their job. The other 50 percent is to care for the patient. “Because I think people really underestimate the power of just caring for somebody,” he says.

Carson says he wanted to take away the noise, take away the chaos, and build an environment that was relaxing, almost to the point of being therapeutic. The pharmacy department is barely visible to the patient.

“It’s enclosed and it’s very dimly lit, which from a retail point is kind of backward,” he says. “Everyone says things have to be bright. Ours is different, we wanted it to be very calm and quiet.”

Carson was watching an episode of “Extreme Home Makeover” where an artificial skylight was



installed on a ceiling with artificial sunlamps behind it. He points out that the body needs sunlight to produce vitamin D, which regulates mood. On this episode it was done for a child who couldn’t go outside, and the skylight was put in his bedroom so he would get a daily dose of sunlight.

“I thought that was pretty neat,” Carson says. “We contacted the company that makes them, and to our knowledge and theirs we’re the only pharmacy who has installed one.”

He says the skylight has been a huge hit. “It really changes the atmosphere,” Carson says. “Patients come in and they immediately look up. It changes their demeanor and their mood. It relaxes them. It has photographic quality ceiling tiles that are semi-clear. If you stand there long enough, you’ll get a tan.”

The pharmacy also has a 42-inch plasma TV that is kept tuned to nature- and science-related channels such as National Geographic and Discovery. Not surprisingly, it also has an aquarium.

Carson says the facility’s color tones are based on outdoor nature themes. It has a stained concrete floor and bamboo laminate on the vertical surfaces of all of the retail space. The horizontal surfaces have a rusted metal laminate for what Carson calls a “very earthy kind of feel.”

The pharmacy also has a conference room for seminars for both patients and physicians. As space is somewhat limited, Carson explains that retail items are set on gondolas that sit on castors, which can be rolled down the hallway back into the kitchen, in an area where it all fits.

“That totally clears the retail space out,” he says. “And we can sit about 25 people comfortably in a very relaxed atmosphere.”

Carson points out that new pharmacies typically use a \$1 million sales figure as a benchmark in their first year. “We started from the ground up, and we did \$1.5 million in first 12 months,” he says. “That just totally blew us away. I had thought we could do that, though both my parents and my accountant kind of chuckled. They said, ‘That’s ambitious, but let’s see if we can do half a million or three-quarters.’ And we doubled their expectations.”

Responding to Challenges

As a compounding pharmacist, Carson is used to challenges and potential threats to his profession. He acknowledges that there is “quite a battle raging between some of the larger drug manufacturers and compounding.” Carson is also troubled by what he sees as manufacturer pressure on the Food and Drug Administration, which he thinks results in stances that are anti-compounding, such as the BHRT area.

As for recent activities by the Drug Enforcement Administration regarding wholesalers and limitations on controlled substances, Carson says Oakdell hasn’t been affected yet.

“I hear a lot of rumbling, and I see things coming, and to be honest with you, I’m very bothered by it,” he says. Carson certainly recognizes need for regulation to prevent illegal distribution of controlled substances. “Absolutely, no question about it.”

But he also sees another side.

“If you’ve never had chronic pain before, you can’t appreciate what they are going through. There are real live people that have horrific pain that needs to be treated. And without it, they have no quality of life.”

Carson thinks the suicide rate would be quite high if patients weren’t able to obtain pain medications legitimately.

“Some of the things that I’ve heard in terms of regulation are, frankly, ridiculous. I think the feds have given up trying to regulate illegal distribution of controlled substances, so they are resorting to unfairly penalizing the wholesalers and make them police illegal distribution.”

On the issue of compounding standardization, Carson does acknowledge that the profession would be well served by it.

“We do need it,” he says. “Because if a patient that receives a compound for compounded drug B in Maine travels to Texas and gets a prescription for the same thing, it should be the same thing. And right now, there is no assurance that that would occur. So that’s a little disturbing.”

But Carson also says that standardization should not be forced on compounding pharmacists by organizations such as the FDA. “It needs to be handled by the state boards of pharmacy, and there needs to be an entity like PCAB (Pharmacy Compounding Accreditation Board) that can provide levels of standardization where it’s needed. That is standard of practice.”

Carson says Oakdell has applied for PCAB accreditation. “I think ultimately in the next 10 years, those that are accredited are going to have a lot better time in the marketplace than those that are not.”

Giving a Helping Hand

Carson says he is passionate about the well-being of his patients, especially so for the youngest ones. He says the vast majority of cases that he sees are from financially challenged parents, and the state Medicaid program does not reimburse for compounding. “Most of the times when we transmit the claims, we do it at a loss,” Carson says. “I do it anyway, because you can’t just deny a patient a prescription just because you can’t make money on it or you can’t even break even on it. But I’ll do it because the patient needs it, and I have the ability to provide it.”

He would, of course, like at least a nominal fee to cover his services. But that’s not his motivation. The power of compounding is what drives him.

“You take an oath when you become a pharmacist,” he says. “And part of that oath, loosely interpreted, is to use the skills and knowledge that were given to you to help all patients achieve the best possible health outcomes.” **ap**

Chris Linville is managing editor of *America's Pharmacist*.