Pharmacy specialization means better patient care 6

NACDS Total Store Expo offers business opportunity 16

Pay for performance: Are you ready? 35

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MORE THAN TWO THIRDS OF PHARMACISTS STILL HOPEFUL ABOUT BUSINESS CLIMATE

PAGE 24

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Drug Topics, a monthly news magazine guided by an editorial advisory board of pharmacy experts, reports on all phases of community, retail, and health-system issues and trends. We offer a forum for pharmacists to share practical ideas for better pharmacy management and patient care.

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**CONTENT**

- **CONTENT CHANNEL DIRECTOR** Julia Talisma
  (440) 891-2779 / jtalsima@advanstar.com

- **CONTENT CHANNEL MANAGER** Julianne Stein
  (440) 826-2834 / jstein@advanstar.com

- **CONTENT EDITOR** Tara Camera
  (440) 891-2795 / tcamera@advanstar.com

- **DIGITAL & INTERACTIVE CONTENT MANAGER** Brandon Glenn
  (440) 891-2638 / bglenn@advanstar.com

- **CONTENT COORDINATOR** Miranda Hester

- **GROUP ART DIRECTOR** Robert McGarr
  ART DIRECTOR Nicole Davis

- **PUBLISHING AND SALES**
  EXECUTIVE VICE PRESIDENT Georgiann DeCenzo
  (440) 891-2778 / gdecenzo@advanstar.com

  VIC PRESIDENT, GROUP PUBLISHER Ken Sylvia
  (732) 346-3037 / ksvilsa@advanstar.com

  NATIONAL ACCOUNT MANAGER Sharon Ames
  (732) 346-3033 / simes@advanstar.com

  NATIONAL ACCOUNT MANAGER Phil Molinaro
  (732) 346-3074 / pmolinaro@advanstar.com

  ACCOUNT MANAGER, CLASSIFIED/ DISPLAY ADVERTISING Darlene Balzano
  (440) 891-2779 / dbalzano@advanstar.com

  ACCOUNT MANAGER, RECRUITMENT ADVERTISING Jacqueline Moran
  (800) 225-4569, ext. 2762 / jmoran@advanstar.com

  DIRECTOR, SALES DATA Gail Kaye
  (732) 346-3042 / gkaye@advanstar.com

  SALES SUPPORT Hannah Curis
  (732) 346-3005 / hcuris@advanstar.com

- **LIST ACCOUNT EXECUTIVE** Tamara Phillips
  (440) 891-2773 / tphillips@advanstar.com

- **PERMISSIONS** Maureen Cannon
  (440) 891-2742 or (800) 225-4569 ext. 2742
  Fax: (440) 891-2650 / mcannon@advanstar.com

- **AUDIO/VIDEO CONTENT DIRECTOR** Tanya Goya
  (440) 891-2742 / tgoya@advanstar.com

- **MANAGER** Joe Martin
  (218) 740-6375 / jmartin@advanstar.com

- **PERMISSIONS** Tamara Phillips
  (440) 891-2742 or (800) 225-4569 ext. 2742
  Fax: (440) 891-2650 / mcannon@advanstar.com

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  (440) 891-2742 / tgoya@advanstar.com

- **MANAGER** Joe Martin
  (218) 740-6375 / jmartin@advanstar.com

**REPRINT SERVICES**
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**LIST ACCOUNT EXECUTIVE** Tamara Phillips
(440) 891-2773 / tphillips@advanstar.com

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(440) 891-2742 or (800) 225-4569 ext. 2742
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**PRODUCTION**

- SENIOR PRODUCTION MANAGER Karen Lenzen
  (218) 740-6371 / klenzen@mediaadvanstar.com

**AUDIENCE DEVELOPMENT**

- CORPORATE DIRECTOR Joy Puzzo
  (440) 319-9570 / jpuzzo@advanstar.com

- DIRECTOR Christine Shappell
  (201) 391-2559 / cshappell@advanstar.com

- MANAGER Joe Martin
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Community pharmacists are not quite as confident that 2013 will outperform 2012 in terms of sales volume and net profits. Health-system pharmacists are a bit more optimistic about the new year. PAGE 24

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Long-term complications

Pharmacists can help prevent the development or progression of macrovascular and microvascular complications of diabetes mellitus and improve diabetes care. PAGE 44

COUNTER POINTS

6 Pharmacy specialization

8 Educate patients about herbal supplements risk

10 Are you a role model for the next generation of pharmacists?

11 VIEW FROM THE ZOO
Benefits from pharmacy cannot always be measured

12 JP AT LARGE
You are a pharmacist, right?

15 LETTERS

62 FINAL WORD
Provider status is long overdue

ISSUES & TRENDS

16 UPFRONT
Walgreens receives Medical Home accreditation

20 UPFRONT IN DEPTH
Short-cycle dispensing for LTC

21 CHAINS AND BUSINESS
Questions are the answers

CLINICAL

36 MEDICATION SAFETY

39 ANTICOAGULATION
New indications for rivaroxaban

43 NEW DRUG REVIEW
A focus on teriflunomide (Aubagio)

REGULATORY & LEGAL

53 AN UNEXPECTED TURN
Tragedy becoms call for new federal legislation

PRODUCT UPDATES

54 COLD AND FLU RELIEF
In search for relief from coughs, colds, sore throats, flu symptoms

57 NEW RX PRODUCTS
See latest FDA approvals from Greenstone and others

DT BLOG

Issues in emergency pharmacy practice
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Specialization is pharmacy’s future

The future of pharmacy—a healthcare profession in which the role in patient treatment and care is continually growing—is specialization. It is pharmacy specialization that will enable our healthcare system to meet the mandate of controlling cost by improving medical outcomes. This will be accomplished through the provision of more care in community settings, as well as by reducing unnecessary hospital readmissions.

We are already seeing it happen. Where, once, all pharmacy services were provided in one place, specialty pharmacies are currently operating in areas such as oncology, geriatrics, diabetes, fertility, HIV, psychiatry, nuclear medicine, nutrition support, the compounding of specialty medications, and pharmacotherapy. Various pharmacy specialty certifications are granted through organizations such as the American Pharmacists Association, the Board of Pharmacy Specialties, the American Society of Health-System Pharmacists, and the American College of Clinical Pharmacy.

I never envisioned the degree of specialization that exists today when I converted my retail pharmacy to one of the nation’s first women’s health and fertility pharmacies in 1982. At that time, specialty pharmacy was considered to be on the periphery of pharmacy, in much the same way that some consider alternative medicine to be on the periphery of the medical field.

The current trend toward pharmacy specialization is rooted in many factors. Chief among them is that pharmacy students today receive more clinical training than ever before. The six-year PharmD program includes many more hours of clinical medication management than did the shorter programs. Residency and fellowship requirements for pharmacists have also become increasingly stringent and demanding.

Also supporting the drive toward specialization is the heightened role of the pharmacist as a collaborator on the patient care team. The nation is confronted with a shortage of primary care physicians, and this has led to the elevation of other members of the care team, including nurse practitioners, physician assistants, and pharmacists. As pharmacists become more involved in evaluating a patient’s therapeutic options, they will need to possess expertise in a broad array of different areas. This is where a specialized approach will be particularly needed.

Pharmacists will be able to drive more cost-effective approaches to treatment because they are trained in these therapies. They can monitor patients and make changes to drug therapies based on a patient’s response, eliminating ineffective treatments that are high in cost, and ensuring that the most targeted and effective therapy is being used. And with $750 billion—with a “b”—in annual, unnecessary healthcare spending, according to the Institute of Medicine, there is no time like the present.

In-home assessments
Massachusetts-based Dovetail Health uses pharmacist care managers to conduct in-home patient assessments. The observations these pharmacists make regarding a patient’s response to a medication can avert costly emergency department visits and hospital readmissions. The pharmacists are capable of doing this work because they know how medications work and how patients should be responding, but they also are trained in how to manage the other complex risk factors that are often present with elderly and sometimes frail patients.

