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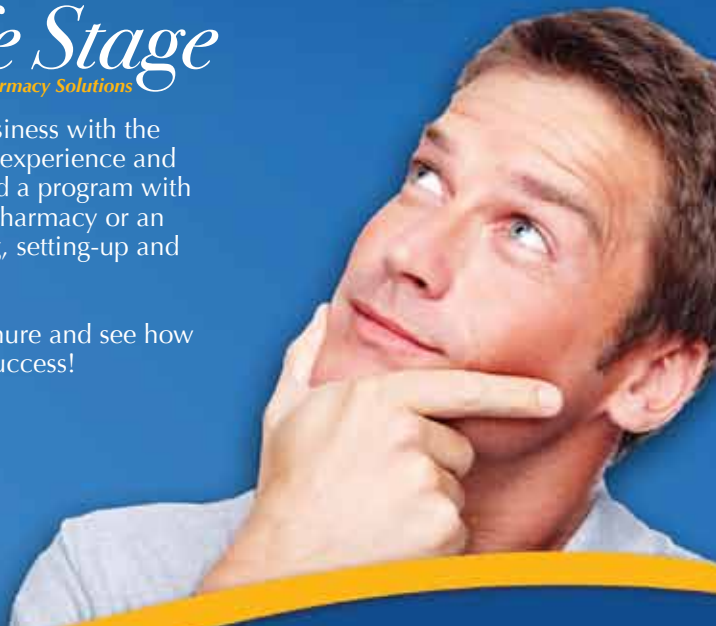

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Features

Departments

Cover: Esmeralda Downs' life changed 15 years ago when she answered Bill and Ann Pearson's ad for a pharmacy technician. In the years since, they have been there every step of the way as Downs overcame the odds to become a pharmacist. (Photo by Jeff Malet.)

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Letters to the Editor—If you would like to comment on an article, email NCPA at **info@ncpanet.org.** Put AP in the subject line and include your phone number. Your letter may be posted on the NCPA website and edited for length and clarity.

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It's *Digest* Time Again

FOR 80 YEARS, STARTING UNDER NARD and now with NCPA, our members have received a valuable annual overview of independent community pharmacy operations, including comprehensive review of financial data. The key trends and statistics come from fax and electronic surveys filled out by hundreds of your colleagues in pharmacies of all sizes in all areas of the country. NCPA compiles and analyzes the confidential information, and the results are double checked for accuracy by the University of Mississippi.

The 2012 *NCPA Digest* is once again sponsored by Cardinal Health. I can't thank Cardinal enough for its continuing generous support of this longtime and useful resource for NCPA members and for all backing and service Cardinal provides community pharmacy throughout the year. Cardinal follows in a rich tradition of partnership between pharmacy and industry begun in 1932 with the *Lilly Digest* and continued over the last two decades variously by Searle, Pharmacia, and Pfizer.

Throughout the years, the *Digest* has remained a reliable summary of selected financial and demographic information that illustrates the value independent community pharmacists provide to their patients by maximizing medication effectiveness. It is still the most comprehensive report on independent community pharmacy available.

The first NCPA members to receive this year's *Digest* are those attending our annual convention this month in San Diego. All members will receive a copy along with their November issue of *America's Pharmacist*. Detailed financial information will be available for members only on the NCPA website.

In today's pharmacy environment, it is more important than ever to take an in-depth look at your pharmacy's financial picture against national pharmacy averages to come up with a real-world strategy for the future. The website will outline an approach to assist you in successfully integrating the key findings of the 2012 *NCPA Digest*, sponsored by Cardinal Health, into an action plan for your pharmacy.

The average independent filled about 63,000 prescriptions, 76 percent of them generics (a 4 percent increase), the *Digest* found. Total sales were about $3.8 million per pharmacy. Medicaid accounted for 17 percent of the average independent's prescriptions, Medicare Part D 32 percent, other third party insurance programs 37 percent, and cash paying patients 12 percent. Independent pharmacists also continued to offer a wide array of patient-centric services and niche products to stay competitive:

- 74 percent provided medication therapy management services.
- 66 percent compounded.
- 65 percent had durable medical equipment sections.
- 50 percent had adherence programs.

Once again the *Digest* underscores that independent community pharmacists continue to provide quality patient care services, promote the appropriate use of generics, and help patients adhere to their medication regimens. aP

Best,

B. Douglas Hoey, Pharmacist, MBA
NCPA Chief Executive Officer

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Consumer Reports Promotes the Value of Independent Pharmacies Again

Best Buy Drugs, a newsletter published by *Consumer Reports*, cites independent pharmacies among its five ways to reduce spending on medicine.

"Negotiate with independent pharmacies," the August newsletter advised. "Although many neighborhood independent pharmacies might not offer or widely advertise a discount generic drug program like their national competitors, store owners might be willing to match the prices of the big chain stores. It's worth asking, especially if you expect to be on a medication for a long time, or even if you just prefer to shop at a neighborhood pharmacy."

The article goes on to mention a recent *Consumer Reports* subscriber survey in which "independent pharmacies scored highest for providing faster service, making fewer errors, and being more likely to have medications ready for pickup when promised. Readers also liked mom-and-pop drugstores for their personal service and the accessibility of pharmacists."

The article also warns of three "savings" on prescription drugs that "might cost you more." You might want to share them with your patients:

- Drug manufacturer coupons—Offers usually only good for a limited time, then prices or copays go back up. Patients on Medicare and Medicaid usually not eligible. (The promotions are effective, though. A 2011 *Consumer Reports* national survey found that 16 percent of Americans who regularly take a prescription medication have used coupons in the last year to save money.)
- Free drug samples—Instead of taking brand name samples, ask the prescriber if there is a generic.
- Brand name "generics"—When a generic version of Pfizer's Lipitor became available last November, said *Consumer Reports*, "Pfizer struck deals with some Medicare Part D plans to offer Lipitor as a tier 1 drug—the least expensive—with a copay similar to those charged for generics. Sounds good until you realize that your plan was charged the entire cost of the drug, not just the copay. Those charges put you closer to Medicare's 'doughnut hole,' which you hit once your prescription drug costs total $2,930 in a calendar year, a risk for people who take multiple medications. Inside the doughnut hole, you'll pay 50 percent of the cost of brand-name drugs and 86 percent of

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TRYING TO DO THE RIGHT THING ISN'T GOOD ENOUGH

"I took over as PIC [pharmacist in charge], noticed some prescriptions filled previously had 'take as directed,' looked up the prescription, conferred with the physician, and corrected the sig[nature] on all future refills to show exact directions. Was audited and had to reimburse 100 percent of all fills for this prescription, not [just] the one with the inaccurate signature, even though the prescriber and the patient both knew the proper dosage…Several thousand dollars had to be reimbursed to the PBM even though the patient received the medication and was using it properly."

THE AUDIT **ADVISOR**

GUIDELINES FOR NEW CHAPTER 9 DRAFT COMPLIANCE PROGRAM

Q: How does durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) Accreditation affect pharmacy requirements for an effective fraud, waste and abuse compliance (FWAC) program?

A: A recent draft proposal for the *Chapter 9 Prescription Drug Benefit Manual—Compliance Program Guidelines* is designed to enhance the operation of both Medicare Advantage and Part D programs. Pharmacies that have met the FWAC certification requirements through enrollment into the Medicare program or accreditation as a DME supplier are deemed to have met training and education requirements for fraud, waste and abuse. However, even if deemed for FWAC training, FDRs (First Tier, Downstream and Related entities **which includes pharmacy**) employees still must have compliance training.

These new proposed rule changes mean that pharmacies with DMEPOS accreditation will not meet all of the Medicare Part D requirement to have an effective FWAC program. This leaves pharmacies vulnerable to sanctions and corrective action plans that can and have included penalties of $12,000 and higher. Don't delay in fulfilling this important Medicare provider requirement.

For any questions concerning compliance training please call PAAS National® at 888-870-7227 or email PAAS at info@paasnational.com.

By Mark Jacobs, RPh, PAAS National, the Pharmacy Audit Assistance Service. For more information call 888-870-7227 toll free or email info@paasnational.com.

INDEPENDENT PHARMACY **TODAY**

- One out of eight prescriptions are paid by cash customers, who depend on community pharmacists to work with them and their prescriber to identify the most cost effective, affordable medication therapy.
- To assist these patients, two-thirds of independents offer charge accounts.

Source: *2012 NCPA Digest, sponsored by Cardinal Health*

the cost of generics until you and Medicare together have spent $6,658. Once you've reached that level, you'll pay 5 percent of your drug costs until the end of the year."

Changes in Medicare Plan Finder Tool Readied for Open Enrollment Season

The Centers for Medicare & Medicaid Services has provided a preview of enhancements to its Medicare Plan Finder tool for the 2013 Medicare Part D open enrollment period, which will occur Oct. 15-Dec. 7 this year. Several changes that pharmacists should be aware of include:

- Added ability to calculate retail and mail order costs—If a mail order component is available, the cost comparisons between mail and retail will now appear on the "plan results" page. It is important to enter all the drugs a patient is taking and to select a pharmacy of choice to get the most accurate estimated costs. Note that for each drug entered, beneficiaries will select whether they get their prescription from a retail pharmacy or mail order (default option is retail).
- Medication therapy management programs will now be highlighted as a plan benefit, and each plan's eligibility requirements (disease states, number of drugs, estimated drug spend) will be included.
- Online enrollment into low performing plans will be sup-

Continued on page 57

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Adding the How to the Who, What, and Why of Adherence

By Carolyn Ha, PharmD

Since NCPA announced its vision for pharmacists advancing medication adherence, the association has been touting the *who*, the *what*, and the *why* of adherence. Community pharmacists are well positioned to have a positive impact on improving health outcomes through proper medication use, while providing a boost to their business (see for yourself, using the NCPA Adherence Calculator (www.ncpanet.org/adherencecalculator). NCPA has also been hard at work to provide pharmacists with the *how* that makes achieving the *what* a reality. Aside from this column, which has provided dozens of tips on ways pharmacists can improve adherence, NCPA launched Simplify My Meds, a turnkey adherence program based on the concept of refill synchronization and a new adherence resource website, www.stick2thescript.org. This month presents additional hands-on opportunities focused on the how. We hope you'll join us for NCPA's 114th Annual Convention and Trade Exposition in San Diego, with unique programming aimed at providing pharmacists with practical solutions to implement adherence services in their pharmacies. The following is a preview of what's in store in San Diego.

We're so jazzed about adherence education, we're getting a head start on the programming before the convention officially kicks off. The NCPA Adherence Institute gets underway on Saturday afternoon. This is an intensive and interactive half-day forum—complete with CE programming and product showcases—that will help you rethink how and why you are (or should be) providing adherence services. Learn from peers about how they are leveraging adherence services to form relationships with local providers and using adherence as a springboard for new revenue opportunities. Experience and test drive some of the new products and technology solutions that are making it easier, more efficient, and more profitable to implement adherence services. Many of these can be added to your workflow with minimal effort and maximum impact on patient care and your business. This convention highlight will leave you reinvigorated about your profession and armed with the tools to implement effective adherence programs in your pharmacy so be sure to arrive early to attend. No advanced registration is required.

They say the customer is always right, and a special session on Sunday will help you determine how best to respond to the adherence needs of your patients. Please join us for lunch on Sunday, for Taking What Patients Need and Making It What They Want: Adherence Solutions for Pharmacy. No matter what type of adherence services you are looking to provide, this session has something for everyone. Learn about a step-by-step course of action to implement and expand adherence services, and address known obstacles with proven solutions. The session will help you identify your best patients to enroll in an adherence program, help you choose which adherence solutions offer the best fit for your patients, discuss ways to modify your workflow for new adherence services, and provide staff training suggestions. You will walk away with marketing tips and ways you can measure the impact of your new services to ensure you are getting your return on investment.

Be sure to check out these programs and visit the NCPA booth for more adherence information. See you in San Diego! aP

Carolyn Ha, PharmD, is NCPA Director, Professional Affairs

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Full Slate of Activities Ahead for NCPA Foundation

By Sharlea Leatherwood, PD

There are plenty of upcoming activities with the NCPA Foundation in upcoming months. The following is a summary of the highlights.

The NCPA Foundation and Arkansas Pharmacists Association are co-sponsoring the Sunrise Breakfast at the 2012 NCPA Annual Convention and Trade Exposition in San Diego. The breakfast, **sponsored by Cardinal Health**, is Tuesday, Oct. 16, from 6:30–8 a.m. It doesn't matter whether you hail from the North, South, East, or West, attendees can expect a hearty meal, entertainment, and lots of jokes to kick off your day. Send an email to ncpaF@ncpanet.org for more details.

NEW LEGACY SOCIETY MEMBER

Individuals who remember the NCPA Foundation through a gift of $10,000 or more or in their estate planning are part of the foundation's Legacy Society. I'm excited to report that Charles and Becky West have joined the distinguished list of members: Ed Berg, Donnie R. Calhoun, David Elm, Holly W. and Mike Henry, Sharlea and Gary Leatherwood, Forrest "Woody" Pack, Nancy Pruitt, Betty Schutte, Andrew Stout. Please visit www.ncpafoundation.org to learn more about the Legacy Society or to make a donation to the foundation.

BONE MARROW DONOR DRIVE

The foundation is continuing its partnership with DKMS Americas in the fight against blood cancers. So far, more than 1,000 individuals have been added to the National Bone Marrow Registry from donor drives conducted at numerous independent pharmacies. This year's drive is Nov. 5–9. We hope you'll participate. To learn more, please email ncpaF@ncpanet.org.

NEW OWNERSHIP AWARD

NCPA was founded in 1898 as the National Association of Retail Druggists. The NCPA Foundation has established the NARD Ownership Award, which recognizes an independent pharmacist who embraces entrepreneurial spirit through promotion and demonstrated excellence in the field of community pharmacy ownership. The award recipient will be announced at the NCPA Annual Convention and Trade Exposition.

AWARDS CEREMONY

During the NCPA Foundation Awards Ceremony at the NCPA Annual Convention and Trade Exposition, scholarship and award recipients, distinguished pharmacy leaders, and corporate partners will be recognized. The ceremony is Sunday, Oct. 14, from 3:30–5 p.m. Please email ncpaF@ncpanet.org if you would like more details.