Pharmacy specialists will also play a bigger role in the Risk Evaluation and Mitigation Strategy (REMS) process, which can keep ineffective drugs off the market.

That the pharmacy industry is moving toward specialization portends better patient care and cost savings for patients and healthcare payers.

As the escalation of healthcare costs leads to new approaches in care—approaches that patients want—the time is right for working smarter and doing things differently. Pharmacy specialization will lead to lower cost and better care. It is time for the profession to embrace it wholeheartedly.

Ernest P. Gates, Jr., RPh, FASCP, FIACP, FACA

Ernest P. Gates, Jr., RPh, FASCP, FIACP, FACA, is the president of Gates Healthcare Associates (http://www.gatesconsult.com/).
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Warn about herbal supplements risk

During our public health rotation, Tommy Wong, my classmate, and I became aware of how often pharmacists are approached with the question: “Where are your supplements?” And, without hesitation, patients are directed to the supplement aisle while pharmacists continue with their other responsibilities.

Sales of herbal supplements have increased such that approximately 20% of the population are using herbal supplements.1 In fact, 72% of individuals using supplements will continue using them even if they were proven to be ineffective.2 Pharmacists need to be more informed about herbal supplements and provide information to patients about their relative benefits and risks.

Rarely are patients asked why they are considering taking herbal supplements, what other medications they are currently taking, and whether they have health issues that may complicate herbal supplement usage. There is a potential that using herbal supplements can do more harm than good.1 The 1994 Dietary Supplement Health and Education Act (DSHEA) classifies herbal and botanical products as dietary supplements, and therefore, herbal products are able to be marketed freely.3

Suboptimal products
The problem with this is that the assurance of safety, efficacy, and quality control of these products continues to be suboptimal.1 Herbal preparations may vary among different manufacturers and even from batch to batch within the same manufacturer.1 Information on the labels can be misleading. Prescription medications such as steroids, nonsteroidal anti-inflammatory drugs (NSAIDs), prescription antibiotics, sedatives, and narcotics have been found in these so-called “natural” products.2

This issue is of a particular concern in Chinese communities and where herbal supplements are readily available. U.S. herbal remedies include imported Asian-patented medicines that have been identified to contain unauthorized or toxic ingredients and Rx medications.1 Wong, fluent in reading Chinese, researched herals locally in Oakland’s Chinatown and found several products with misleading information and containing unauthorized agents. Prescription-only ingredients such as erythromycin were available over the counter as eye ointment. Products such as URI Tract Care Formula (Niao Lu Xian Yan Ling) is marketed “to help with inflammation of the urinary tract” in Chinese. However, the English translation only states to “help promote and maintain a healthy urinary system by establishing the body’s natural balance.” Niu Huang Jie Du Pian is a popular product advertised to help treat swelling, upset stomach, and sores in the mouth. Although it is indicated to be “safe and reliable,” there were many ingredients found in it that may interact with anticoagulants and antiplatelet drugs by increasing the risk of bleeding.

Some formulations may include acetaminophen, even though they are noted as “natural.” Patients may not look at product labeling and are at a higher risk of liver damage, especially if they are taking medications containing acetaminophen. These were just a few examples that were found at local Chinese herbal stores, demonstrating that drug-herbal interactions are just as important to keep in mind as drug-drug interactions.

Unfortunately, consumers are usually only educated about herbal supplements. They believe that, at best, herbal supplements will improve their health and, at worst, there is no impact because they are “natural” anyway.

This is why the role of pharmacists is so important. Pharmacists have the responsibility to educate and help people understand why it may be dangerous to take herbal supplements in conjunction with prescription medication. Providing this full spectrum of knowledge can result in overall better healthcare for our patients.07

References

Michael Hang is a 2013 PharmD candidate at Touro University-California, College of Pharmacy. He can be reached at michael.hang@tu.edu.
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Are you a role model for the next generation of pharmacists?

Many of us had role models that influenced us to enter the pharmacy profession. Back in the 1970s, there was an independent retail pharmacy located across the street from the hospital in the small western suburb of Chicago, Berwyn, Ill. They filled prescriptions. No magazines, milk, bread, eggs, or cigarettes. It was purely an ethical pharmacy.

To a youngster, it always seemed busy, with customers continually coming in and out. A brass bell rang when the front door was opened and closed. It even smelled like a pharmacy! The pharmacists were always in motion, typing prescription labels, filling prescriptions, answering the phone, ringing up customers, and counseling patients. One pharmacist even smoked behind the counter. (It was the 1970s.)

In any case, these individuals always seemed cheerful, competent, and willing to help. My mother would take me there when I was sick. She would ask the pharmacist what he thought was wrong with me and what she needed to do. The pharmacist would take a brief history of my symptoms from my mother or me, assess me, and advise my mother accordingly. Sometimes, he would recommend over-the-counter (OTC) medications for symptomatic relief for self-limiting illnesses. Once in a while, the recommendation was to “Take Mark to see the doctor!” These pharmacists were well respected in the community. Role models for future pharmacists—including me!

Over the last 25 years of pharmacy practice, I have had my share of mothers bring their children to me for advice on medical issues. I’ve recommended OTC medications for symptomatic relief of self-limiting illnesses. And, yes, I’ve advised parents to take their child to see their doctor. It’s rewarding to have someone value your opinion and trust your judgment.

Why a career as a pharmacist?

Frequently, teenagers and young adults approach me to ask why I picked pharmacy as a career choice. I tell them, “Because I enjoyed science and wanted to help people.” Are you a role model in your community? Are you inspiring the next generation of pharmacists? Or are you a negative role model? Does what you say, your nonverbal communication, and your body language communicate “I enjoy being a pharmacist”? At a recent conference I attended, the speaker stressed, accurately, “To succeed in healthcare, you must excel!” Do you add a “wow factor” to your patient and physician interactions?

If you are uncertain, you may need to conduct a personal “reality check.” Am I clinically competent? Am I reading enough? Do I need to go back for a “refresher course” offered through a college of pharmacy? If your state pharmacy organization or college of pharmacy offers a Medication Therapy Management (MTM) certification, obtain it!

Practicing MTM skills on Sunday

I have the opportunity to practice my MTM skills every Sunday at church. Yes, at church. Every Sunday morning, I usually have a line of older ladies and gentlemen who know I’m a pharmacist and want to ask me questions about medications or a medical condition. If you do not belong to a house of worship, consider offering your availability through a service organization or social club in your community. Consider giving talks at the local junior high or high school on career day. Reach out to contacts at the local college of pharmacy. Perhaps they hold a career fair and would welcome you as a guest speaker for individuals interested in pharmacy.

Keep in mind that, regardless of the practice environment, you are a potential role model for the next generation of pharmacists. If you see yourself as a role model, why not promote the profession? You can start by presenting yourself in a positive manner in your current role. It may be as simple as striving to provide the best customer service, smiling, or listening empathetically to a patient or customer. Like it or not, you are a role model for the next generation of pharmacists!

Mark E. Greg, PharmD, is a clinical pharmacist with Advocate Physician Partners in Oak Brook, Ill. E-mail him at mark.greg@advocatehealth.com.

Mark E. Greg, PharmD

IN MY VIEW Mark E. Greg, PharmD

Are you a role model for the next generation of pharmacists?
One thing I've never seen in this coastal jewel is a supertanker pull into port. The reason for that was standing across the counter from me this workday. If you've ever seen the Monterey Bay, you would be shocked to know that at one point people wanted to do exactly that. You could even be excused for flat not believing it, as I did when I first heard the tale of the woman at my counter.

Validating rumors
There's no marker along the shoreline to note what she had done, no note at the world-famous aquarium, not even much of any general awareness in the community. The word "tale" might actually be a little strong. The story of the woman at my counter was more like a rumor. Still, my writer's instinct said there would be a great story here if it turned out to be true, so I hit the library to do a little research. Sure enough, I found articles in the newspaper archives suggesting the supertanker scheme was a fait accompli, one mere rubber stamp away from being implemented.