SCHOLARSHIP PROGRAM

The NCPA Foundation takes great pride in helping up-and-coming new leaders realize their aspirations of pharmacy ownership. The foundation's and Partners in Pharmacy (PIP) scholarship programs help NCPA student members with a demonstrated interest in community pharmacy ownership offset rising tuition costs. This year, the foundation and PIP are awarding over $50,000 in educational aid to high achieving pharmacy students. The **McKesson Foundation** is the newest sponsor of the NCPA Foundation's scholarship program.

Sharlea Leatherwood, PD, is NCPA Foundation president and was NCPA president in 2003–2004.

Scholarship Winners

This year, the NCPA Foundation and Partners in Pharmacy are awarding educational aid to the following high achieving NCPA student members:

Samantha Arrants - *University of Mississippi*
Rima H. Bouajram - *University of Texas, Austin*
Dustin G. Brooks - *Auburn University*
Bobby Clay - *University of Houston*
Elizabeth Crandall -*Ohio Northern University*
Margaret Ann DeLeo - *Massachusetts College of Pharmacy*
Andrew Heinz - *University of Washington*
David H. Jones - *University of Georgia*
Kim Karwoski - *Drake University*
Tahlia L. Aarstad - *University of Washington*
Clarissa Manzi - *University of Colorado*
Bri Morris - *University of Arkansas*
Erik Nelson - *Washington State University*
Mylinh Nguyen - *Washington State University*
Chris Perling - *University of Texas, Austin*
Cortney Phillips - *Ohio Northern University*
Lacy Rudd - Texas *A&M University*
Madeline Shurtleff - *University of Rhode Island*
Lucas Smith - *University of Colorado Health Sciences*
Megan E. Sneller -*Texas Tech University*
Sarah Squires - *Harding University*
Anne Stegeman - *University of Missouri, Kansas City*
Abby R. Switzer - *University of Kansas*
Vivian Tang - *Oregon State University*
Trey L. Tietz - *Wilkes University*
Tadeh Vartanian - *University of Southern California*
Yu Wang - *Roseman University, South Jordan*
Holly Wilkerson - *Harding University*

Scholarship sponsors *(as of 8/2/12)*: Apotex, McKesson Foundation, Rochester Drug Cooperative, Smith Drug Company, and TEVA.

NCPA's 114th Annual Convention and Trade Exposition

San Diego Convention Center

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Leadership Dinner
Second General Session

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National Preceptor of the Year Award

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Novo Nordisk
Lunch Symposium

Oklahoma University COP
Presidents Reception

Oklahoma Pharmacists Association
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PACE Alliance
Reception

Parata Systems
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Prescription Drug Safety Award

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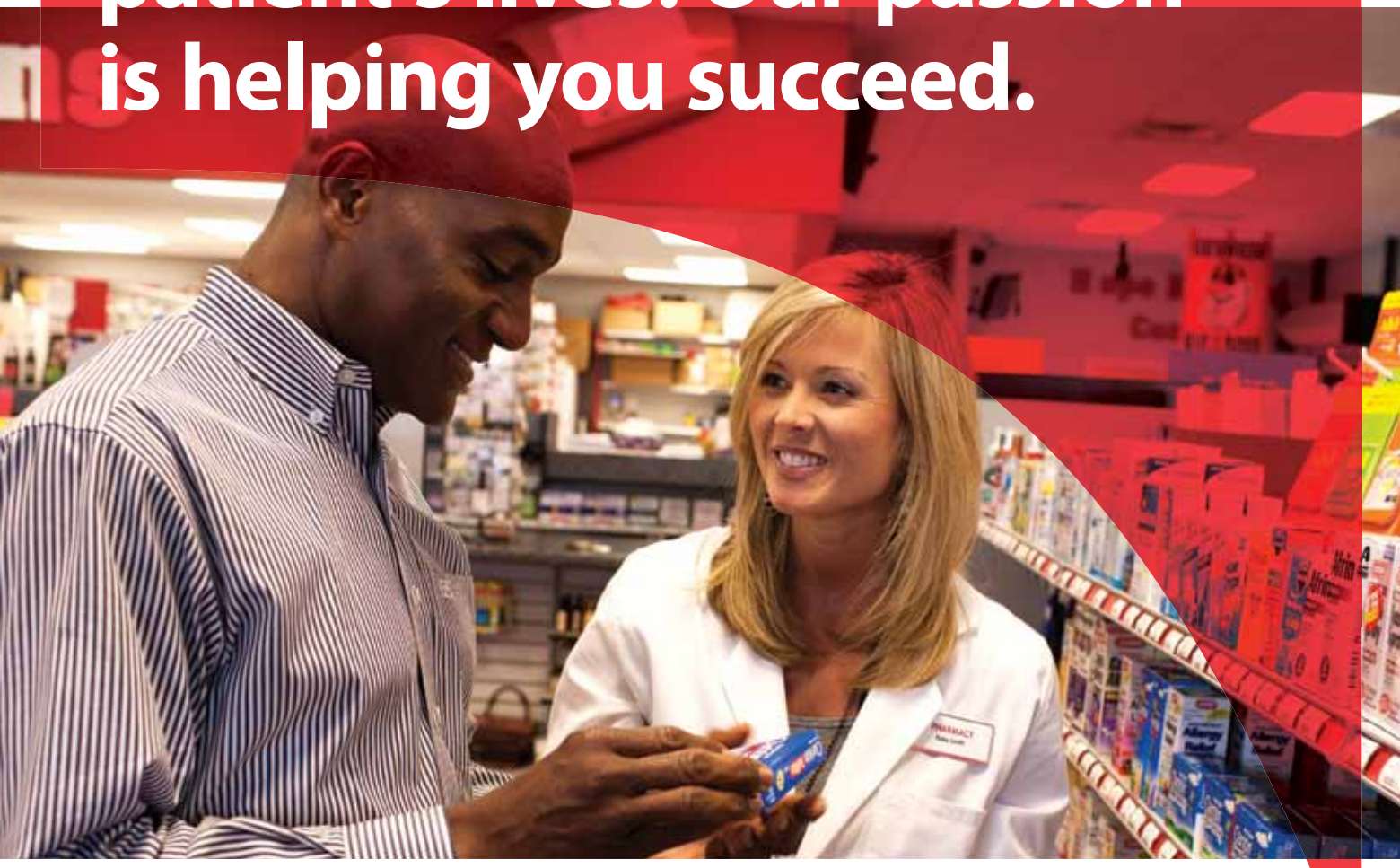

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Bill and Ann Pearson with Esmeralda Downs

Lending a helping hand

Pearson's Pharmacy pays a debt forward for bus driver to pharmacy graduate Esmeralda Downs

By Jeff Malet

Photography by Jeff Malet

Esmeralda Downs' life changed 15 years ago when she answered Bill and Ann Pearson's ad for a pharmacy technician.

In addition to hiring her and paying her a good salary, the Pearsons paid for her education at Western University of Health Sciences in Pomona, Calif., where she earned a PharmD degree from the College of Pharmacy in 2012. They also paid for some community college tuition, a class at Cal State University, San Bernardino, her health insurance, and for a gas card so she could commute to college.

"It's very seldom you find people like these," Downs says. "I've had a hard time with my life, and I could not have done it without them. They just cuddled me, just held me, protected me, and gave me anything I needed."

She calls the Pearsons her guardian angels.

Bill and Ann Pearson met at the University of Southern California School of Pharmacy, and both graduated in 1967. Bill went to work for Redlands Community Hospital, and Ann worked at an independent pharmacy in San Bernardino that they ended up buying and later selling.

In the late 1970s, the Pearsons took over another

small pharmacy in San Bernardino from Ann's uncle. For more than 40 years, the Pearsons have been helping pay for the education of their workers—from a few courses for clerks and delivery driver clear up to the Western University degree for Downs.

Bill said that his father's story of being accepted into Stanford University during the Depression —but his grandfather not paying for him to go because he did not believe in education—motivates him to help people get through college.

"If you have somebody who has the ability, you've got to help them get there," Bill said.

Career Change

Before becoming a pharmacy technician, Downs had been a forklift driver and a bus driver. She needed to change careers after the Foothill Transit bus she was driving in downtown Los Angeles was hit by a big rig and driven into an electrical pole. The company offered

▲ *Downs beat the odds to become an independent pharmacist.*

to pay for a career change, and she decided to earn a pharmacy technician certificate because she was unable to continue working as a bus driver.

Downs, 43, of Yucaipa, Calif., is one of 20 brothers and sisters born in Zacatecas, Mexico. Of those 20 siblings, 13 have survived. Her parents worked in the United States in the 1950s to help support their large family. Her father worked as an agricultural laborer and her mother was a seamstress.

"Although my parents were not formally educated, they taught me good work ethics, to be compassionate of others, and to always be grateful to those that help you along the way," Downs says.

During her early childhood, she lived on a farm in Mexico. She also lived in Southern California, attending elementary school in the United States part of the time.

Downs returned to Mexico after the fifth grade and did hard manual labor on a farm, helping her family financially—with no schooling.

At age 15, her parents agreed to send her and her little sister back to the United States.

"They brought me over and left me with my brothers, and I began working right away," Downs says. "I started paying my own rent. I began attending Bloomington High School in the morning and working from 3 to 11 p.m., working for a food truck catering company."

When she came back to the United States, she was detained a grade because she lacked academic performance, which prevented her from graduating high school. A year later, she went to adult school and earned a GED.

Downs ended up marrying her high school sweetheart, Robert, at age 18 and gave birth to the first of their two children. Soon after, she received her resident visa, and six years later she became the first person in her family to be sworn in as a U.S. citizen.

Pharmacy Path

While working for the Pearson pharmacy, Bill and Ann encouraged Downs to take pre-pharmacy courses at the local community college in hopes that she would consider a career as a pharmacist. Downs consented but said that she only had a GED and wasn't sure how would she qualify. Bill went as far as to make an appointment with a counselor at the local community college. Downs kept the appointment and began taking pre-pharmacy courses while working full time. After a number of years, she completed her pre-pharmacy requirements and was ready to apply to a pharmacy program.

Sam Shimomura, PharmD, associate dean for College Advancement at Western University College of Pharmacy, met Downs in 2006. At the time she was a licensed pharmacy technician, and helped with a project

▲ *Ann Pearson recalled the support she had received as motivation to help with Downs' pharmacy path.*

to create mock prescriptions with M&Ms for one of Shimomura's community workshops.

Shimomura mentored and advised her, and encouraged her to apply to Western, thinking she would gain valuable experience by applying even if she was not admitted the first time around. Down's interview during the admission process went so well, she was offered a job on the spot from one of the interviewers.

After receiving a letter of acceptance from the college, Downs says she was overcome with excitement, but also was nervous and worried about how she would measure up with other classmates who came from high academic programs. She also was concerned about how to manage the cost, family, work, and school.

But the Pearsons were determined to get her through pharmacy school.

"It's like paying a debt forward," Ann says. "People helped me go to school, so I felt I should help other people go. I think she deserves every single penny of it. People like Esmeralda should be rewarded."

Shimomura says that it's rare for someone to be accepted into Western University's Doctor of Pharmacy program without a bachelor of science degree, although having a bachelor's degree is not a requirement for admission. Downs was one of 1,800 people who applied for 120 seats as first-year pharmacy students.

"I didn't think she was going to get in, to be honest with you," he says. "I advised her to show up; learn what you can, and then once you get your [bachelor's] degree, you'll have a good shot at admission. She surprised me and got in without a degree on the strength of her academic performance in undergraduate courses and her interview. I think it's miraculous."

Downs says she had an enjoyable experience at Western because of the caring staff.

"I felt as if I were part of a family, not just a student," she says. "I learned amazing and valuable information, which I will apply throughout my profession."

Down's husband also was supportive throughout the years by helping run the household while she went to school and studied, which she said she greatly appreciates.

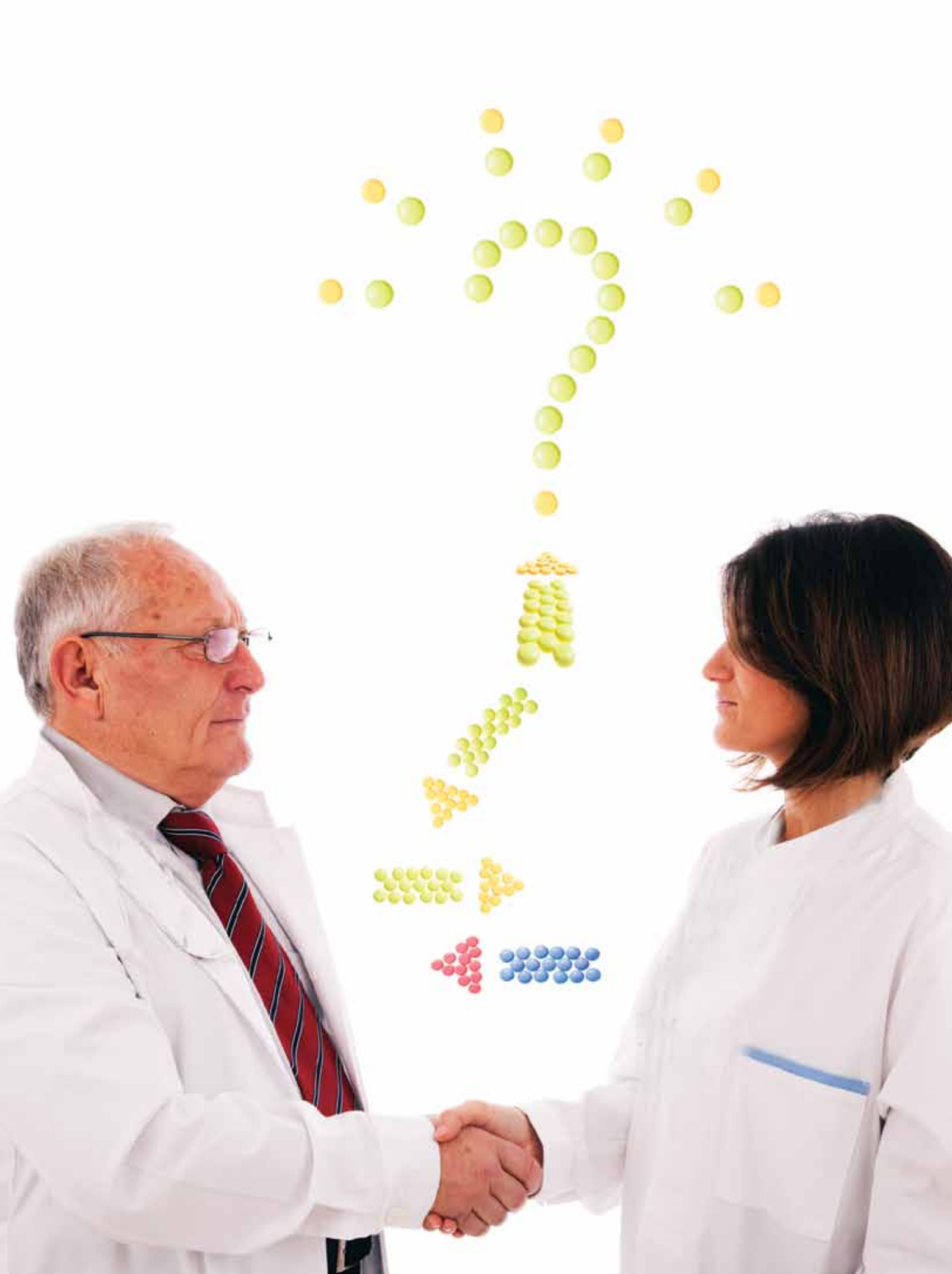
When the Pearsons retire, Downs and a relief pharmacist, Omar Albaiti, would like to buy the pharmacy. For now, there is no specific plan on when or how that might happen, but Esmeralda has worked on a business plan if that opportunity should present itself.