Big environmental groups had taken their shot at stopping it and lost — rolled over by a political machine on a mission that nobody could stop. Until one person got involved.

What I saw in those newspaper archives was a force of nature, organizing, agitating, biting into the establishment and not letting go. “Tanker Berth Okayed” read the headline from April 1979. Fourteen months later that had changed to “Army Engineers Deny Permit For Port.” The stories in between explained how the woman at my counter, almost single-handedly, made it happen.

Glimpsing a time past
Today she's ravaged by Alzheimer's disease. Frail and declining far too quickly. She has only the faintest recollection of what she accomplished. When I see her I’m reminded that, while I am indeed fortunate to be surrounded by the beauty of this place, it took more than just luck to make it happen.

People that came before me hoped and dreamed and worked and fought and paved the way not only to ensure that precious places got preserved, but for so many of the things that give me and so many others an incredible quality of life. You make your own luck in this world, and when people work together, we can ensure that we are all lucky indeed.

Serving the patient
The woman who stopped the ships needed some help that day, and I was glad to give it. Sinuses were clogged and it was reported to me that she was feeling miserable. I gave her a little guidance through the cough and cold product maze, determined that some-thing she already had in her medicine box was exactly what she needed, and thought about how what I was doing was something that would make it harder to meet any business metrics that come down from above.

Nothing in that conversation would be measured. No data generated that could be printed out to show that goals were being met, which says something about the goals those in charge of our profession choose to measure.

Later it was reported to me the woman who stopped the ships was feeling better. She won't be here much longer, but there will never be a day when I look outside my window and see a supertanker. Regardless of any chart or graph that would generate at the end of the business day, I knew my goal was met. Every customer at your counter has a story, and every person you see can benefit from your profession. There's a reason they call it community pharmacy. Don't forget it, and don't let anything take it away from you.
How many times have you wanted to reach over the counter with your feminine right hand and give Ms. Pompous and her supercilious smirk a good slap? “Yes, I am the pharmacist and I am a doctor. You will call me Dr. Patel from now on or you get another slap.” You stab at her with your right forefinger. “I am an American and if I go back where I came from it will be with my American husband named Perkins and my American son to see my mom and dad in the west suburbs of Chicago to celebrate Christmas.”

A copay dispute
That felt good, but it would not be helpful. How do you turn around and double-slap Ms. Pompous when she demands a $5 copay for an antibiotic prescription?
“I have Bazooka Excellent-Level Prescription Insurance powered by Out-to-Pasture Citizens Association. My copay is not $20,” she insists.

What you want to say is: “You have Bazooka Chicken-Level Insurance powered by Insurance Pimp Association.”

With a smile and a sugary tone, you say: “Bazooka is spelled M-A-I-L O-R-D-E-R, Ms. Pompous. You can get 30 days right here at your neighborhood drug store just a block from your house with a half hour wait, or you can get 90 days for $5 from the Real Supply Dispensary that is owned and operated by Bazooka in a warehouse in the Sonora Desert 3,000 miles from your home, with a wait of at least 10 days. If you want this prescription before 10 o’clock this morning, it will cost you 20 bucks.”

“I hate mail order,” she argues. “I told you I have Bazooka Excellent-Lev....” Ms. Pompous throws her forearm over her face. “Please Doctor Paddle, don’t be mean to me. I’m just an old lady who needs her medicine.”

“Oh for gawd’s sake, you are barely 65 years old. That is the new 45. You bought crappy insurance,” you respond.

“But it is excellent-level,” she says again. She is arguing with you now, as if that would make you give her a $5 copay.

“Excellent is their lowest level. Platinum is Bazooka’s best.”

Make someone happy
Oh oh, the non-pharmacist store idiot is watching you. The next thing you know she will hand Ms. Pompous a $50 gift card to make her happy. Big Stupid Drug Store with a share price of less than what they charge for a 20-ounce diet cola has been throwing money as the solution to everything for over a decade.

The gift card changes hands. Ms. Pompous hands over the antibiotic prescription. She grins, “You said 10 minutes?”

“But more like 45 now. There are three more people ahead of you,” you say. The store idiot is about to say something, but you stare her down. She can give away the store if she wants, as long as Big Stupid never misses a payroll. She needs to keep her nose out of the pharmacy. That is your domain.

Ms. Pompous is now your friend.

“One can’t get my eye drops from you? They are supposed to stay refrigerated.”

Your staff pharmacist is a strapping young man from farming country. You don’t want to get slapped by him. He has been listening. He holds up a box. Latanoprost ophthalmic solution by Greenstone, a progenitor of that venerable brand Upjohn. Is Dr. William rolling over in his grave?

“That’s it. That’s my refrigerated eye drop.”

The staff pharmacist hands it to her, “Read it and weep,” he drawls. “Read under the red letters.”

During shipment to the patient, the bottle may be maintained at temperatures up to 40° C (104° F) for a period not exceeding 8 days.

Why do we have to refrigerate this stuff at all? Talk about pimping. This is brazen pandering to the mail-order outfits. Greenstone has the nerve to print on the back panel: Store unopened bottle under refrigeration at 2° to 8° C (35° to 46° F). I didn’t know that the U.S. Postal Service has changed the storage standard of no higher than 78° F. I think that you will find that most states define drugs stored at temperatures exceeding 78° F as adulterated. What about pills sitting in a mail box in July over the weekend in south Texas? Are the state three monkey board$ ignoring patient safety? Let them conduct a meeting in a closed, parked mail truck in the sun.

Jim Plagakis is a community pharmacist in Galveston, Texas. You can e-mail him at jpgakis@hotmail.com and cc us at drugtopics@advanstar.com. You can also check out his website at jimplagakis.com.
Letters

What about pharmacists’ rights?
I read the October issue and have never been left with such a bitter taste in my mouth after reading a pharmacy publication.

Starting with Frederick Mayer’s “Patient Bill of Rights for Prescription Drugs,” nowhere mentioned are the pharmacists’ rights, starting with the right to set the prices for providing all of the services that Mr. Mayer asserts should be rights of the patient. Yes, they are good ideals, but the reimbursement we’re seeing for medications is no longer enough to even cover the cost of dispensing the meds, let alone provide a bunch of ‘extras’.

Right after that was David Stanley’s “Feeling Like a Real Pharmacist.” I’m glad he had that experience, but really, should the lady who was ‘beyond embarrassed’ have expected that advice for free? What he provided to her had real value, as well as providing him with a sense of professional pride—yet it was provided for free which only promotes the idea that a pharmacist’s advice has no value. Make an appointment with a doctor or lawyer and you expect to pay. Contact a pharmacist for advice that can have major repercussions on your life and a request for payment is unexpected and offensive.

Finally, I made it through the rest of the magazine and at the end was Ned Milenkovich’s “Pharmacy Cooperative Settles Price Fixing Charges.” Just the memory of reading that one gives me a hopeless feeling for the profession. We all know who is fixing the prices. Why is it that when a group of pharmacists get together to demand true negotiation and fair reimbursement, they’re demonized and tagged with the label of causing “higher prices for Puerto Rico’s healthcare consumers”? Did the FTC consider the pharmacy’s costs in reaching their conclusion, or just take the PBM’s word for it that because its right to set the prices was challenged that somebody else was acting illegally? In any case, for the FTC to allow the merger of Express Scripts and Medco, and then turn around and accuse ANY pharmacy of price fixing is beyond belief and sends a clear message that anyone who claims to lower prices for the consumer is automatically right, anything that raises prices is wrong, and that open and fair negotiation between two parties is unnecessary.

So go ahead. Throw a burden of extra patient ‘rights’ at us. Don’t allow us to charge a fee for expert advice. Give the PBMs clear permission to merge as much as they want, force or badger our patients to use the pharmacies that they own, and
Walgreens receives Medical Home accreditation

Many of the primary care worksite health centers managed by Walgreens Employer Solutions Group have received Medical Home accreditation from the Accreditation Association for Ambulatory Health Care (AAAHC), the company recently announced. By the middle of 2013, the company says all of its employer-based primary care centers will be accredited.

The accreditation recognizes that each of the worksite health centers complies with clinical, quality, and organizational standards established by AAAHC for patient-centered medical homes.

“This accreditation recognizes that worksite clinics and these primary care worksites can be a key point of access, serving as a medical home to provide coordinated care to patients and clients,” the company said.

More employers are exploring on-site health and wellness services to keep workers healthy, productive, and on the job, according to a 2012 survey by Towers Watson and the National Business Group on Health.

According to the report, many employers feel that these on-site services have a direct impact on employee productivity by decreasing the travel and wait times associated with visits to primary care physicians. In addition, many employers are expanding this access to spouses and dependents, which signifies the perceived value of these on-site clinics, the report notes.

“We’re proud to have received accreditation from AAAHC, an organization that shares our commitment to ensuring healthcare delivery meets the highest quality standards and is coordinated across the healthcare spectrum, benefitting both employers and employees,” said Trent Riley, divisional vice president for Walgreens Health and Wellness division.

—Heather Onorati, Contributing Editor

NACDS Total Store Expo offers unique business opportunity in August

This year the National Association of Chain Drug Stores (NACDS) is offering a one-of-a-kind business opportunity by combining its three trade shows—the Marketplace Conference, the Pharmacy and Technology Conference, and the Supply Chain & Logistics Conference—into one, Total Store Expo.

From August 10-13, 2013, the NACDS Total Store Expo will offer participants from the retail side and the supplier, manufacturing, and technology side to come together at one forum for productive conversations and potential business opportunities. The Total Store Expo will be held at the Sands Expo and Convention Center in Las Vegas, NV.

“Senior leaders and executives of the industry are going to be able to attend one show, instead of three, making it a much more efficient use of time for everyone concerned. It has the potential for doing business in a new more productive way,” explained Jim Whitman, senior vice president of NACDS.

Retail buyers from more than 250 companies, representing approximately 145,000 retail outlets are expected to be in attendance. At the Meet the Market session held on August 10, new small- and mid-sized companies will be able to meet with retailers during 10-minute appointments.

“It has been very effective to introduce yourself, your company, your products, and to learn about some of the requirements of the retail buyers. Not everyone does business the same,” explained Whitman. “You can have a meeting anywhere. It can be at Meet the Market, at the traditional exhibit floor, or at a cocktail reception in terms of networking. So our goal on Saturday through Monday is to have multiple areas for interaction and opportunity for conversation and business.”

Total Store Expo also offers attendees sessions to learn about business and pharmacy topics during the business and educational programs on Sunday and Monday, he said. Individuals can attend any of the supply chain and logistics sessions, pharmacy and technology sessions, and front-end consumer goods sessions as well as crossover sessions. “This is a great opportunity to get employees engaged in other areas within their own company,” Whitman noted. The pharmacy sessions will offer CPE credits.

Exhibitor space is still available for the Total Store Expo and can be purchased online. Go to http://tse.nacds.org and click on Exhibitors and then Floorplan to see a map of the show floor. In the lower left corner, click on View Available Booths to see what space is still available for purchase.

If you need more information about registering for the NACDS Total Store Expo, visit http://tse.nacds.org/ or email registration@nacds.org.

—Julia Talsma, Content Channel Director
Indications and Usage

VASCEPA (icosapent ethyl) is indicated as an adjunct to diet to reduce triglyceride (TG) levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridemia.

• The effect of VASCEPA on the risk for pancreatitis in patients with severe hypertriglyceridemia has not been determined.
• The effect of VASCEPA on cardiovascular mortality and morbidity in patients with severe hypertriglyceridemia has not been determined.

Please go to www.VASCEPA.com for full Prescribing Information and more information on VASCEPA
**VASCPEPA® (icosapent ethyl) Capsules, for oral use**

**Brief summary of Prescribing Information**

Please see Full Prescribing Information for additional information about VASCPEPA.

1 **INDICATIONS AND USAGE**

VASCPEPA® (icosapent ethyl) is indicated as an adjunct to diet to reduce triglyceride (TG) levels in adults with patients with severe (≥500 mg/dL) hypertriglyceridemia.

**Usage Considerations:** Patients should be placed on an appropriate lipid-lowering diet and exercise regimen before receiving VASCPEPA and should continue this diet and exercise regimen with VASCPEPA.

Attempts should be made to control all medical problems such as diabetes mellitus, hypothyroidism, and alcohol intake that may contribute to lipid abnormalities. Medications known to exacerbate hypertriglyceridemia (such as beta blockers, thiazides, estrogen) should be discontinued or changed, if possible, prior to consideration of TG-lowering drug therapy.

**Limitations of Use:**

- The effect of VASCPEPA on the risk for pancreatitis in patients with severe hypertriglyceridemia has not been determined.
- The effect of VASCPEPA on cardiovascular mortality and morbidity in patients with severe hypertriglyceridemia has not been determined.

2 **DOSAGE AND ADMINISTRATION**

Assess lipid levels before initiating therapy. Identify other causes (e.g., diabetes mellitus, hypothyroidism or medications) of high triglyceride levels and manage as appropriate. [see Indications and Usage (1)].

Patients should engage in appropriate nutritional intake and physical activity before receiving VASCPEPA, which should continue during treatment with VASCPEPA. The daily dose of VASCPEPA is 4 grams per day taken as 2 capsules twice daily with food. Patients should be advised to swallow VASCPEPA capsules whole. Do not break open, crush, dissolve, or chew VASCPEPA.

4 **CONTRAINDICATIONS**

VASCPEPA is contraindicated in patients with known hypersensitivity (e.g., anaphylactic reaction) to VASCPEPA or any of its components.

5 **WARNINGS AND PRECAUTIONS**

5.1 Monitoring: Laboratory Tests

In patients with hepatic impairment, alanine aminotransferase (ALT) and aspartate aminotransferase (AST) levels should be monitored periodically during therapy with VASCPEPA.

5.2 Fish Allergy

VASCPEPA contains ethyl esters of the omega-3 fatty acids, eicosapentaenoic acid (EPA), obtained from the oil of fish. It is not known whether patients with allergies to fish and/or shellfish are at increased risk of an allergic reaction to VASCPEPA should be used with caution in patients with known hypersensitivity to fish and/or shellfish.

6 **ADVERSE REACTIONS**

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Adverse reactions reported in at least 2% and at a greater rate than placebo for patients treated with VASCPEPA based on pooled data across two clinical studies are listed in Table 1.

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>Placebo (N=309)</th>
<th>VASCPEPA (N=612)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arthralgia</td>
<td>3</td>
<td>10</td>
</tr>
<tr>
<td>%</td>
<td>1.0</td>
<td>1.6</td>
</tr>
<tr>
<td>n</td>
<td>14</td>
<td>23</td>
</tr>
</tbody>
</table>

*Studies included patients with triglycerides values of 200 to 2000 mg/dL.

An additional adverse reaction from clinical studies was oropharyngeal pain.

7 **DRUG INTERACTIONS**

7.1 Anticoagulants

Some published studies with omega-3 fatty acids have demonstrated prolongation of bleeding time. The prolongation of bleeding time reported in those studies has not exceeded normal limits and did not produce clinically significant bleeding episodes. Patients receiving treatment with VASCPEPA and other drugs affecting coagulation (e.g., anti-platelet agents) should be monitored periodically.