The Pearsons' only worry in selling their pharmacy to people they trust and care for like family, they say, is that the business may not be successful due to the current economic times.

In the beginning, when Ann met and worked with Downs, she had no idea that she would aspire to become a pharmacist.

"But I recognized that here is someone who really had some grit and had a lot of drive. I realized there was a kindred spirit there," Ann says, "I think that she looked at me and thought if I could do it, she could do it too." aP

Jeff Malet is a writer and photographer for the Western University of Health Sciences, Pomona, Calif. This article was originally published in the Summer 2012 edition of *RxBound*. Reprinted with permission.



IT'S WHAT'S INSIDE THAT COUNTS

A case for junior partnerships and how to make them work

By Rick Coakley, CLU, CFBS, CLTC, AEP

Photography by Leonard R. Lowery

THE PROS AND CONS

of succession strategies that pivot around the sale of a pharmacy to a junior partner have long been debated. The side of the argument that wins out always depends on several factors.

- The owner's desire to see their business survive beyond their watch
- The willingness to include another person's needs and goals in succession planning
- The ability of the owner to ultimately let go of the business.

Final Test of Greatness

A quick accounting of strategies chosen by pharmacy owners show that two out of three plans include selling to junior partners. This includes those who have successfully moved beyond life in pharmacy, and those who are actively working towards doing so.

"The final test of greatness in a CEO is **how well he chooses a successor and whether he can step aside and let his successor run the company."**

— Peter Drucker

Though my experience may seem skewed toward junior partnerships, NCPA survey results confirm that the vast majority of owners want to sell to another pharmacist. Generally speaking, deep inside owners want their business to fulfill its critical role long after the sale is complete. Logically, there is a conflict between fulfilling this critical role and merely selling to the highest bidder. If, as Peter Drucker said, the final test of greatness lies in choosing and empowering a successor, junior partnership must certainly be considered.

Decide Now, Maintain Control Later

The first, most critical decision made at the outset of succession planning is simply the decision to do it. While it is an over-used maxim, the simple truth is you can take control of succession or it will take control of you; one way or another, succession will happen. Here again, it is what is inside of you that counts and to succeed, you must acknowledge your life in pharmacy will come to an end.

The second decision is choosing the path you wish to take. Generally speaking, your alternatives are:

- Selling to a big-box or national chain
- Selling to another independent community pharmacist
- Selling to a junior partner (or family member)
- Winding down the business
- Dying on the job and letting someone else pick up the pieces

With the exception of the last "alternative," all the others can be optimized to your advantage by taking control well before they occur. This means making the decision to get out of your pharmacy, choosing a date for your exit, and then working whatever succession plan is most appropriate.

Life After Pharmacy

For each of the anticipated exit alternatives listed, outcomes will be enhanced by including and implementing a plan for your life after pharmacy. This is critical. Putting a plan in place gives you even greater motivation to make your pharmacy as successful as possible. At the same time, because it helps you clarify what is most important in life, it compels you to enjoy greater balance during your life in pharmacy.

Making your pharmacy as successful as possible while enjoying greater balance in life can be a challenging balancing act. It has been my observation that reconciling these opposing sets of demands is made easier when you choose to empower and leverage the intelligence, energy, and enthusiasm found in a junior partner.

Every successful succession plan begins with a clear, powerful vision for your future. This is not a vague, "someday I will…" type of vision. It is a practical, solid vision, containing these elements:

- The legacy your business continues to create after you are gone.
- Your personal growth, goals, and activities
- Your family relationships and how you will spend time with your spouse, children, parents, and grandchildren
- Your contribution to your community

Vision for the future: Imagine you are talking to a very good friend five years after selling your pharmacy. **What accomplishments and experiences that indicate you are living an enjoyable and fulfilling life will you be most excited to tell them about?** Write these down… it's a great beginning

Medicine Cabinet pharmacy owner Dan Bushardt (left) and junior partner Terry Blackmon have established an effective relationship. (See page 27)

• Your spiritual life
• Your overall lifestyle

One of the most important things you have to consider is how you will replace the meaning and purpose your pharmacy fulfills. I have learned that the pharmacists who experience the greatest enjoyment after they retire are those with a strong sense of purpose that has very little to do with the pharmacy.

Financing Life After Pharmacy

While a compelling vision and clear goals for life after pharmacy are critical, they are merely wishful thinking if you do not take care of the money side of the equation. Consider these questions:

• What is the pharmacy actually worth?
• What will it be worth?
• From where will the buyout financing come?
• What kind of taxes will you have to pay?
• Will your assets generate enough income to protect your family's security and lifestyle?

You must also realize that succession planning is not done in isolation, merely considering your business. Consider for a moment how much greater your options would be if you could finance your retirement independent from any revenue generated by the sale of your pharmacy.

A tip for turning your vision and goals into reality is to list your buckets. This means listing the different types of assets you can accumulate during your life in pharmacy. For example, most pharmacy owners identify and fill up five different buckets, including:

1. Pharmacy
2. Real estate
3. Retirement account
4. Investment portfolio
5. Life insurance

Once you have acknowledged that the actual and desired contents of your existing and desired buckets count, look at the role they will play in the achievement of your goals and vision. For example, to maintain or improve lifestyle after your life in pharmacy, you need to quantify the portion of cash flow each bucket will generate.

Empowering Junior Partners

As you can tell, I believe the climb up the ladder to community pharmacy success does not have to end in a swan dive off of the top. Instead, I know you can build a platform at the top that enables you to reach down and give a hand up to the junior partner.

…the **climb up the ladder** to community pharmacy success does not have to end in a swan dive off of the top.

To begin, think of the transition as simply the sale of the business over a protracted period of time. In bringing on a junior partner, you are not hiring a "key holder," you are beginning the process of selling your pharmacy.

The next step is to acknowledge that the buyer has the right to see the real picture of your business before entering into an official agreement. Protect yourself with a non-disclosure agreement. If you are planning three or more years in advance, talk to your accountant about preparing your financial statements for eventual review by a buyer. What's inside your business counts.

Giving someone the straight goods is made much easier when you find someone who possesses the characteristics and capabilities you believe are important for an ideal junior partner.

Certainly what is inside them at the beginning of the relationship counts, but do not lose sight of the fact they have time to augment their skills, knowledge, and capabilities during the transition from junior to senior partner. A person with great values, intelligence, and drive can learn and master what they need if they have a compelling vision for the future and are given the appropriate incentive, means, and time.

Beyond choosing a junior partner with the best possible potential, you must also work with them to address the following:

- What you need
- What they need
- How differing expectations will be reconciled
- Going beyond the handshake (If you cannot create a contract from the outset, chances are you should be walking away.)
- Living with and keeping promises, as accountability cuts both ways
- The junior partner's "career maturity." (For example, if the partner is fresh out of school, you will need to be careful not to overburden that person with responsibility too soon.)
- How they will engage in an ownership mindset far in advance of full ownership (Having the junior partner write and frequently revisit and update a business plan is a practical consideration here.)
- Role reversal. This is a big deal! When the junior partner takes over, what will you, the ex-senior partner, do? How will you act when you no longer call the shots?

Most Common Obstacles

The old saying, "It takes two to tango" applies in any discussion about overcoming obstacles. As a buyer, the junior partner's perspective can be one of fear, doubt, and trepidation if the following questions are not answered:

- Will the pharmacy be able to pay the debt and afford me a good living at the same time?
- What is the business worth at the outset?
- What does it need to be worth at the time of transition?
- Will the pharmacy be bearing the brunt of funding the senior pharmacist's retirement?

For the seller, the inability to let go will be the greatest obstacle. That last two percent that tips the junior partner from 49 to 51 percent ownership is a critical milestone you may never pass if you have not committed to a vision and a workable plan for life after pharmacy.

One Final Thought

I have seen amazing possibilities come to fruition when

A Partnership That's Working

Profile: The Medicine Cabinet of Lake City, S.C.

What follows are the results of a brief interview conducted by Waypoint Strategic Advisors, LLC. Pharmacy owner (senior partner) Dan Bushardt and his junior partner Terry Blackmon are both highly regarded community pharmacists. Each has served a term as the president of the South Carolina Pharmacy Association Board of Directors. They have been partners for more than 20 years.

Dan Bushardt

Q: Why did you choose to go this route?
A: To carry on the legacy of the Medicine Cabinet. Also, when you sell to chains, a lot of times they move the prescriptions and the name doesn't carry on

Q: What sort of relationship do you have with your junior partner?
A: It helps that we are friends, have the same values, and share the same vision for the business. It is the closest thing to being married… which means compromise is very important. We've learned both partners need to be included in decision making.

Q: What will it be like when you hand over majority ownership?
A: I will not be a burden on the pharmacy, and, even though I will be available to fill in if necessary, once the change occurs, I don't expect to have any input unless asked.

Q: Any tips for other partners or would-be partners?
A: When you do a business valuation, bring in a third party. This gives you a good starting point for the relationship and it helps to eliminate animosity. We had several valuations done, threw out the highest and lowest values and then averaged the middle ones to come up with a number we both felt was reasonable

Terry Blackmon

Q: What advantages has junior partnership given you?
A: I am part owner of an established business and have avoided the risks associated with starting from scratch. I have been able to learn why the pharmacy is successful, and I am building on that success.

Q: Any tips for other partners or would-be partners?
A: Be sure to have something in writing that covers the length of the probationary period and when ownership is going to transition. It is a mistake to wait too long; when I become the senior partner, I will begin looking for a junior partner almost immediately. The partners can't be greedy; they have to embrace what being a partner means.

"The **net worth of a man does not of itself establish his credit.** The power behind that net worth is more important."

Edward Mott Woolley (From *The Junior Partner* circa 1912 and available in digital format on Google Books)

the senior and junior partners share a great vision for the future of the pharmacy. Figuring out how to get there as true partners, negotiating for greatness on both sides, and implementing a shared business plan, creates a win, win, win scenario. By counting on what's inside of each other, the senior partner wins, the junior partner wins, and every one around them wins. aP

Rick Coakley, CLU, CFBS, CLTC, AEP is a co-founder of Waypoint Strategic Advisors, LLC, a registered investment advisor, and its specialized consulting division, Waypoint Pharmacy Advisors. He is the managing partner of Waypoint's Summerville, S.C., office. Coakley was introduced to community pharmacy while working with family businesses in the rural communities of South Carolina more than 30 years ago. He can be reached at rick@waypointus.com

1.

2.

TIME TO FIRE THE BOSS

BY GABE TRAHAN

Don't let fixtures, plumbing, and walls dictate store design

Photography by Gabe Trahan

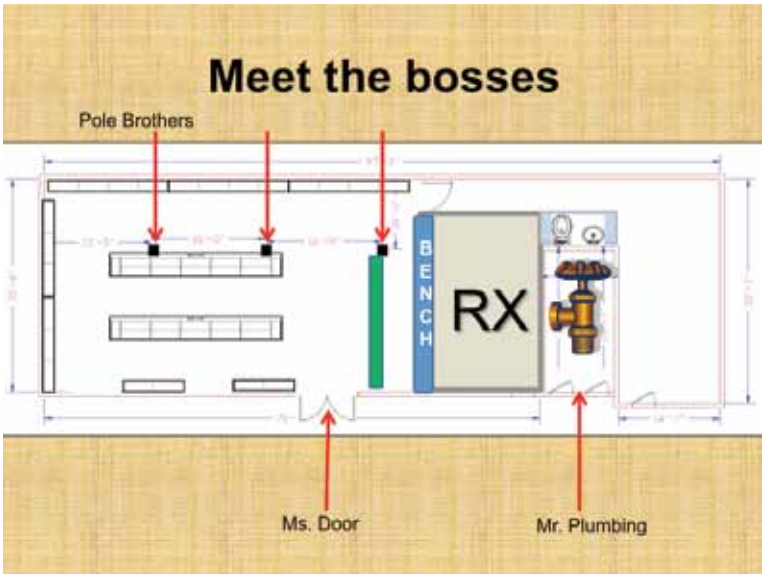
Examples of Front-End Overhaul (Right to Left): 1. Nice looking rolling display; however there is not the right space for it. Place displays and/or merchandise where they belong, not where they fit. 2. Product taken off free rack and displayed on end-cap. Notice companion sale item, ACT, was added to the display. Header card used on end-cap originated from the rolling display. See more examples of end-caps by going to Front-End Overhaul and click on galleries. 3. After adjusting departments to their more efficient sizes, four feet of merchandising space was unearthed. Canes were displayed in the space across from the antacid/laxative department. The store owner reports new interest in canes now that they are displayed in a more 'main street' area. 4. Instead of blocking aisles with two separate cardboard displays, displays were dismantled and product was used for creating a dynamic end-cap. Floor display header cards repurposed as attractive signage for end-cap. Front-End Overhaul recommends this to avoid narrowing aisles with displays.

YOU WOULD BE AMAZED if you knew who or what is making crucial decisions on how a new or remodeled store will look. It may surprise you that more often than not it isn't the owner. Oddly enough, at times the boss of the project makes a decision without saying one word. For example, when a new store is being designed or an older store is being remodeled, the physical placement of the pharmacy is determined by two bosses: plumbing and the drive-up window.