8 **USE IN SPECIFIC POPULATIONS**

8.1 Pregnancy

Pregnancy Category C: There are no adequate and well-controlled studies in pregnant women. It is unknown whether VASCPEPA can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. VASCPEPA should be used during pregnancy only if the potential benefit to the patient justifies the potential risk to the fetus. In pregnant rats given oral gavage doses of 0.3, 1 and 2 kg/g/day icosapent ethyl from gestation through organogenesis all drug treated groups had visceral or skeletal abnormalities including: 13 reduced ribs, additional liver lobes, testes mediately displaced and/or not descended at human systemic exposures following an oral dose of 4 g/day based on body surface area comparisons.

In a multigenerational developmental study in pregnant rats given oral gavage doses of 0.3, 1, 3 g/kg/day ethyl-EMA from gestation day 7-17, an increased incidence of absent optic nerves and unilateral testes atrophy were observed at ≥0.3 g/kg/day at human systemic exposure following an oral dose of 4 g/day based on body surface area comparisons across species. Additional variations consisting of early incisor eruption and increased percent cervical ribs were observed at the same exposures. Pups from high dose treated dams exhibited decreased copulation rates, delayed estrus, decreased implantations and decreased surviving fetuses (F2) suggesting multigenerational effects of ethyl-EMA at 7 times human systemic exposure following 4 g/day based on body surface area comparisons across species.

In pregnant rabbits given oral gavage doses of 0.1, 0.3, and 1 g/kg/day from gestation through organogenesis there were increased dead fetuses at 1 g/kg/day secondary to maternal toxicity (significantly decreased food consumption and body weight loss).

In pregnant rats given ethyl-EMA from gestation day 17 through lactation day 20 at 0.3, 1, 3 g/kg/day complete litter loss was observed in 2/23 litters at the low dose and 1/23 mid-dose dams by post-natal day 4 at human exposures based on a maximum dose of 4 g/day comparing body surface areas across species.

8.3 Nursing Mothers

Studies with omega-3-acid ethyl esters have demonstrated excretion in human milk. The effect of this excretion is unknown; caution should be exercised when VASCPEPA is administered to a nursing mother. In lactating rats, given oral gavage “C-ethyl EPA, drug levels were 6 to 14 times higher in milk than in plasma.

8.4 Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

8.5 Geriatric Use

Of the total number of subjects in clinical studies of VASCPEPA, 33% were 65 years of age and over. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

9 **DRUG ABUSE AND DEPENDENCE**

VASCPEPA does not have any known drug abuse or withdrawal effects.

10 **NONCLINICAL TOXICOLOGY**

10.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

In a 2-year rat carcinogenicity study with oral gavage doses of 0.09, 0.27, and 0.91 g/kg/day icosapent ethyl, respectively, males did not exhibit drug-related neoplasms. Hemangomas and hemangioscarcomas of the mesenteric lymph node, the site of drug absorption, were observed in females at clinically relevant exposures based on species differences across species relative to the maximum clinical dose of 4 g/day. Overall incidence of hemangomas and hemangioscarcomas in all vascular tissues did not increase with treatment.

In a 6-month carcinogenicity study in Tg.rasH2 transgenic mice with oral gavage doses of 0.3, 1, 2, and 4.6 g/kg/day icosapent ethyl, drug-related incidences of benign squamous cell papilloma in the skin and subcutis of the tail was observed in high dose male mice. The papillomas were considered to develop secondary to chronic irritation of the proximal tail associated with fecal excretion of oil and therefore not clinically relevant. Drug-related neoplasms were not observed in female mice.

Icosapent ethyl was not mutagenic with or without metabolic activation in the bacterial mutagenicity ( Ames ) assay or in the in vitro mouse micronucleus assay. A chromosomal aberration assay in Chinese Hamster Ovary (CHO) cells was positive for clastogenicity with and without metabolic activation.

In an oral gavage rat fertility study, ethyl-EMA, administered at doses of 0.3, 1, and 3 g/kg/day to male rats for 9 weeks before mating and to female rats for 14 days before mating through day 7 of gestation, increased anogenital distance in female pups and increased cervical ribs were observed at 3 g/kg/day (7 times human systemic exposure with 4 g/day clinical dose based on a body surface area comparison).

17 **PATIENT COUNSELING INFORMATION**

17.1 Information for Patients

See VASCPEPA Full Package Insert for Patient Counseling Information.

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Manufactured by: Catalent Pharma Solutions, LLC, St. Petersburg, FL, USA

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**Amarin**

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12/2012 120707
**NABP action plan created to help enforce compounding regulations**

Last month NABP Executive Director Carmen Catizone, MS, RPh, unveiled an action plan to inspect nonresident compounding pharmacies and create a database to share regulatory information about these pharmacies with the state boards of pharmacy nationwide. This was in response to the fungal meningitis outbreak that took the lives of 39 individuals and injured more than 600.

Catizone spoke to attendees of the American Society of Health-System Pharmacists (ASHP) Midyear meeting in Las Vegas.

These patients had received contaminated compounded steroid injections that were produced and distributed by the New England Compounding Center, Framingham, Mass.

“This is a tragedy like no other that NABP has faced,” said Catizone who has served the association for 27 years. “This issue has totally consumed NABP and the state boards of pharmacy. This will change pharmacy regulation like no one has anticipated.”

NABP’s action plan began in November during the meeting of the board of pharmacy executive directors. The Iowa Board of Pharmacy had already requested that NABP develop an inspection plan for all of its nonresident pharmacies dispensing compounded drugs that were licensed by Iowa.

“Based upon that agreement, we will be acting as an agent of the state of Iowa and going into all the other states where these pharmacies are located and physically inspecting those pharmacies. We will do so with the cooperation of the resident states,” Catizone said. The state boards have been supportive and cooperative in providing a list of pharmacies for inspection, the first part of NABP’s action plan, he said.

The week of December 10, NABP started implementing the second part of its action plan to inspect these facilities that are compounding and to determine whether the pharmacies are compounding pursuant to a prescription in compliance with state regulations, or are engaged in manufacturing.

The third part of the action plan involves the creation of a database with information pertaining to compounding pharmacies identified by the Iowa Board as well as those indicated by other state boards.

“Initial data collected from the boards and the inspection reports will be stored in an NABP Pharmacy e-Profile, allowing the NABP to disseminate pertinent public information among state boards,” NABP reported on its website. “Ultimately, states will be able to submit inspection reports and other related information to NABP for inclusion in pharmacies’ e-Profiles.”

NABP also plans to provide training and education of board of pharmacy inspectors via Web seminars and field training, according to its website. State boards are supportive of these efforts. “They have said, ‘We can’t sit back and we can’t argue this for 20 more years—what is the definition of compounding versus manufacturing. Too many patients have been killed or injured. We have to act. And we will do so in the best interest of the patient.’” Catizone said.

--Julia Taltsma, Content Channel Director

**Collaboration may improve medication adherence**

Collaboration between pharmacy benefit managers and community pharmacists may improve patient compliance to vital drug regimens.

Patients who fail to adhere to prescribed medications cost the U.S. healthcare system an estimated $100 billion annually, according to a study published online in *The American Journal of Managed Care*. Researchers found that pharmacists who received regular alerts regarding patient adherence gaps were able to close more gaps than pharmacists who did not receive regular alerts.

“Collaborating with community pharmacists and providing necessary information to drive adherence and reduce omissions of essential therapies helps to improve health outcomes for patients,” according to Glen Stettin, MD, senior vice president of Clinical Research and New Solutions at Express Scripts, Inc.

Through prescription claims, Dr. Stettin, along with Daniel Touchette, PharmD, MA, assistant professor of pharmacy practice at University of Illinois at Chicago, College of Pharmacy, and colleagues identified 2,500 patients with diabetes, hypertension, high blood pressure, or heart failure who had gaps in medication adherence and omitted essential therapies. Patients were assigned to a participating pharmacy.

A total of 92 pharmacies participated in the study. Of those, 45 pharmacies received training on disease management, motivational interviewing, and communication. In addition, they were notified daily through an online portal of any patient gaps in care. The pharmacists then addressed these gaps directly with each patient and documented each interaction using the web-based tool.

Omission gaps were considered when a patient failed to receive a medication on their profile, and these were sent directly to the prescribing physician. The additional 47 control pharmacies continued to provide regular services. They did not receive specialized training or alerts for gaps in care.

At 30 days, the authors noted that medication adherence gaps were closed more often by pharmacists in the intervention group than those in the control group (55.5% percent vs 50.6%). At 90 days, pharmacists in the intervention group had closed 73.0% vs the 72.9% closed by the control group. Although the difference narrowed, it was statistically significant (HR=1.242; P=.022; 95% CI, 1.115-1.385).

The authors conclude that with the right support, community pharmacists can play an important role in validating and addressing medication adherence gaps.

“Pharmacists are in an optimal position to address therapeutic gaps in care,” the researchers wrote. “Community pharmacists are knowledgeable about potential barriers and solutions to adherence issues. They have frequent contact with their patients, know them well, and when needed, reach out to physicians on their behalf. They are also widely considered a trusted source for providing information to patients and practitioners about medication therapies.”

--Heather Onorati, Contributing Editor
Short-cycle dispensing applies to pharmacies serving LTC

For pharmacists serving long-term care facilities, January 1st was the start date for the requirement that many Part D medications are to be dispensed in increments of no more than 14 days.

For anyone who hasn’t focused on the issue, the new rule says such pharmacies, “must dispense solid oral doses of brand-name medications to enrollees in such facilities in no greater than 14-day increments at a time,” according to the National Council for Prescription Drug Programs (NCPDP).

NCPDP cautions that these, “Appropriate Dispensing Requirements,” or the short-cycle rule as they have been nicknamed, apply to all pharmacies that dispense to long-term care facilities, including retail and mail-order pharmacies.

The rule, intended to reduce waste, was made final by the Centers for Medicare and Medicaid Services (CMS) in a Federal Register notice, April 15, 2011.

Asking questions

If they have not already done so, pharmacists should ask the facilities they serve how they want to receive their medications under Medicare Part D, says Teresa Strickland, technical advisor for standards development for NCPDP. For example, one question might be if they want them in 7- or 14-day increments.

Another issue is whether they want to do the same increment for all drugs or just the required brand oral solid drugs. For instance, will they include generics at the increment level? Will they have all patients at that level or just Medicare Part D patients?

Some of the drugs excluded from the rule are things that have to be in the manufacturer’s original packaging or antibiotics for short-term use, Strickland notes.

NCPDP planned to have a survey of pharmacists on their readiness for the rule.

NCPDP’s analysis, she says, found there are advantages and disadvantages to pre-dispensing billing, post-dispensing billing or bill as dispensed, so there was no recommendation on how to bill.

Carol Sirianni, RPh, vice president of AmerisourceBergen, a pharmaceutical services company, notes that just weeks before the January 1st deadline a number of drug plans had not released the reimbursement rates for short-cycle dispensing. This left pharmacies to make last-minute decisions on how best to implement it. Group purchasing organizations had been negotiating the contracts for their members.

The short-cycle dispensing issue could be revisited with CMS as the industry learns more about how it is working out, she says.

Strickland says pharmacists also need to ensure that their software can handle the submission of multiple submission clarification codes; that they can submit special packaging indicators; and that they can submit the patient’s residence code because those will be required to determine whether a claim is for short-cycle dispensing.

NCPDP published new values in 2011 in its external code list and it expected to publish guidance dealing with the use of submission clarification codes on its “Public Documents” under “Resources” on its website.

In general, she says, the rule is, “a lot more complicated than it sounds like, because you have to know the excluded drugs and there really is not a list of excluded drugs.”

In its Federal Register discussion of its final rule, CMS said, “Although we are prohibited from intervening between negotiations between Part D plans and pharmacies, we do expect that dispensing fees will increase with the increased number of dispensing events in a billing cycle up to a point.”

CMS notes, “We also believe that appropriate dispensing fees that differentiate among the various dispensing methodologies could incentivize more rapid adoption of the most cost-effective technologies and effectively align facility, plan sponsor, and public interest in minimizing costs associated with unused drugs.”

Plans in motion

As of mid-November there were a few plans already accepting claims with the submission clarification codes, says Strickland.

Sirianni says that with the conversion to generics and the number of branded medications used likely to decline in 2013, the biggest question she has is how much savings short-cycle dispensing of brands will realize.

On the other hand, Strickland says that many in the industry feel that eventually the rules will expand to cover all medications, depending on how many pharmacies actually put generics under short cycle.

Kathryn Foxhall is a healthcare journalist based in the Washington, D.C. area.
Questions are the answers

In his book, “Awaken the Giant Within,” Tony Robbins talks about how to make lasting change in any area of your life. He states: “I believe that 20% of any change is knowing HOW and 80% of that change is knowing WHY.” This principle is absolutely imperative, especially in order to encourage behavioral change in our patients.

As healthcare professionals, we would all like to see our patients compliant, taking their medications as prescribed and reaching therapeutic goals. Patients may not understand ‘why’ they are expected to continue their medication and this is where the pharmacist can have a huge impact. In our daily pharmacy encounters with patients, we uncover many who are noncompliant. Often these patients stop taking their medication due to a bothersome side effect such as dizziness, forgetfulness, or even fatigue from a large pill burden. At Kings Pharmacy, we conduct routine blood pressure...
Questions are the answers

Continued from pg. 21

screenings and counsel patients on the goals to reduce their cardiovascular risk. Many of the patients we serve do not want to take medication and ask for advice on how to avoid long-term treatment with a drug. However, if they cannot control their blood pressure through lifestyle changes, a prescription can prove to be lifesaving.

Help noncompliant patients

How do we empower patients who do not want drug therapy to take their routine medications? Actually, one simple tweak can make all of the difference. We tell them ‘why’ they are taking the medication. Think about it. If you tell a patient to avoid drinking while taking metronidazole, they may still have a drink that Friday night. But if you tell them ‘why’—it will cause severe nausea and vomiting if you have any alcohol—I guarantee they will abstain. The same principle goes for adherence. Telling patients to take their medication at the same time every day may not be enough to maintain long-term compliance. Explaining that controlling your blood pressure can slash the risk for stroke and heart attack will give the patient the motivation to continue taking that medication.

For example, I had one patient who was on three blood pressure medications and was only taking two of them. Her blood pressure was 130/80 and she was not diabetic. I inquired about the water pill that she was admittedly skipping every day. She explained that she thought her blood pressure was being controlled with two medications and didn’t want it to drop too low with the addition of the water pill. I explained to her that sometimes three different medications are needed if two do not bring the blood pressure down enough. Those three medications all work differently in the body to normalize the blood pressure, reducing cardiovascular risks. A metaphorical light bulb went off and she mentioned twice during that counseling session that the way I explained it made her realize that she should be taking all three medications.

Link short-, long-term goals

The explanation of ‘why’ bridges the link between the short term (daily blood pressure pill) with the long term (avoiding stroke and heart attack). We can integrate this justification in our counseling sessions to advocate for compliance.

“Patients may not understand ‘why’ they are expected to continue their medication and this is where the pharmacist can have a huge impact.”

The ‘why’ is very important for other reasons. Without being informed of what to expect when taking new medications, patients have to figure it out for themselves. In this way, cultural competency plays an important role because our patients have different backgrounds and perceptions of health. Often patients are not told that a medication will have to be taken every day to maintain the positive results seen upon initiation of the treatment. Another patient who had been coming to my blood pressure monitoring program for several years was still not compliant despite years of sporadic counseling. It wasn’t until I asked the appropriate questions that I discovered that she feared her blood pressure going too low. We spend a significant amount of time talking about lowering blood pressure in order to decrease the risk of complications. However, we do not address the benefit of blood pressure being even lower than 120/80 and that it is only when blood pressure falls below 100/50 mm Hg that there is concern about it being too low.