Sound familiar? It doesn't matter if the pharmacy would make better retail sense being placed somewhere else—a 1 ½" sink trap is having the final word, and easy access to the hot water source seconds the motion. After all, every pharmacy has to have a sink. There's not much you can do. Once I asked a contractor if he could move a sink from one wall to the opposite side. His reply? "Anything can be moved, you just apply money." He explained that the amount of copper I would need in the big picture is not something to lose sleep about, and PEX tubing is even cheaper and easier to install. What about the drain? You can get a drain pump system for between $223 and $400. This project was going to cost less than $1,000, and the owner of the store had planned on being in the same location for at least 25 years. The pharmacy was placed where it belonged for fewer than 11 cents a day. Two years ago a new store owner and I looked into moving a drive-up window that was estimated to have an annualized cost over a 25-year-span to be between 25–30 cents per day.

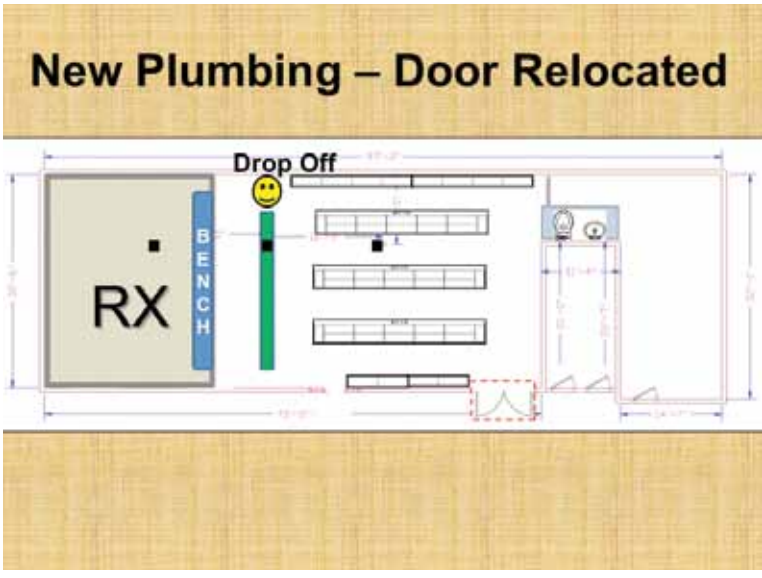
Recently NCPA's **Front-End Overhaul** (www.ncpanet.org) and the owners of a store in the Midwest developed a plan to relocate an entry door in a cement block building, and in its place install a window. The cost of this project was to be approximately $2,000–$2,500. In the long run this was going to be a bargain. (See photos on next page) When thinking

BEFORE



Left Image: *Original building before moving door, adding window, signage, and awning.*
Right Image: *Original drawing of pharmacy with wrong bosses in control. Notice door location would lead customers directly to pharmacy counter and the OTC area of the store would see little or no foot traffic. Luckily the real owner, Independent Pharmacist, took control of their new location.*

AFTER



Left Image: *New entrance to a stunning pharmacy with a floor plan created to compliment the entire store. Store owners Beth Wharam, RPh, and Kari Pastorek, RPh, are great pharmacists, true bosses of their own stores, and destined for a continued prosperous future.*
Right Image: *Door moved. Plumbing concerns addressed. Now customers will enjoy seeing the complete store. Position of drop off is crucial.*

about remodeling or designing a new store, you are the boss. Look at the cost of each project involved, divide the cost by the number of years you plan on being in that location, subtract a portion for gained sales for designing the store the right way, and then make your decision. And it should be YOUR decision. After all, you wouldn't design your home by where it is easiest to put the plumbing, would you?

Fixated on Fixtures

Who is the boss that decided the sizes of your OTC categories? Sadly, in almost every case it is the fixtures. Once at a presentation in front of 100 people I asked, "If a fixture was 24–foot–long, how many of you would make your cough and cold department 12–foot–long and the pain relief 12–foot–long?" All the hands went up. Yes, all. I then asked, "If the fixture was 20 foot, how many of you would go with 12–foot cough and cold and 8–foot pain relief?" All hands went up. How about 16–foot, 8 and 8? All.

Obviously the department's sizes in many stores have been determined by a boss named Fixture Length. If that boss is in your store, then you need to fire him. With the combination of recalls, reformulations, and product line extensions, departments need to be adjusted. Oversized departments will cost you money, significantly diminish the turns of inventory you need to make a profit, and turn you sour on keeping product on hand. Oversized departments are one of the big reasons why some stores tragically harness their sales in growth by stocking only one of each item on the shelves. Twelve feet of skin care with one of each on the shelf will not have better sales than a 4–foot section that has been correctly inventoried. It is time to re-evaluate each of your over-the-counter departments. If you end up with empty sections, then do one or all of the following:

- Double face your private label (two of the same item side by side).
- Double face the major brands that your customers are looking for when shopping.
- Cross merchandise for companion and impulse sales.
- Take down the fixtures to allow more room for your customers to shop.

There is one more boss you may have to toss out. His name is Free Display Rack. He may be the trickiest of them all. Not all displays are bad, just the ones who trick you into putting them where they fit and not where they belong. F.D.R. (apology Mr. President) will end up in places that block your aisles, discourage customers to continue browsing, and eventually become an eyesore. Many F.D.R.s are sentenced to stay on the floor until the last item sells, and that could be years. Merchandise things where they belong, not where they fit. Be the boss. aP

CHANGE YOUR PHARMACY'S RED SNEAKERS

Putting the customer first and providing superior service is the competitive edge of independent community pharmacy, and in this environment of shrinking margins, that edge becomes more important every day. In November 2011 NCPA hired popular industry consultant Gabe Trahan to launch a new initiative to help members sharpen that edge—NCPA's Front-End *Overhaul*.

Trahan's signature is his red sneakers. Picture a well-dressed man wearing, instead of wing tips, red sneakers—something in the picture does not make sense. Trahan has spent most of his career in pharmacies and has seen that many of our stores have their very own pair of red sneakers, something that just doesn't fit; something that takes away from the image of the store. The Front-End *Overhaul* program has been developed to help you find and change your red sneakers, to improve your image and build traffic and profits in your front-end.

Trahan will be making multiple presentations for attendees of NCPA's 2012 Annual Convention and Trade Exposition in San Diego, Oct. 13-17. For more information, visit the members-only Front-End overhaul section on the NCPA website (www.ncpanet.org).

Gabe Trahan is NCPA senior director of Store Operations and Marketing and a team member of Front-End Overhaul. He can be reached at gabe.trahan@ncpanet.org.

ARE YOU READY?

Resources are available to help pharmacists prepare for emergencies—use them

By Lisa Schwartz, PharmD

Do you remember the Zombie Apocalypse of 2011? Chances are the answer is no, because there was no such disaster. Regardless, the Centers for Disease Control and Prevention (CDC) Zombie Apocalypse Preparedness Guide (http://www.cdc.gov/phpr/zombies.htm) brought thousands of people to the CDC webpages to learn about the steps they should take to prepare for

any emergency requiring shelter-in-place. What started out as a light-hearted awareness campaign was a great success to reach a broad audience.

Emergency preparedness is a broad and sometimes misleading notion. Emergencies take many forms, may affect a few or millions and may occur with no notice or several hours' notice. There is a good chance that you have a disaster recovery plan if you attempted or accomplished the feat of becoming an accredited durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) supplier. There is an even better chance that a little bit of legwork or delegation will go a long way to shoring up your plan. For the sake of your family, your employees, and your community, it's time to evaluate your preparedness.

Plan for Minor Emergencies

Start with a plan for a minor emergency. Do your employees know what to do when the power goes out for more than a minute or two? Tomorrow, ask each of your employees if they know where to find a flashlight and spare batteries. Ask them to role-play and escort you calmly to the front door or a safe location in the pharmacy designated for shelter during severe weather. Assign one or more employee to be responsible for a sweep through the store to be sure all customers have been escorted to an exit or safe location and that all employees are safe and have been accounted. If you have expensive refrigerated inventory, an emergency generator is good insurance against loss of inventory.

Did you pass? The next challenge is to consider natural disasters which, though they may be rare, are most likely to affect your normal operations. How should you respond to a fire, flash flood, major flood, hurricane, tornado, earthquake, or winter storm?

Sometimes, emergency preparation just means you've taken measures to minimize losses and downtime. The Disaster Preparedness Checklist offered by the NCPA Foundation at NCPAFoundation.org (see sidebar) is an excellent resource to make sure your business is ready to get back online or ready to start over.

Rx Response.org (see sidebar) has a template for you to help patients prepare for an emergency. Helping patients fill out the Vital Information Card may help you identify prescriptions from other pharmacies, regular over-the-counter drugs and dietary supplements the patient takes. Helping people fill out cards at a community service event may lead you to make an important intervention. The Rx Response Pharmacy Status Reporting tool is turned on when disaster strikes to tell health officials and patients which pharmacies are open and transmitting reimbursement claims—an excellent proxy for normal operations. Pharmacies that want to ensure they are reporting to the Pharmacy Status Reporting tool should email the name and location of the pharmacy to contactus@rxresponse.org and ask to "opt-in."

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Disaster Preparedness Checklist

The following checklist offers some suggestions to help minimize the potential consequences of a disaster or adverse circumstances.

1. Compile primary phone numbers
   - ☐State board of pharmacy
   - ☐Computer company
   - ☐DEA/fire and police departments
   - ☐Insurance agents(s)/landlord
   - ☐Wholesalers and major suppliers
   - ☐Employees
   - ☐Utility companies
2. List of all vendors
   - ☐Mail and email addresses
   - ☐Phone and fax numbers, including help desk
   - ☐Complete representatives' information, including after-hours phone numbers
   - ☐Phone/electric/cable/DSL/computer
3. Maintain important documents—copies of current licenses
   - ☐State license/DEA license/pharmacist and tech licenses
   - ☐Diplomas
   - ☐Controlled substance inventories
   - ☐State tax license/federal tax license
   - ☐Copies of your corporate charge cards
   - ☐Copies of your bank account numbers
   - ☐Any other license or posted notice that would normally be required to be posted at your business site
   - ☐All of your insurance documents
   - ☐Original drafts/all riders/all changes
4. Have the ability to store the appropriate quantity of invoices/claim advices/contracts/etc.
5. Take pictures of everything (including aisles, fixtures, basement, technology, and office areas).
6. Retake pictures when needed—keep a current visual history of your business.
7. Create a "before" video
   - ☐Use of video and narration of damage reduces the time needed by the insurance adjuster to make a decision on damage.
   - ☐Update video p.r.n.
8. Back-up tapes/CDs/hard drives
   - ☐Dual/redundant external hard drives—back up each day
9. Full system backup (Rx and POS)
   - ☐Business office computers
   - ☐Take home each day and swap out next day
10. Before entering the damage area:
    - ☐Check with police/fire departments and utility companies
    - ☐Work in pairs
    - ☐Wear protective clothing
11. Form a "cooperative agreement" with another pharmacy on an in-case-of-emergency basis.
12. Scope out potential storage sites.
13. Maintain a good rapport with your business neighbors.
14. Consider having an off-site answering service or device.
15. Delegate authority when possible to key personnel who will obtain and maintain store information that can aid your business during a transitional period.
16. Prepare a policy analysis and claim strategy.
17. Set up a post-loss plan to protect your operations and market, and to notify your customers, banks, and suppliers.
18. Pre-prepare a public relations program to inform all stakeholders and the public of the store's status and where they can obtain their medications.
19. Know the players, including insurance company representatives.
20. Make the decisions that are best for the survival of your company.

12/11/07

Shelter in Place Drill

In June, Rx Response hosted a drill for the health care associations who are members. NCPA and two NCPA pharmacy owner members participated in this four-hour event that simulated what could happen if dirty bombs went off in Philadelphia; Wilmington, Del.; and Newark, N.J. We responded to the initial reports of the first imaginary bomb, putting together a list of members who would be directly affected, those who would likely have moderate to severe business interruptions and those who would need guidance on responding as thousands evacuated. Then there was the uncertainty that came with the second, and then the third, we wondered where the next one would be. The simulation issued orders from government officials to "shelter in place" aiming to reduce the number of people exposed to radioactive debris or avoid evacuating to a subsequent target city.

RX RESPONSE—PROVIDING MEDICATIONS IN TIME OF NEED

Rx Response supports the continued delivery of critical medicines to patients whose health is threatened by a severe public health emergency, such as a natural disaster, terrorist attack, or pandemic that disrupts the normal bio-pharmaceutical supply chain. Rx Response does this through its role as an information-sharing and problem-solving forum for a coalition of bio-pharmaceutical supply chain organizations, disaster relief agencies, and local/state/federal government agencies.

Rx Response members continually monitor news media across the United States to identify potential or realized threats to public health and engage Rx Response as soon as possible. This response can often be pre-emergency, if forewarning permits. Additionally, the program continues to develop new and innovative ways for partners to share critical information internally and with the general public. These include InfoCenter—Rx Response's online information-sharing forum—and the Pharmacy Status Reporting Tool, which enables those in affected areas to determine the closest open pharmacy in a specific location during a public health emergency.

To learn more about Rx Response, including the history of the Rx Response program, visit www.rxresponse.org.

NCPA staff involved in the Rx Response exercise learned what it meant to shelter in place. Shelter in place generally lasts for hours, versus days or weeks. The ideal room is large, has few windows and has a water supply or a gallon of water per person in bottles. After an emergency is better understood, authorities are able to determine whether emergency shelter or possibly, evacuation, is warranted. The CDC and American Red Cross both have checklists of supplies and steps necessary to shelter in place (http://emergency.cdc.gov/preparedness/kit/disasters/, www.redcross.org/preparedness).

If not directly affected, NCPA will be an excellent source of current information gathered from the Rx Response partners. One other important partner to highlight is the NCPA Foundation. As mentioned previously, NCPAFoundation.org has a free disaster preparedness checklist and an application for pharmacies seeking relief funds after a disaster. aP

Lisa Schwartz, PharmD, is a pharmacist on staff in NCPA's Management Institute, Alexandria, Va. She practiced in independent community pharmacy in Minnesota before coming to NCPA.

The Pharmacodynamics, Pharmacokinetics and Clinical Use of *Echinacea purpurea*

By Kevin Spelman, PhD

Upon successful completion of this article, the pharmacist should be able to:

1. List the main Echinacea species in use today.
2. Identify four active constituents in E. purpurea extracts.
3. Contrast doses used for acute infections versus doses used for chronic conditions.
4. Identify a strategy for converting adult doses to children's doses.

Upon successful completion of this article, the pharmacy technician should be able to:

1. List the main Echinacea species in use today
2. Identify four active constituents in E. purpurea extracts.
3. Contrast doses used for acute infections vs. doses used for chronic conditions.
4. Identify at point-of-sale when a pharmacist should be consulted to calculate a child's dose.

BOTANY

Depending on how this Asteraceae family member is classified, there are up to 12 different species of *Echinacea*. The most commonly used species for medicinal purposes is *Echinacea purpurea*, which is easy to cultivate and therefore, product demand does not put a stress on native populations of *Echinacea* species that are difficult to cultivate. Most preparations found in the market are derived from the above ground, or aerial, parts of *E. purpurea* and/or underground parts of *E. purpurea*; these preparations account for 80 percent of commercial production. In addition, *E. angustifolia* and *E. pallida* are also utilized in commerce but much less than *E. purpurea*.

CHEMISTRY

All three species of *Echinacea* seen in commercial preparations have undergone chemical and pharmacological studies. However, there are several other species of *Echinacea* that have little to no research on their chemistry and pharmacology. Due to the confusion between *Echinacea* species the current body of scientific literature on *Echinacea* can be confusing due to the three species in use – namely *E. purpurea*, *E. pallida* and *E. angustifolia.* These three have phytochemical similarities but have notable differences, particularly around the identity and concentration of key constituents. A number of German studies in the 1980s were called into question when it was discovered that the species they intended to study was the wrong *Echinacea* species. Because of multiple species, plant parts, and preparations used, there are different constituent profiles for various products. *"Echinacea"* may refer to the roots, aerial parts, whole plant or a combination of the above; *Echinacea* products can be made from fresh or dried plant parts, and may be prepared by juicing, alcohol extraction, infusion, decoction, or consumed as tablets or capsules. Most preparations are derived from the aerial parts of *E. purpurea* and/or underground parts of *E. purpurea*, *E. angustifolia*, or *E. pallida*.

In spite of the prolific research done on *Echinacea* spp, there is still uncertainty as to which constituents *primarily* contribute to the purported immunomodulatory action of *Echinacea* species, although many believe it to be the alkylamides. Importantly, it appears that multiple constituent groups are responsible for *Echinacea's* activity. Since *E.*

purpurea makes up most of the *Echinacea* material available this discussion will be limited to that species.

To date more than 216 different phytochemicals have been identified in the literature based on *E. purpurea*. These compounds cover a diverse number of constituent families with varying polarities. Besides the alkylamides, three other constituent groups may have activity; the hydroxycinnamates (such as caffeic acid derivatives), the polysaccharides and the glycoproteins. More divergent research points at generally unrecognized, but active, lipopolysaccharides and/or lipoproteins present in *Echinacea* root capsule and extracts occurring from the endophytes of the roots, although this is not yet well established.

In regard to tincture extractions with ethanol concentrations above 40 percent, only very low levels of polysaccharides are left in suspension, and denaturing of proteins is expected. Thus, the major constituents of ethanolic *Echinacea* extracts are caffeic acid derivatives and alkylamides (and possibly the before mentioned lipopolysaccharides and/or lipoproteins). The capsule or powder of *Echinacea* spp. root would have all four constituents available including the important polysaccharides and glycoproteins, provided the starting material is of good quality.

PHARMACOKINETICS

Absorption of Hydroxycinnamic Acids

In order to fully discuss the absorption of hydroxycinnamates in *Echinacea*, it is necessary to first examine the research from other plant species. Hydroxycinnamic acids are one of the major classes of phenolic acids. Members of this group are ubiquitous in food stuffs, herbal medicines and beverages such as coffee. This group includes cinnamic acid, cichoric acid, coumaric acid, ferulic acid, rosmarinic acid, cynarin, caftaric acid, caffeic acid, and chlorogenic acid.

Gut absorption of caffeic acid is well characterized in both humans and animal models. However, the absorption of chlorogenic acid is more controversial. Some groups have failed to detect chlorogenic acid in the plasma of humans or rats after ingestion as either a pure compound or coffee, a rich source of chlorogenic acid. However, metabolites of chlorogenic acid, caffeic acid derivatives and its O-methylated metabolites (such as ferulic acid) are commonly found in plasma and urine after ingestion of chlorogenic acid in humans and rats. This research shows that chlorogenic acid is absorbed and quickly metabolized, particularly into its methylated derivate, ferulic acid, by catechol-O-methyltransferase which is present in the intestines. Others have shown metabolites of chlorogenic acid, such as ferulic acid, isoferulic acid, vanillic acid, dihydroferulic acid, hippuric acid and 3-hydroxyhippuric acid, are detected in human urine samples after ingestion of multiple cups of coffee. However, caffeic acid is better absorbed than chlorogenic acid. In human studies with volunteers who had undergone colonic resection, chlorogenic acid absorption was a third of caffeic acid absorption. Other studies concur, Lafay *et al*. utilizing a murine model, reported that while 19.5 percent of caffeic acid is absorbed in small intestines only, 8 percent of chlorogenic acid is absorbed in small intestines. The time frame for maximum concentration in human plasma for caffeic acid has been reported to be one hour.

In the case of *Echinacea*, we are particularly interested in caftaric acid, cynarin, caffeic acid, chlorogenic acid, cinnamic acid and echinacoside. The occurrence of these compounds differs depending on the particular *Echinacea* species. While one in *vitro* study done on an *Echinacea* product showed absorption of only about 3 percent of ingested cichoric acid and 1 percent of caftaric acid over 90 minutes, there was a substantial absorption of cinnamic acid (83 percent) over the same time frame. However, this research was on a specific Echinacea product and the results differ significantly from other research that examined hydroxycinnamate pharmacokinetics. For example, in a murine model, caftaric acid was detected in plasma at 10 minute (293 ng/mL) and 20 minute (334 ng/mL) time points. By 20 minutes a derivative of caftaric acid, fertaric acid, was detected in plasma as well. Caftaric acid was detected in kidney, and in some animals, in the brain. In general, hydroxycinnamates are eliminated rapidly from the circulatory system with T1/2 values ranging from 0.3 to 1.9 h.

Alkylamide Absorption

The alkylamides have also been studied for absorptive capacity. Thus far, it has been reported

that the higher the unsaturation of the alkylamide, the higher the absorbability. For example, the 2,4-diene alkylamides have been reported to cross Caco cells more readily than 2-ene alkylamides (see table 1). Incidentally, *E. purpurea* has a higher concentration of 2,4-dienes than *E. angustifolia*, which has a higher concentration of 2-ene alkylamides (table 1.9).

The concentrations of alkylamides reported in serum have been between 10.88 - 336 ng/mL. The $T_{1/2}$ of the predominant alkylamide dodeca-2,4,8,1 0-tetraenoic acid isobutylamide in a murine model has been reported to be 71.9 minutes, while in another study a $T_{1/2}$ of 0.4 -1.03 hr. was observed for the same compound. Of particular interest, two independent studies have reported that there is no difference between alkylamide absorption between liquid extracts (tinctures) and tablets except for a delay in T_{max} which would be expected due to the necessary digestion of the tablet. One group reported alkylamides being detectable in serum for up to 12 hours. $T_{1/2}$ values range from 1.8 – 5.0 depending on the molecular structure of the alkylamide.

Murine models investigating alkylamide absorption have shown that the alkylamides cross the blood brain barrier with an elimination half-life of 253 minutes with a mean residence of 323 minutes. Others have reported a rapid passage across the blood brain barrier. This may be related to *Echinacea's* recently reported anxiolytic activity.

TRADITIONAL USE

Native Americans utilized *Echinacea* for a number of uses including as an anesthetic, analgesic, for coughs and sore throats and as an antidote for poisons such as snake venom. The physicians of the early 20th century learned many of these uses from the native Americans and utilized *Echinacea* for many indications, including sepsis, as well as less severe infections. At this point in time, *Echinacea* spp. have been documented in therapeutic use for more than a century by physicians for a variety of infections (Couch and Giltner, 1920). Even though 80 percent of the *Echinacea* products sold to consumers are made from *purpurea*, all three species are often used interchangeably for the treatment of cold, flu, respiratory infection, and inflammation. However, this crossover between species and plant parts for the same indications should be examined more closely for further refinement in indications. With further evolution of the understanding of the clinical effects of various extractions and constituents of *Echinacea*, an enhanced understanding of species and products will develop.

MODERN USE

Echinacea is one of the most frequently used medicinal plants in clinical settings. There are more than 800 *Echinacea* products on the market. For example, of the most prescribed drugs in Germany, *Echinacea* preparations have been in the top 200 for many years. Despite the hesitancy to use *Echinacea* products clinically in the United States, German physicians have written more than three million prescriptions annually for *Echinacea* products for the treatment of upper respiratory tract infections for well over a decade.

Medical doctors, naturopathic physicians and professional clinical herbalists in the United States have utilized *E. purpurea* as an acute remedy for upper respiratory tract infections. In addition, for clinicians comfortable with *Echinacea* as an immune enhancer, it is used as an addition to antibiotics to improve the therapeutic outcome. For example, *Echinacea* added to an antifungal regime of topical econazole nitrate reduced fungal reoccurrence rates from 60.5 percent to 16.7 percent. Those clinicians with more in depth understanding of *Echinacea* may also use it to accelerate wound healing both topically and internally.

In Russia, *E. purpurea* tops are mixed with animal feeds to improve the natural resistance of cattle to diseases, and improve milk production and quality. A study in horses showed that *Echinacea* is effective in strengthening immune response and acts as a hematinic agent, increasing hemoglobin levels, the number of red blood cells, and improves exercise physiology parameters and performance. A study in humans athletes demonstrated a significant increase in erythropoietin and IL-3. A recent experiment in aquaculture showed that *Echinacea* improved weight gain, resistance against infection, resistance to cold stress during the winter season, and survival in fish. Echinacea is proving to be so useful that numerous attempts have been underway in some non-traditional *Echinacea* growing countries, in Africa, Asia, Latin America,

and the Middle East to introduce cultivation, processing, and marketing.

INDICATIONS

Indications given are for *E. purpurea* root.

1. Treating the common cold, flu, and upper respiratory tract infections.
2. To increase general immune system function.
3. Treating vaginal candidiasis.
4. Non-healing wounds (topical or oral formulation)
5. Prophylaxis of common cold, flu, and upper respiratory tract infections. (weak evidence)

WHERE DOES THE RESEARCH POINT?

The bottom line: The most consistent results identified by the majority of the studies previous to the year 2000 indicate that *Echinacea* has nonspecific immunostimulating properties through the triggering of the innate immune system. However, more recent work indicates that *Echinacea* is a true immunomodulator and in some cases may be useful for conditions exhibiting an autoimmune response.

Research suggest that *Echinacea* species have immunological effects, as well as anti-viral, antibacterial, antifungal, insecticidal and anti-inflammatory properties. Although there is ongoing controversy in the literature as to whether the immunomodulating properties of Echinacea are attributable to the alkylamides, caffeic acid derivatives or the polysaccharides/glycoproteins, the in *vitro* and in *vivo* investigations previously performed demonstrate that there are multiple compounds that are active. Full spectrum extracts are, based on research, clinical experience and this author's opinion, the wisest choice of therapeutic application for *Echinacea* products.

A great deal of excitement has been generated due to the recent elucidation of the alkylamides activity on cannabinoid 2 receptors (CB2R; see section below entitled Cannabinoid activity). Some in the natural products industry now think that the basis of *Echinacea's* activity has finally been established. This may be short-sighted as CB2R activation comes up short as an explanation as to the various observations clinicians and researchers have made. If the alkylamide activation of CB2R was the primary basis of activity for *Echinacea*, it would suggest that *Echinacea* is essentially a complex antiinflammatory. Both research and clinical experience strongly suggest otherwise. Most of the Echinacea preparations that have shown an effect in clinical trials are not impressively high in alkylamides and contain the caffeic acid derivatives and often the polysaccharide/glycoproteins as well. Extracts that contain a wide spectrum of constituents currently appear to be the most reasonable direction for clinical use since it is not clear what compounds are the most important.

However, the CB2 activity strongly does suggest that *Echinacea* may also be used for a broader array of immune dysregulation than its current indications. For, example CB2R activation is therapeutic in autoimmune diseases. This challenges the Commission E's contraindication of autoimmune diseases for *Echinacea*.

Interesting new directions in *Echinacea* research investigate a much wider application than immune issues. Recent research suggests the possibility that *Echinacea* may be useful in type II diabetes and metabolic syndrome, although this still needs further work. The CB2 activity alone would potentially be useful in these conditions. However alkylamides have been shown in two independent models to activate PPAR-γ, the site of action of the thiazolidines commonly used to treat insulin resistance. Investigations on gene response show that *E. purpurea* root extract upregulates PPAR-γ expression in cells infected by human rhinovirus and the polysaccharides of *E. purpurea* extracts upregulate PPAR expression in non-infected cells. Provided that the PPAR activity can be shown in *vivo*, Echinacea may have an intriguing new indication on the horizon.

IN VITRO AND EX VIVO ACTIVITY IMMUNOMODULATION

Immunomodulators are defined as agents that modulate the dynamic regulation of immunologically relevant informational molecules such as cytokines, hormones, neurotransmitters, and other proteins and peptides. Physiological effects of *Echinacea* include immunomodulatory activities, such as stimulation of phagocytosis and induction/inhibition of cytokines from various leukocytes depending on the research model utilized. In addition, investigators report antioxidant activity. Immunostimulating activity of extracts from

Echinacea appear to be well established as well. Studies have reported that *Echinacea* extracts have the ability to activate human phagocytic function both in *vitro* and in *vivo*.

Other researchers have noted up-regulation of immune function in ex vivo models including in human immunodeficiency disorders. Conversely, down regulation of TNF-α and IL-8 have been demonstrated by *E. purpurea* extracts in ex vivo models of healthy individuals. While this appears contradictory, keep in mind that the 'physiological context' appears to be crucial as to *Echinacea's* direction of the pharmacological effect. One of these studies examined individuals with immunodeficiency disorders, the other examined healthy individuals. Intriguingly, *E. purpurea* extracts appear to function differently in a healthy individual's system than in an ill individual's system.

In human cells lines that are infected by a pathogen, a normal response is the upregulation of proinflammatory cytokines to counteract the infection. Recall that during upper respiratory tract infections (URIs) upregulation of inflammatory cytokines is responsible for the majority of clinical symptoms. A number of studies demonstrate that *E. purpurea* extracts will counteract this proinflammatory response due to infection from virus or bacteria. This has been suggested to be the main effect of *Echinacea* by many in the natural products industry whom have suggested that Echinacea is a simple CB2R agonist. Furthermore, interviews with experts on *Echinacea* from the natural products industry are quick to point out that *Echinacea* is not an antibiotic, rather the majority of its action is due to immunomodulatory activity. While there is quite a significant body of research on the immunomodulatory activity of *Echinacea*, there is also a body of research on specific antimicrobial activity.