We often discuss ‘too low’ in regard to diabetes but may neglect to do so with other disease states. The patient’s neighbor had warned her that if blood pressure goes too low it could be dangerous. Upon checking her blood pressure one day, she saw that her systolic number was 113 mm Hg. She was so nervous that she not only stopped taking her medications but also consumed salt to raise it. Since then, she had her blood pressure checked by our student pharmacists several times and it was always borderline or above. This incident was never mentioned even though the importance of compliance was often discussed.

Once her barriers were identified, I was able to appropriately counsel her on the importance of compliance and what to expect. She walked away knowing her goals and when to be concerned about the pressure being too low. She also learned not to get medical advice from friends, family, or neighbors.

The best way for patients to know that they can turn to us for accurate and individualized counseling is through our communication. Understanding a patient’s belief system can make that 80% ‘why’ work to our benefit to influence long-term change. Explaining that 80% makes our efforts 100% worthwhile.

Bhavna Desai

Sweta Chawla, PharmD, MS, CDE, is director of Clinical Services and Residency Program at Kings Pharmacy, located in Manhattan and Brooklyn, N.Y., and clinical assistant professor of pharmacy practice, Arnold & Marie Schwartz College of Pharmacy, Long Island University. Christina Tarantola, PharmD, is a PGY-1 resident at Kings Pharmacy.
Letters

Continued from pg. 15

tell us how much we’ll be paid for our products and expertise. What you’ll be left with is mail order and big box service where Mr. Mayer’s rights are irrelevant and Mr. Stanley’s services no longer exist.

Steve Burney, PharmD
COLUMBUS, NC

Drug-disposal options

After reading your article, “First-in-nation drug-disposal mandate aims to protect patients,” [November] which I found very informative, it came to mind the time back in the ‘90s that I wrote to Drug Topics after a similar call for safe disposal that so much concern was being paid to the left-over drugs and none to the drugs excreted in the urine or feces. If you look at most package inserts, you will see that any particular drug is excreted either unchanged or only slightly changed in the urine or feces. This is probably the actual source of 80% of the contamination of waterways. In my opinion, for leftover drugs, the coffee ground method is actually very good because here in Massachusetts all the trash is incinerated.

Mike Saija, RPh, CIP
SHARON, MA

Your November article, “First-in-nation drug-disposal mandate aims to protect patients,” notes the “lack of options for disposal of unwanted or expired medications.” Since its launch in 2010, the National Community Pharmacists Association’s Dispose My Meds program has collected more than 50 tons of unused or expired medications. Drop offs of non-narcotic prescription drugs are accepted every business day at some 1,600 participating pharmacies. Their locations can be found at NCPA’s companion consumer website, www.disposemymeds.org. Pharmacies that wish to participate should visit the NCPA website, www.ncpanet.org.

Donnie Callhoun, RPh, NCPA president
ANNISTON, AL

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3For Relief of Flu-Like Symptoms
Pharmacists are approaching 2013 with tempered optimism as the economy seems to be slowly rebounding and consumer confidence is the best it has been since 2009. However, compared with last year, community pharmacists are not quite as confident that 2013 will outperform 2012 for sales volume and net profits. Health-system pharmacists, on the other hand, are more optimistic about 2013 with expectations that their pharmacies will reach their financial goals and be able to contribute positively to net revenues.

These were some of the findings from Drug Topics’ 2013 Business Outlook Survey, an annual survey of more than 600 community and health-system pharmacists that examines the current climate and future prospects. This year’s survey was fielded for two weeks in October 2012.

Positive, negative factors
Community pharmacists ranked the top five factors that contributed positively to their businesses last year as follows (Figure 1):

- Major brand-name drugs going off patent
- Increase of electronic prescriptions
- Immunization certification
- Medicare Part D
- Healthcare reform

There was little difference compared with 2011, although medication therapy management (MTM) made the list and healthcare reform did not.

In terms of the factors that negatively affected community pharmacists in 2012, the top ranking factor was mandatory mail-order programs, followed by lower reimbursements from third parties, $4 generics from competitors, the completed merger of Express Scripts Inc. and Medco Health Solutions, and healthcare reform (Figure 2).

Approximately three quarters of community pharmacists (73%) of the 436 pharmacists who responded to Drug Topics’ survey expected a good, very good, or excellent business year in 2012. However, their expectations dropped for 2013 with approximately two-thirds (67%) predicting a good to excellent business climate (Figure 3). One third of community pharmacists expect sales to increase this year and one-third expect sales to remain the same. However, 17% expect sales in 2013 to decrease and 17% don’t know what to expect. This is in sharp contrast to last year’s survey in which 40% expected sales to increase, 32% expected sales to remain the same, 15% expected a dip in sales, and 13% did not know what to expect.

Only 20% of community pharmacists expect net profits to climb in 2013 compared to 25% last year. Approximately 31% expect net profits to remain steady in 2013 compared to 24% last year. Almost 32% expect net profits to go down in 2013, compared with 35% last year.
Medicare Part D impact

For community pharmacists, Medicare Part D, which has been in effect since January 1, 2006, was considered a positive factor by one quarter of survey respondents for 2012; yet it also ranked as a challenge in 2013 by one-third of those surveyed. Obviously, more lower- and middle-income Medicare beneficiaries are able to have prescriptions filled, providing better and cheaper care for more seniors.

“This program has been instrumental in getting people to buy prescriptions they could not have otherwise afforded. This has lead to increased compliance,” according to one survey respondent.

Some of the Medicare Part D plans offer limited formularies, so patients really need information about their coverage and the step therapy requirements, according to pharmacists who responded to our survey. In addition, the coverage gap, known as the donut hole, has continued to pose problems for many patients.

“Many seniors do not understand the [Medicare Part D] program and do not refill medications when they reach the donut hole,” explained another survey respondent.

Pharmacists will need to work with patients to ensure that they remain compliant with their drug regimen. The Affordable Care Act of 2010 provided a 50% discount in 2012 on brand-name drugs for beneficiaries who reached the donut hole of $2,930 to $4,700. By 2020, the discount will reach 75%, with Medicare beneficiaries paying 25% of the cost of their drugs up to the annual out-of-pocket spending limit.

In addition, some community pharmacies are taking a hit with the increase in Medicare Part D beneficiaries as the number of cash customers has declined and Medicare reimbursements provide decreased profit margins.

“Many cash customers are now covered by low-profit Medicare,” said another survey respondent.

Others who responded to the survey blamed pharmacy benefit managers (PBMs) for low Medicare payments.

Mail order, restricted networks

“PBMs squeeze margins to increase their profits. [Medicare] Part D gives more power to the PBMs,” a pharmacist wrote in the survey.

With the increased volume of prescriptions and lower returns, pharmacists note that they have no time to “thoroughly counsel every patient” who fills a prescription.

Other challenges that community pharmacists face include mail-order competition, which continues to rank as one of the top five factors that negatively affect these pharmacies.

Some survey respondents explained that PBMs that are administering the Medicare Part D plans still continue to promote mail order and preferred networks of the pharmacies that they own.

“Medicare Part D is good for Humana, Express Scripts, and the like,” said another respondent.

MTM services

More community pharmacists (45%) are getting involved in MTM services under Medicare Part D, a slight uptick from last year’s participation of 43%. However, only 28% of the surveyed pharmacists who are offering MTM services under Medicare Part D are getting paid.

The majority of pharmacists delivering MTM (55%) received between $0 and $249 during 2012 for these services. One quarter reported payments received between $250 and $999, 15% reported payments between $1,000 and $4,999, and 10% said payments were $5,000 and above.

The biggest hurdle to effective MTM services is inadequate reimbursement, according to Randy McDonough, PharmD, MS, CGP, BCPS, at Towncrest and Medical Plaza Pharmacies, Iowa City, Iowa. He spoke about compensation for MTM services during a program at the American Pharmacists Association annual meeting last year.