E. purpurea has been shown to have "potent virucidal activity against viruses with membranes" including specific rhinoviruses, influenza virus, respiratory syncytial virus, adenovirus types 3 and 11, and herpes simplex virus type 1. In addition, antibacterial activity has been found against pathogenic bacteria such as *Streptococcus pyogenes*, *Hemophilus influenza*, *Legionella pneumophila, Propionibacterium acne and Clostridium difficile.* In recent studies that received very little attention, investigators showed that the virus known as H5N1 HPAIV was inhibited from replication and entry into cells by an E. purpurea extract. Moreover, while oseltamivir (Tamiflu®) induced resistance after multiple passages, *E. purpurea* extract did not induce resistance. These researchers also found that oseltamivir resistant virus were sensitive to *E. purpurea*. Other in *vitro* experiments show that *E. purpurea* extracts have the potential for use in alleviating the symptoms and pathology associated with infections with H1N1 influenza A virus by attenuating the production of TNF-α, G-CSF, CCL2/MCP-1, CCL3/MIP-1alpha and CCL5/RANTES from infected cells. In monocytes exposed to aerial or root extracts of E. purpurea, upregulation of IL-1α, TNF-α , ICAM, IL-8, and IL-10 was observed consistent with an activated antiviral physiological response. In these studies, the aerial versus root extracts did not differ significantly in their effects. Recall that both aerial parts of the plant and the root contain the hydroxycinnamates and the alkylamides, although in different concentrations.

Cyclooxygenase (COX) and COX-2 inhibition, as well as minor lipoxygenase inhibition, have also been noted for *Echinacea* extracts and specific alkylamides. This would potentially have an additive, or possibly synergic, effect in the anti-inflammatory activity that the CB2R activation has demonstrated.

While the inhibition of proinflammatory cytokines and chemokines in infection will make a significant difference in symptoms of upper respiratory tract infections, the anti-inflammatory activity and the direct antibacterial/antiviral activity will also be important. Add to these actions the inhibition of mucin secretion by goblet cells in the respiratory tract when infected by rhinovirus and the direct upregulation of phagocytosis and it is obvious that *E. purpurea* has multiple activities that should not be attributed to one class of constituents or one pharmacological target.

CANNABINOID ACTIVITY

The alkylamides (examples shown in Table 1, compounds 3, 4, 5, 9 and 10) found in *Echinacea* species and other medicinal plants, have been of pharmacological interest since humans first noted the tingling and numbing effect from chewing plants rich in these compounds. This

anesthetizing tingling of these compounds is associated with activation of tactile and thermal trigeminal neurons. This property was utilized by native Americans and eventually by physicians in the early 20th century for a variety of purposes including toothache and infections. Alkylamides were later recognized as insecticidal by a number of researchers, but eventually interest in these compounds waned. Recently, however, these fatty acid derivatives have become a subject of renewed interest due to their recent identification as cannabinoid ligands. The endogenous cannabinoid ligands are specific fatty acid metabolites, known as eicosanoids. It should be explicitly stated that the alkylamides do not interface with the cannabinoid 1 receptor, which is responsible for the psychotropic effects of the cannabinoids from *Cannabis* spp.

The CB2R is located on T & B lymphocytes, natural killer cells, macrophages, neutrophils, and mast cells and provides immunomodulatory responses. The CB2R has been found to play a significant role in immune dynamics including the resolution of inflammation, cancer, atherosclerosis, osteoporosis and chronic pain. This is a particularly attractive site for cannabinoid agonists selective for CB2R because of a paucity of psychomimetic activity. Nonetheless, in the face of remarkable volumes of preclinical data, only one CB2 drug molecule (cannabinor) has made it to phase II clinical trials. Data from marijuana smokers provide leading clues as to the effects of CB2 ligands on immune function. Lung alveolar macrophages removed from marijuana smokers have diminished capacity for the generation of TNF, gmCSF and IL-6 (inflammatory cytokines). Moreover, marijuana smokers that are matched with tobacco smokers for the frequency of smoking, have significantly lower rates of lung cancer that tobacco smokers or non-smokers. Further data suggest that CB2 ligands can inhibit the production of TNF and other cytokines by several different pathways, some independent of cannabinoid receptors. Conversely, cannabinoids have also been shown to increase the production of cytokines (including TNF, IL-1, IL-6, and IL-10) if administered with appropriate immune stimulation (bacteria or antigens) or, in some cases, without immune stimulation. These data strongly suggest true immunomodulation and not simple immunosuppression by Echinacea. Again, it should be stated that *Echinacea* has no psychotropic effects as the alkylamides of *Echinacea* do not bind to the CB1 receptor found in the central nervous system.

Induction of tumor necrosis factor (TNF) mRNA by alkylamides is greatest (12 fold) with alkylamides known as the tetraene isomers at a concentration of 5 μM. Another alkylamide common to both *E. purpurea* and *E. angustifolia* is dodeca-2E,4E-dienoic acid isobutylamide, which also upregulated TNF mRNA nine-fold. Dodeca-2E,4E,8Z-trienoic acid isobutylamide, also common to *purpurea* and *angustifolia* up regulates TNF mRNA five-fold. The effect of these alkylamides on TNF is blocked by the CB2R antagonist WR144528. In another study on CB2R binding, investigators demonstrated that the isobutylamides dodeca-2E,4E,8Z,10Z-tetraenoic acid (Table 1.3) and dodeca-2E,4E-dienoic acid (not shown) inhibited the binding of a CB2 ligand.

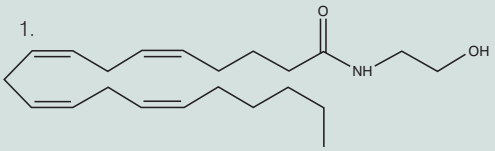
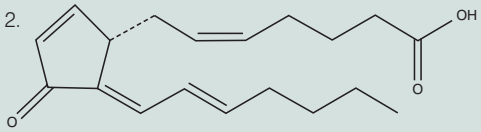
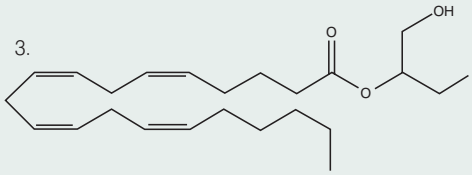
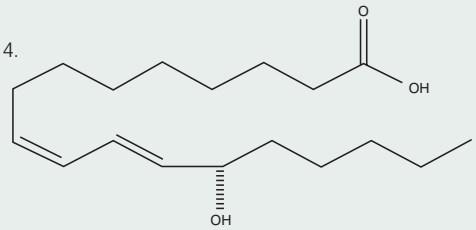
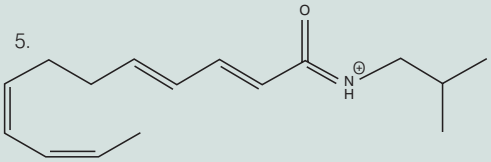
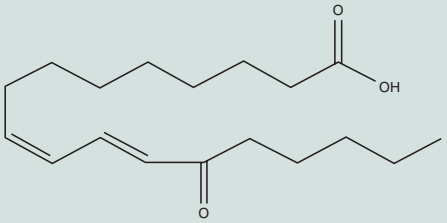
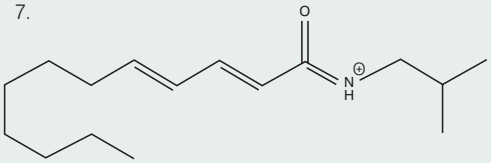
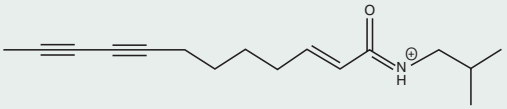
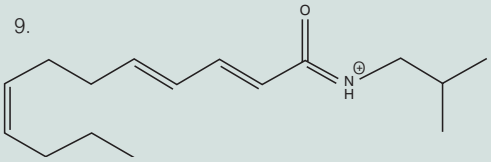
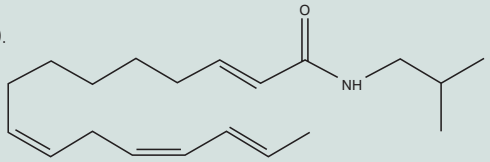
As previously mentioned, extracts with a wide array of constituents, not focused primarily on alkylamides appear to be important. For example, while TNF-α induction has been induced by the alkylamides, one of the caffeic acid derivatives, cichoric acid (also known as, chichoric acid), as well as extracts of *E. purpurea* and *E. angustifolia* roots have demonstrated counteraction of increases in TNF-α levels. Again these data suggest that the effects of Echinacea may be dependent on the immunological "tone" of the system as well as the type of extract.

HUMAN RESEARCH *IN VIVO/EX VIVO*

While a number of clinical trials have shown a beneficial effect for *Echinacea* spp. on colds and flus, a number of trials have failed to show a reduction of the symptoms of colds and flus. For example, Turner *et al* demonstrated no effect of *E. angustifolia* on the reduction of symptoms or duration of an experimentally induced cold.

Further research with an *E. purpurea* extract that was dosed with a loading dose (5 mL for 8 doses) for the first day and subsequently 5 mL three times daily for six days, in volunteers with URIs demonstrated a reduction in cold symptoms compared to placebo from days 2–7 of treatment (constituent doses 0.25/2.5/25.5 mg/mL alkylamides, cichoric acid, polysaccharides respectively). In *ex vivo* analysis of these sub-

Table 1: Ligands of CB2 and PPARγ

CB2 ligands	PPARγ ligands
1.  Anandamide MW 347.3 (PPARγ)	2.  15-deoxy-Δ-prostaglandin J2 MW 316.4 (fibroblasts activity 7 μM)
3.  2-arachidonylglycerol MW 378.3 (PPARγ)	4.  13-hydroxyoctadecadienoic acid MW 296.4
5.  Dodeca-2E,4E,8Z,10Z-tetraenoic acid isobutylamide MW 247.3 from Echinacea spp.	6.  13- oxooctadecadienoic acid MW 294.4
7.  Dodeca-2E, 4E-ene-dienoic acid isobutylamide MW 251.3 from Echinacea spp.	8.  Undeca-2E-ene-8,10-diynoic acid isobutylamide MW 231.3 from Echinacea spp.
9.  Dodeca-2E,4E,8Z-trienoic acid isobutylamide MW 249.3 from Echinacea spp.	10.  Hexadeca-2E,9Z,12Z,14E-tetraenoic acid isobutylamide MW 303.3 from Echinacea spp.

a. When information was available concentrations found to be active are stated.
b. Compounds 3 & 4 are also PPARγ activators. From with Ki of 57 nM and 60 nM. Other studies confirm similar affinities for these alkylamides. Notably, these affinities are within range of serum concentrations previously observed (10.88 - 336 ng/mL). Other observations in these studies include the activation of MEK 1/2 as well as JNK1/2 and NF-κB.

jects' blood, the number of circulating total white blood cells, monocytes, neutrophils and NK cells was significantly increased by the seventh day of treatment. In the later stages of the cold, the *Echinacea* treatment normalized the increase in neutrophilic superoxide production by day eight while the placebo group continued to show increases in superoxide production up to day eight.

The most recent clinical trial to date studied *E. purpurea* mixed with *E. angustifolia* and weighted heavily with alkylamide concentrations in 1,422 subjects, showed a non-statistical effect on shortening colds and flus. In addition, the researchers reported an increase in neutrophils and IL-8. However, due to high inter-individual variability this was not statistically significant.

Despite the negative outcomes, there are enough positive data in the human trials to offset the negative results. As a result, the meta-analyses that have been performed suggest that *Echinacea* products are effective. A Cochrane review reports some *Echinacea* preparations may be better than placebo and that the majority of the Echinacea studies demonstrate positive results. A meta-analysis by Schoop *et al*., reports that standardized extracts of *Echinacea* were effective in the prevention of symptoms of the common cold as compared with placebo. Islam and Carter conclude that there is a beneficial effect from *Echinacea*, but also suggest that differences in products and doses make evaluation challenging. Linde *et al*. suggest that there is evidence, although inconsistent, that *Echinacea* is effective in treating URIs. A meta-analysis of studies with children (under the age of 18) found that *Echinacea* reduces the incidence of URIs by 40 percent. Finally, the most recent meta-analysis finds that the evidence supports *Echinacea's* benefit in decreasing the incidence and duration of the common cold in adults.

Recent data on 995 patients with chronic recurrent respiratory disease shows that treatment with an *E. purpurea* extract reduces the incidence of illness by 2.3 times and saves 1.4 days with each illness. These researchers calculated the average daily cost per patient and reported that there is an economic benefit to the use of *Echinacea*.

In a study of URI prevention, subjects were dosed with 2.5 mL three times daily of *E. purpurea* extract or placebo, for seven days. After the initial seven days of dosing the subjects were inoculated with rhinovirus and dosed with another seven days of *E. purpurea* extract or placebo. URIs developed in 58 percent of the *Echinacea* group, as compared to 82 percent of placebo recipients. A recent trial which failed to show a positive outcome for treating URIs in children (ages 2 and 11) with *E. purpurea* did find that there was a prophylactic effect reducing the incidence of a second acute respiratory tract infection over a four month period. In a study of athletes, an *E. purpurea* tablet was rated as "good" or above by 75 percent of patients and investigators and prevented colds in 71 percent of the subjects. *Echinacea* products to date have never resulted in a false positive for banned substances used by athletes. A meta-analysis of the prevention studies suggest that there is a 55 percent reduction in the occurrence in URIs when using *Echinacea* as compared to placebo.

In another human *ex vivo* study researchers gave 1,500 mg three times daily of capsule of *E. purpurea* aerial parts and roots and *E. angustifolia* root to human subjects for two days plus one additional morning. After the dosing period a downregulation of a number of inflammatory genes was observed in most subjects; IL-1β (4 of 6 subjects); TNF-α (5 of 6 subjects); IL-8 (3 of 6 subjects); COX-2 (4 of 6 subjects); and ICAM-1 (4 of 6 subjects). These results achieved statistical significance on day five, despite dosing having ceased two days earlier. Cownversely, the relative expression of IFN-α2, an endogenous antiviral cytokine found to decrease symptoms and duration of colds, increased steadily in all subjects reaching statistical significance by day 12. Another study found that after seven days of dosing with *E. purpurea* extract, immune function, measured by CD69 expression on CD4 and CD8 cells, was upregulated.

Other research has shown that a lozenge of *E. purpurea* root in a range of doses (0.07–0.9 mg alkylamides) downregulates the production of IL-12p70, IL-8, IL-6, IL-10, and TNF within 24 hours of the dose. These researchers also showed that the alkylamides in the *E. purpurea* product were absorbed in 10 minutes, suggesting that absorption is taking place through the oral mucosa.

Brinker has done an excellent analysis of *Echinacea* clinical trials and pointed out that of the studies that have shown an effect on URIs,

the products used were all liquid extracts. Further analysis by Brinker has suggested that of the studies that failed, none used liquid extracts. Thus, Brinker speculates that liquid extracts may be a more efficacious dosing strategy, especially using the small doses that have been used in the clinical trials. An important factor when treating URIs may be oral mucosal exposure to the extract. However, both small and large infrequent doses of whole fresh plant extract tablets have produced benefit. In studies of the liquid juice (above ground parts of the plant) using frequent and early but small doses or larger infrequent doses of the juice positive effects have been achieved, but not with regular moderate doses of the dried juice.

A recent review of the *Echinacea* clinical trials showed that less than 9 percent of studies that had a "high-quality" rating incorporated phytochemical testing as an investigational criteria. As Cooper points out, clarity and consistency on identity and dosing are essential for validating and comparing outcomes when carrying out research. Researchers who study specific product formulations administered in appropriate doses will vastly improve the quality of available data.

CLINICAL OBSERVATIONS

While *Echinacea* preparations, properly dosed, are generally associated with the treatment of URIs, they can be potentially effective for the treatment of many different types of infections. Keep in mind that the eclectic physicians of the late 19th century and early 20th century used *Echinacea* spp. for sepsis. In the case of infections, proper dosing is crucial. (See Dosage section.) Additionally, topical *Echinacea* can be useful for non-healing and spreading wounds. For instance, in combination with turmeric (*Curcuma longa*), both internally and topically, *E. purpurea* root has been useful for the particularly difficult-to-heal bites of brown recluse spiders (*Loxosceles reclusa*). A clinical observation of a brown recluse bite that occurred two years before herbal treatment makes an interesting case study. The bite had progressed into severe dermonecrotic lesions migrating up the left arm and down the right arm. The lesions were resolved over about 16 weeks' time with topical and internal use of *E. purpurea radix* and *Curcuma longa rhizoma*. This is likely due to *Echinacea's* stimulation of fibroblast activity, its hylaronidase inhibition and its wound healing properties. Native Americans also used *Echinacea* for rattlesnake bites. It is quite likely that the anti- hyaluronidase effect is the basis of this anti-venom activity, since viper venom contains hyaluronidase, allowing it to break down connective tissue.

One of the most intriguing uses of Echinacea in 1:1 combination with dandelion root have been the reports of attenuating IgE mediated allergic responses to food and other substances. However, until conclusive evidence is available, life threatening allergic responses should be treated with proper medical care.

DOSAGE

The suggested dose varies widely on various *Echinacea* products. Moreover, clinician's opinions on what dose is effective for the treatment of URIs vary extensively. But one thing appears to be obvious to most clinicians: The dosages suggested on most *Echinacea* products are subclinical and ineffective for most acute infections. Based on the above discussion of the pharmacokinetics of hydroxycinnamates and alkylamides which show half-lives of a few hours, as well as clinical experience, the efficacious dose of *E. purpurea* root extract for treating URIs is one teaspoon (of a liquid extract) as a loading dose (or 1,500 mg capsule), followed by a half a teaspoon (or 500–750 mg capsule) every one-two hours for the first day (sleep should not be interrupted). While this may sound like a high dose, there is support for this dosing regimen. The following two days one teaspoon (1,500 mg capsule) should be used three times a day to make sure the virus doesn't regain a foothold. For preventing an impending URI, this dosing regimen must be started *at the first signs of illness*. This dosing protocol is based on the most common extract available 1:2 fresh root extracts. Clarks rule should be used for dosing children age 2–17 based on the above dosing. Clark's rule looks like this (Child's weight in pounds/150)(Adult dose) = Child's dose.

If consumer use is to support general immune function, a lower dose is used. In this case half a teaspoon is used once daily of the liquid extract (or 750–1,000 mg capsule).

SAFETY AND HERB DRUG INTERACTIONS

The search for and appraisal of information relating to the metabolism of phytochemicals and the phytochemical influence on drug metabolism has thus far been a challenge for researchers and educators, and readily accessible information among the scientific and medical community is lacking. Metabolic studies on phytochemicals have only recently been published in the scientific literature. Unfortunately, it appears that in regard to phytochemical influence on the metabolism of pharmaceuticals, much of the literature does not evaluate the quality of evidence from which conclusions are drawn.

Of particular concern for healthcare providers, Freeman and Spelman report that drug-herb interactions related to *Echinacea* products were cited in some 49 articles, only 16 percent (eight) of these 49 papers contained primary data relevant to interactions between *Echinacea* products and pharmaceuticals. Two studies were clinical trials and the remaining were in *vitro* assays, three of which did not contain complete information about the concentration of extract used; only half of the studies verified the authenticity of the *Echinacea*.

The most clinically relevant study done to date on the potential of *Echinacea* spp. to interact with pharmaceuticals was a study done on HIV patients (n = 15) who were receiving antiretroviral therapy including darunavir-ritonavir (600/100 mg twice daily) for at least four weeks. *E. purpurea* root capsules (500 mg every six hours) for 14 days were used by patients. Darunavir-ritonavir plasma concentrations were determined before, during and after the *E. purpurea* dosing. Although patients did show a decrease in darunavir concentrations, this did not affect the overall darunavir or ritonavir pharmacokinetics. Coadministration of *E. purpurea* with darunavir-ritonavir was safe and well tolerated.

The available data on the metabolic influence of *Echinacea* spp. and the alkylamides mainly focuses on the predominant alkylamides known to be responsible for drug interactions such as the CYP1, CYP2 and CYP3 families. Three different reviews conclude that *Echinacea* supplements pose minimal risks for interacting with most conventional medications.

Regarding concentrations of alkylamides used in in vitro research; recall that the highest serum concentration documented for alkylamides is 336 ng/mL, and this was 10 fold higher than the majority of pharmacokinetic studies investigating these concentrations. This should provide information for realistic analysis of future drug-herb interaction literature.

Cytochrome P450 Isoenzymes

Studies show *E. purpurea* herb and root may minimally inhibit CYP1A2. Patients taking drugs with a narrow therapeutic index metabolized by CYP1A2 (such as theophylline and clozapine) should avoid taking them with *E. purpurea*. However, studies conclude that no clinically significant interactions were expected between *E. purpurea* and substrates of CYP2D6, CYP2C19 and CYP2E1. There is no reliable research on *E. purpurea's* interaction with CYP2C9.

CYP3A4

There are a number of investigations done with real world dosing with humans on *E. purpurea* root extracts influence on CYP3A4. Human investigations by Gorski *et al*., (2004), found no changes in the metabolism of midazolam, a 3A4 substrate, after participants ingested 1,600 mg of *E. purpurea* root daily for eight days. While the authors observed an 85 percent increase in intestinal availability of midazolam, a 15 percent reduction of hepatic availability ($p < 0.003$) was also noted. The authors postulated that the induction of hepatic 3A4 counteracted inhibition of intestinal 3A4, leading to little to no effect in midazolam metabolism overall. Using *E. purpurea* whole plant extract (aerial and root combined) in a human trial Gurley *et al*. (2004) found no statistically significant differences in 3A4 phenotypic ratios. CYP 450 phenotypic ratios have been shown to provide a practical method for predicting CYP mediated drug interactions. Finally, in another human trial with healthy volunteers (n = 13) given lopinavir (400 mg-ritonavir 100 mg twice/day) with meals for 29.5 days, found that *E. purpurea* (500 mg three times a day for 28 days) induced CYP3A activity but did not alter lopinavir concentrations. The authors concluded that *E. purpurea* is unlikely to alter the pharmacokinetics of ritonavir-boosted protease inhibitors.

Organic Anion-Transporting Polypeptide (OATP-B)

Fuchikami et al., found inhibition of OATP-B by the aerial parts of *E. purpurea* in vitro. The clinical significance of this finding is unclear, as few

drugs are metabolized via this pathway and the findings have not been demonstrated in *vivo*.

P-Glycoprotein

Romiti *et al*., report that the hexane root extracts of all three *Echinacea* species inhibited P-glycoprotein, with *E. pallida*, a little used species, having an effect at 3 μg/mL. The *E. angustifolia* and *E. purpurea* extracts were inhibitory at 30 μg/mL. Considering the concentrations of the extracts used in this study, these data appear to have no relevance to real world use of *Echinacea* spp., especially since the percentage of *E. pallida* extracts in the market place is less than 5 percent.

Although drug-herb interactions are generally thought to be negative, there are potentially positive drug-herb interactions due to the potential of immune enhancement by *Echinacea*. For example, *Echinacea* may protect white blood cell counts in chemotherapy induced myelosuppression from myelosuppressive antineoplastic chemotherapies. In therapies exploiting TNF-α antagonists and other immunosuppressive drugs, *Echinacea* may theoretically be used to protect against opportunistic infection by enhancing cellular immunity during temporary drug withdrawals.

Echinacea is considered to be one of the safest herbal medicines, with few reported adverse effects. Given that Echinacea generally ranks in the top five in herbal sales in the United States from year to year, this is particularly notable. Barrett notes that less than 100 serious adverse events have been reported for over 10 million courses of treatment, leaving the risk estimate of less than one in 100,000. Echinacea products consisting of roots and aerial parts do not appear to be a risk to consumers provided that the preparations are authenticated.

ADVERSE EVENTS AND TOXICOLOGY

Short-term use of *Echinacea* is associated with a relatively good safety profile, with a slight risk of transient, reversible, adverse events. In clinical trials the most common complaint was gastrointestinal side effects. Adverse events are rarely reported with *Echinacea*, though in rare cases *Echinacea* has been associated with severe allergic reactions. The severe allergic responses are predominantly with the use of intravenous or intramuscular injection. Mild reported allergies, though rare, suggest that those with tendencies towards atopic dermatitis or asthma should use caution. People are more likely to experience allergic reactions to *Echinacea* if they are allergic to related plants in the daisy family, which includes ragweed, chrysanthemums, marigolds, and daisies. In ethanol extracts, as the proteins are denatured, allergic response to the ethanol extracts should not occur.

It should be noted that a good quality liquid extract (made with ethanol) of *Echinacea*, due to the alkylamide content, will induce a sensation of numbness and tingling on the tongue, mouth and throat. It is possible if the user is not expecting this sensation, it could be mistaken as an allergic reaction.

There appears to be no in vivo toxic level (overdose level), as defined by several assays and criteria of *Echinacea* spp. Research shows the toxic dose of *E. purpurea* is extremely high; chronic administration of hundreds of times the therapeutic dose has shown no toxicity. Furthermore, inducing toxic effects on cell cultures by *E. purpurea* extracts are possible with only with very high concentrations of *Echinacea* extracts that would not be possible to attain in even high dose use by humans.

TIPS FOR THE PHARMACIST

While *Echinacea* products are ubiquitous in the market place, it can be challenging to distinguish between these products in regard to quality of product, proper part of plant used and, importantly, ease of use for the consumer. Most American generated products are made with root and/or flower and seed. These parts provide the highest availability of alkylamides and will have reasonable levels of caffeic acid derivatives. Polysaccharides will be present if these plant parts are put into capsule, but if extracted with ethanol, polysaccharides are present only in substantial concentrations if the ethanol concentration is below 40 percent. Conversely, most European-based products (primarily German) are juiced above ground parts of the plant. These products will be rich in caffeic acid derivatives and polysaccharides, but low in alkylamides (notice the lack of numbing and tingling from one of these products – a sure sign of very low alkylamide content).

Clinicians in the United States prefer products richer in alkylamides since these are CB2R agonists. However, alkylamides are not the only active constituent in *Echina-*

cea. Since a primary active constituent in *Echinacea* has yet to be identified, a full spectrum phytochemical extract is a prudent choice.

For consumer use, the easiest approach is probably in liquid extract form. The taste of *Echinacea* can be (mostly) hidden in juice or teas. However, the capsule is easier if consumers are sensitive to the taste. For both capsules and liquid extracts, proper dosing is important if attempting to shorten the discomfort of an URI.

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Editor's Note: For the list of references used in this article, please contact *America's Pharmacist* Managing Editor Chris Linville at 703-838-2680, or at chris.linville@ncpanet.org.

CONTINUING EDUCATION QUIZ

Select the correct answer.

1. What is the primary *Echinacea* species used in products?
a. *E. purpurea*
b. *E. angustifolia*
c. *E. pallida*
d. All of the above

2. Which is a list of three active constituents in *E. purpurea* extracts
a. Alkylamides, caffeic acid derivatives and polysaccharides
b. Eicosanoids, Alykylamides, glycoproteins
c. Alkylamides, polysaccharides, cannabinoids
d. Alkylammines, polysaccharides and the glycoproteins

3. What is the $T_{1/2}$ of caffeic acid derivatives?
a. 253–323 minutes
b. 0.4 to 1.9 h
c. 2–3 hours
d. 1.8–5 hours

4. What is the $T_{1/2}$ of alkylamides of *E. purpurea*?
a. 253–323 minutes
b. 0.4 to 1.9 h
c. 23 hours
d. 1.8–5 hours

5. What is the serum Cmax for the alkylamides of *E.purpurea*?
a. between 10.88–336 ng/mL
b. between 293–520 ng/ mL
c. 20–30 μg/mL
d. Cmax has not been studied for alkylamides of *E. purpurea*

6. State three basis of activity for *Echinacea purpurea's* immunomodulatory activity.
a. CB2 activation, downregulation of inflammatory cytokines, Antioxidant activity
b. CB1 activation, downregulation of inflammatory cytokines, antioxidant activity
c. CB1 activation, upregulation of inflammatory cytokines, antioxidant activity

d. CB2 activation, upregulation of inflammatory cytokines, PPARγ activity

7. List a traditional use by the Native Americans for *Echinacea* spp.
a. Snakebites
b. Coughs and sore throats
c. Toothaches
d. All of the above

8. Which answer below best defines: immunomodulator?
a. Agent that inhibits the production of inflammatory cytokines
b. Agent that catalyzes the activity of hyaluronidase
c. Agents that modulate the dynamic regulation of informational molecules such as cytokines, hormones, neurotransmitters and other proteins and peptides
d. Agent that stimulates the production of prostaglandins

9. Which cannabinoid receptor are the alkylamides known to activate? Name a tissue (or cell type) where this receptor is found.
a. CB2R in the brain
b. CB1R in the brain
c. CB2R in immune cells
d. CB1R in immune cells

10. Identify clinical indications for *Echinacea*.
i. Lowering glycosylated hemoglobin A1C
ii. Treating the common cold, flu, and upper respiratory tract infections.
iii. To increase general immune system function.
iv. Other uses may include treating non-healing wounds (topically and internally)

a. i, ii and iii
b. i, iii and iv
c. ii, iii and iv
d. All of the above

11. N. S. is a 38-year-old female with no significant past medical history, allergy to penicillin and current medication is a multivitamin with iron. Which of the following doses might you recommend to her to treat what she suspects is a cold that began bothering her this morning?
a. One teaspoon as a loading dose, followed by a half a teaspoon every two hours for the first day. Then one teaspoon three times daily for two days.
b. A single dose of 1,500 mg at the earliest onset of symptons
c. One teaspoon or a 1,500 mg capsules once daily for seven days.
d. *Echinacea* is not recommended for patients with allergy to penicillins.

12. Describe the current conclusion on drug-*Echinacea* interactions.
a. *In vitro* research shows a mild inhibition of CYP3A4.
b. Studies show CYP1A2 inhibition.
c. Inhibition of *P-glycoprotein* is problematic and *E. pallida* should be avoided.
d. A. and B. only

13. Which of the following is a major safety concerns for the use of *Echinacea* products?
a. Toxicity at doses 10 times recommended
b. Common cross-allergenicity with penicillins
c. Irreversible numbing of oral mucosa
d. No serious adverse events are commonly reported

14. What are the rare adverse events that could occur with *Echinacea* products?
a. Allergic reaction to active constituents
b. Guillain-Barre Syndrome
c. Angioedema
d. Maxillofacial neuropathy

15. What indication might the pharmacist have to predict an allergy to *Echinacea* products?
a. Asthma
b. Atopic dermatitis
c. Seasonal allergy to ragweed, chrysanthemums, marigolds, and daisies
d. All of the above

16. What warning should consumers be given about liquid extracts of *Echinacea*?
a. Alcohol concentrations may impair driving.
b. Athletes may test positive for banned substances.
c. It is common for liquid extracts to cause tingling or numbness.
d. All of the above

17. What is the toxic dose of *Echinacea* spp. products?
a. 10 times the recommended dose (15,000 mg)
b. 25 times the recommended dose (37,500 mg)
c. 50 times the recommended dose (75,000 mg)
d. Studies have not identified a toxic dose, even at 100 times the recommended dose.

18. Which formulation of *Echinacea* will have the highest alkylamide content?
a. Alcohol extract
b. Capsule of whole, dried plant
c. Juiced aerial plant

19. Which formulation will have the highest polysaccharide content?
a. Alcohol extract
b. Capsule of whole, dried plant
c. Juiced aerial plant

20. N.S. returns to the pharmacy the next day with her son. She asks the pharmacist what dose her 11-year old, 39-kilogram, son, who is otherwise healthy, can take to keep from catching her cold; how do you reply?
a. 390 mg daily
b. 858 mg daily
c. 1,500 mg daily
d. Echinacea is not recommended for children 12 and under

The Pharmacodynamics, Pharmacokinetics and Clinical Use of Echinacea Purpurea

October 1, 2012 (expires October 1, 2015) • Activity Type: Knowledge-based

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Quiz: Shade in your choice

	a	b	c	d	e		a	b	c	d	e
1.	❑	❑	❑	❑	❑	11.	❑	❑	❑	❑	❑
2.	❑	❑	❑	❑	❑	12.	❑	❑	❑	❑	❑
3.	❑	❑	❑	❑	❑	13.	❑	❑	❑	❑	❑
4.	❑	❑	❑	❑	❑	14.	❑	❑	❑	❑	❑
5.	❑	❑	❑	❑	❑	15.	❑	❑	❑	❑	❑
6.	❑	❑	❑	❑	❑	16.	❑	❑	❑	❑	❑
7.	❑	❑	❑	❑	❑	17.	❑	❑	❑	❑	❑
8.	❑	❑	❑	❑	❑	18.	❑	❑	❑	❑	❑
9.	❑	❑	❑	❑	❑	19.	❑	❑	❑	❑	❑
10.	❑	❑	❑	❑	❑	20.	❑	❑	❑	❑	❑

Quiz: Circle your choice

21. Is this program used to meet your mandatory C.E. requirements?
a. yes **b.** no

22. Type of pharmacist: **a.** owner **b.** manager **c.** employee

23. Age group: **a.** 21–30 **b.** 31–40 **c.** 41–50 **d.** 51–60 **e.** Over 60

24. Did this article achieve its stated objectives? **a.** yes **b.** no

25. How much of this program can you apply in practice?
a. all **b.** some **c.** very little **d.** none

How long did it take you to complete both the reading and the quiz? _____ minutes

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Is Elder Tech an Oxymoron Or an Opportunity?

By Bill G. Felkey

I GET OCCASIONAL pushback from my pharmacy audiences when I talk about technology use by patients. The typical feedback comes from someone who has a parent or grandparent who struggles to operate a cell phone. Technology solutions are never going to solve the problems of 100 percent of any population. With that said, we have been hearing for years about the aging of America, and as such we are in the beginning years of a tsunami of having to deal with the health care needs of this growing elder population.

Most of the pharmacists who work in long-term care focus on medication use and distribution for patients who are residents of an institution. I have been working closely with the health services for the aging industry in recent years. This industry's current focus is how to maximize their care delivery within the walls of their institutions, ranging from independent and assisted living at one end of the spectrum and skilled nursing and end-of-life care at the other. While everyone in health care who I work with has a vision that LTC is sitting out there on the continuum of care, very few have come up with support outside of established, traditional institutions.

I ask a question these days in every presentation I make. Consider your response to the following: "By a show of hands, is it important for you [and for those you love] to stay in your own home and out of an institution for as long as possible?" Would you raise one or two hands? This question seems to resonate with every audience I address. Think about it. We all love our independence. We desire to remain as healthy as possible throughout our life span. The older we get, the more likely that disease management will occupy a significant portion of our attention. Patients have adult children with active lives, but who need the peace of mind that comes from knowing that those who you care about are in as good a health status as possible.

When we are very young, our parents and grandparents see to our health for the first third of our lives. As adults, we practice self-care management throughout the second third of our lives, often with the assistance of a caring spouse. In the final third of our lives, our children frequently take a more active role in our care. Do you, as a pharmacist, have a vision for your practice that includes support for your patients and their nonprofessional caregivers throughout each of these trimesters? I am assuming that most would say yes to this question. Now, let's focus on technology in support of the elder portion of this lifespan.

HUNDREDS OF RESOURCES

The good news is that they are hundreds of technology resources available that can be targeted to support the needs of your elder patients and their families who are caring for them. These resources are frequently affordable, simple to use, and can focus on solving a single problem being experienced by patients. Others are more complex but will help manage a broader range of problems. The other good news is that resources have already been aggregated by a variety of reputable sources to assist in the identification of these technologies.

The best way to structure the business opportunity

for your practice, in this area, is to first understand the activities of daily living categories for your patients and their families. These activities, according to Wikipedia (with one category added by me) include personal hygiene and grooming; dressing and undressing; self feeding; functional transfers (getting into and out of bed or wheelchair, getting onto or off toilet, etc.); bowel and bladder management; ambulation—walking with or without use of an assistive device (walker, cane, or crutch or using a wheelchair); and medication regimen adherence. An excellent chart that you can use in your practice for assessment of these can be found at http://www.pbs.org/wgbh/caringforyourparents/caregiver/pdf/cfyp_adl_checklist.pdf.

One resource that recently assisted my siblings and me in taking care of our mother is called This Caring Home. See: http://thiscaringhome.org/. This site was produced by New York-based Weill Cornell Medical College with the assistance of several charitable grants. While the site does review technologies, it also includes tips for caregivers and the simplest solutions such as strategically placed Post-it notes that remind patients to use their glaucoma eye drops prior to going to bed.

My mother has had several strokes in the past year. Her most recent one has taken away much of her usefulness of the left side of her body. To return to an assisted living environment she must demonstrate that she is capable of exiting her apartment in the case of a fire. At night, the challenge is needing assistance in getting out of bed and into a wheelchair with only half of her body functioning. The possible solution offered on this site was called the Bed Handle, which consisted of a small, adjustable ladder that clamps to the bed frame at the edge of her mattress. The device will allow her to pull herself into a sitting position with her good right hand.

Another excellent resource is a site called Technology for Long Term Care. (See http://www.techforltc.org/). This resource zeroes directly in on the activities for daily living. It has an extensive resource in support of products that address the needs for medication management. Some of these products help patients to remember to take their medication. Others simplify a complex medication regimen, while others address problems with refill reminders and how to determine that a scheduled dose has been taken or not. The site does not allow purchasing of any of the products, but is there to assist pharmacists and patients with finding technological solutions to address specific needs.

CONSUMER ELECTRONICS GETS IN THE MIX

As you would expect, some very large corporations are focusing on this space. Companies such as General Electric and Intel have products and solutions from which to choose. The entire consumer electronics industry is producing software and devices that can be utilized. Consider products such as sensors that can turn off gas or electric stoves when they have been left unattended. There is also the shoe company Navistar, which places a GPS tracker into the heel of a shoe worn by an Alzheimer's patient. In addition, products such as the Philips Medication Dispensing device can support up to six dosing times per day and up to 40 days of medication into paper dispensing cups while communicating with external monitoring services. I would need an additional six pages of space to describe all of the mobile applications that are available in support of this area when we bring in smart phones and other information appliances to the mix.

The reality is that patients and their loved ones need some serious handholding to navigate these uncertain waters. While everyone realizes the need and motivation of patients to address this area, I am hoping that entrepreneurial pharmacists will step up and innovate the business models needed to solve important problems being faced right now by this elder population. If you have a vision for what I am describing in this article and you need someone to kick around the options, as Doc Holliday said in the movie *Tombstone*, "I'm your huckleberry." Write an email to me at felkebg@auburn.edu and we'll set up a time to talk. ap

Bill G. Felkey is professor emeritus of health care informatics at Auburn University's Harrison School of Pharmacy.

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Continued from page 8

pressed. Beneficiaries must contact the plan directly in order to enroll.

Another Settlement in Long-Running Average Wholesale Price Litigation

McKesson Corp. has agreed to pay 29 states $151 million to settle allegations that it had inflated the Average Wholesale Prices of brand name drugs that it reported to First DataBank by as much as 25 percent from Aug. 1, 2001 through Dec. 31, 2009. This caused the states' Medicaid programs to over pay millions of dollars in pharmacy reimbursements, a settlement agreement signed by the parties states.

McKesson denied the states' contentions and any wrongdoing or liability, and said it settled to avoid the uncertainty and expense of protracted litigation, according to the settlement agreement.

The states covered by the settlement are Arkansas, California, Colorado, Delaware, Florida, Georgia, Idaho, Illinois, Indiana, Iowa, Maine, Michigan, Minnesota, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Pennsylvania, South Dakota, Tennessee, Texas, Vermont, Washington, West Virginia, and Wyoming and the District of Columbia.

In April 2012, McKesson settled the federal portion of the lawsuit, which was filed by a whistleblower in 2005, for more than $187 million.

Federal and state officials have reached settlements worth more than $2 billion with drug manufacturers over drug price inflation in recent years, according to the Justice Department.

In an earlier round of the First DataBank litigation, NCPA in 2007 presented an expert witness who testified that community pharmacies never benefited from the alleged inflation of AWP because managed care plans steadily reduced AWP-based payments to pharmacies over the period. ap

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Grassroots Engagement Reaping Results for Pharmacies, Patients

By Michael Rule

Over the past few months, community pharmacy grassroots efforts have led to some modest, but important, legislative and regulatory victories in Washington for community pharmacists and the patients they serve. Continued grassroots engagement by pharmacists will drive future successes.

While NCPA and independent community pharmacy share the concerns of policymakers in regard to prescription drug abuse and drug diversion of hydrocodone products, for example, we had serious concerns that proposals to reschedule hydrocodone-containing products to Schedule II wasn't the most practical approach and could have serious, negative potential consequences for patients. Due in part to more than 1,000 pharmacist emails and phone calls to their legislators, the proposed reclassification was rejected. While our voices and those of patient advocates carried the day, NCPA and its members remain committed to working with policymakers to find a workable solution that addresses the problems of prescription drug abuse.

But voices of individual pharmacists will be needed to echo the message.

Additionally, the grassroots efforts of pharmacists have increased congressional awareness of potential efforts by the Pentagon to further incentivize mail order usage in TRICARE. This will be addressed in the Department of Defense Authorization bill that Congress is expected to pass this fall. The proposals are less harmful to patient choice than the original Pentagon proposal, and the fact that Congress is addressing it has led the Pentagon to withdraw a proposal creating further mail order incentives. Additionally, eight bipartisan House members have asked DoD to audit TRICARE's mail order program with an eye on the extent which unneeded or incorrect drugs are sent that wind up as waste. NCPA will continue to evaluate the TRICARE pharmacy benefit and will strenuously work to advocate for TRICARE beneficiaries' choice and to maintain adequate access to independent community pharmacies. But voices of individual pharmacists will be needed to echo the message. Also, Congress will likely take up legislation after the Nov. 6 elections to address taxes and spending. It is possible that community pharmacies and their patients could be affected, positively or negatively, by the decisions Congress makes on what to include in this package.

While these modest successes are welcome, obviously major marketplace and legislative challenges remain. That is all the more reason for independent community pharmacy to remain engaged and/or get involved.

To be successful, it is imperative that independent community pharmacy owners, their employees, and their patients, take a few moments to contact their members of Congress and demand that issues such as MACs, audits, and access to diabetes testing supplies for Medicare beneficiaries be addressed before the end of the year. Please visit the NCPA Legislative Action Center (www.ncpa-actioncenter.com/) to look up your elected officials and their contact information. ap

Michael Rule is NCPA's manager of public affairs and grassroots advocacy.

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