“Payments generally vary depending on insurance coverage, initial time required, and follow-up visits needed,” said Dr. McDonough. “MTM is covered by some Medicare Part D plans.”

Dr. McDonough believes that dispensing and MTM are usually regarded as separate functions by pharmacists, but “this doesn’t have to be the case.” MTM activities occur across a continuum of patient care from dispensing to the comprehensive medication review.

However, survey respondents said that companies need to be realistic about the actual time available to provide MTM. Both MTM and immunizations take time to per-
Business Outlook Survey

Form. A number of pharmacists responding to our survey complained that the working conditions for pharmacists needed to be addressed.

"Too much emphasis is placed on MTM. We've done that for years (it's called taking care of patients). How about the work conditions pharmacists have to deal with on a daily basis?" said another survey respondent.

2013 Hospital Pharmacy Outlook

Hospital pharmacists (73%) are as optimistic as last year about reaching their hospital financial goals and contributing to their hospital net revenues in 2013 (Figure 3). Compared with their 2012 drug budget, about 41% of hospital pharmacists said that they expect their 2013 drug budget to increase, and 43% said that their 2013 drug budget will remain the same—which is similar to last year's survey.

In terms of 2013 salaries for hospital pharmacists, approximately 58% believe their compensation would remain the same, 30% believed it would increase, 6% anticipate a decline, and 7% are not sure. For those who believe that salaries will climb in 2013, the average increase will be about 1% to 3% according to 95% of those surveyed.

Improving Patient Care

The top five actions that hospital pharmacies took in 2012 to improve patient care were:

- Increased efforts to reduce drug errors
- Implemented steps to document pharmacist interventions
- Reconciled medications for incoming and outgoing patients
- Took action to reduce hospital-acquired infections
- Encouraged pharmacy technicians to become certified and avoided purchasing medications from secondary wholesalers

In 2013, the top five actions that hospital pharmacies are expected to perform to improve patient care include many of the same actions as last year (the first four are the same). However, hospital pharmacies are using pharmacists to go on hospital rounds and are allowing pharmacy technicians to take over more functions that were previously performed by pharmacists (Figure 4).

The American Society of Health-System Pharmacists (ASHP) and ASHP Foundation have been working on the Pharmacy Practice Model Initiative (PPMI), "to advance the health and well-being of patients by developing and supporting a futuristic practice model that efficiently utilizes pharmacists as direct patient care providers," according to David Aguero in his blog on the ASHP website.

Hospitals that are interested in the PPMI and advancing the role of health-system pharmacists can complete a self-assessment known as the Self-Assessment Tool to assess a hospital’s alignment with the PPMI recommendations. The tool has over 100 questions, which assess the adoption of the PPMI recommendations at the hospital level. Following the self-assessment, hospitals can see how they score and then can create an “action list” to move forward with the PPMI. More information about the PPMI tools can be found at http://www.ashpmedia.org/ppmi/tools.html.

Top Challenges in 2012

Hospital pharmacists continued to face a number of challenges in 2012, with the top 3 still being (Figure 5):

- Drug shortages
- Cutbacks in state Medicaid reimbursements
- Implementation of electronic health records

According to a number of survey respondents, the pharmacy associations have helped on the drug shortage issue by increasing awareness, and by expanding opportunities for pharmacy, such as immunizations given by pharmacists. However, “more legislative action is needed on billing, scope-of-practice expansion, training, and advancing pharmacy tech education and scope of practice,” said one respondent.

One survey respondent said that associations should promote the value of the pharmacist in patient care both in and out of the hospital. Several pharmacists surveyed also would like pharmacy organizations to work toward the goal of recognition of the pharmacist as a practitioner. Until that occurs, “pharmacists will continue as a nonentity and at best a super tech with a doctoral degree,” said another pharmacist who was surveyed.
have larger increases. Monitor all patients for hypertension and tachycardia.

• Use of stimulants may cause psychotic or manic symptoms in patients with no prior history, or exacerbation of symptoms in patients with pre-existing psychiatric illness. Evaluate for bipolar disorder prior to Quillivant XR use.

• CNS stimulants have been associated with weight loss and slowing of growth rate in pediatric patients. Growth should be monitored during treatment with stimulants, including Quillivant XR. Patients who are not growing or gaining weight as expected may need to have their treatment interrupted.

• Based on accumulated data from other methylphenidate products, the most common (≥5% and twice the rate of placebo) expected adverse reactions are appetite decreased, insomnia, nausea, vomiting, dyspepsia, abdominal pain, weight decreased, anxiety, dizziness, irritability, affect lability, tachycardia, and blood pressure increased. There is limited experience with Quillivant XR in controlled trials. Based on this limited experience, the adverse reaction profile of Quillivant XR appears similar to other methylphenidate extended-release products. The most common (≥2% in the Quillivant XR group and greater than placebo) adverse reactions reported in the Phase 3 controlled study conducted in 45 ADHD patients (aged 6-12 years) were affect lability (9%), excoriation (4%), initial insomnia (2%), tic (2%), decreased appetite (2%), vomiting (2%), motion sickness (2%), eye pain (2%), and rash (2%).

• Based on animal data, use of Quillivant XR during pregnancy may cause fetal harm. Quillivant XR should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Nursing mothers should be advised to discontinue drug or discontinue nursing, taking into consideration the importance of the drug to the mother.

Please see Brief Summary of Prescribing Information, including BOXED WARNING regarding Abuse and Dependence, on following pages.
Quillivant XR™ (methylphenidate HCl) for extended-release oral suspension, CI Rx only

BRIEF SUMMARY: Consult Full Prescribing Information for Complete Product Information.

WARNING: ABUSE AND DEPENDENCE

CNS stimulants, including Quillivant XR, other methylphenidate-containing products, and amphetamines, have a high potential for abuse and dependence. Assess the risk of abuse prior to prescribing, and monitor for signs of abuse and dependence while on therapy [see Warnings and Precautions, Drug Abuse and Dependence].

INDICATIONS AND USAGE

Quillivant XR is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD). The efficacy of Quillivant XR was established in a 2-week, placebo-controlled, laboratory classroom, crossover study in children aged 6-12 years with a diagnosis of ADHD. Patients in the trial met DSM-IV-TR criteria for ADHD. Accumulated efficacy data from other methylphenidate products were also considered.

CONTRAINDICATIONS

Hypersensitivity to Methylphenidate or other Components of Quillivant XR. Quillivant XR is contraindicated in patients known to be hypersensitive to methylphenidate, or other components of Quillivant XR. Hypersensitivity reactions such as angioedema and anaphylactic reactions have been reported in patients treated with other methylphenidate products.

Monoamine Oxidase Inhibitors Quillivant XR is contraindicated during treatment with monoamine oxidase inhibitors, and also within 14 days following discontinuation of treatment with a monoamine oxidase inhibitor (MAOI), because of the risk of hypertensive crisis.

WARNINGS AND PRECAUTIONS

Potential for Abuse and Dependence CNS stimulants, including Quillivant XR, other methylphenidate-containing products, and amphetamines, have a high potential for abuse and dependence. Assess the risk of abuse prior to prescribing, and monitor for signs of abuse and dependence while on therapy [see Drug Abuse and Dependence].

Serious Cardiovascular Reactions Stroke and myocardial infarction have occurred in adults treated with CNS stimulants at recommended doses. Sudden death has occurred in children and adolescents with structural cardiac abnormalities and other serious cardiac problems, and in adults taking CNS stimulants at recommended doses for ADHD. Avoid use in patients with known structural cardiac abnormalities, cardiomyopathy, serious cardiac arrhythmias, coronary artery disease, or other serious cardiac problems. Further evaluate patients who develop exertional chest pain, unexplained syncope, or arrhythmias during treatment with Quillivant XR.

Blood Pressure and Heart Rate Increases CNS stimulants cause an increase in blood pressure (mean increase approximately 2 to 4 mmHg) and heart rate (mean increase approximately 3 to 6 bpm). Individuals may have larger increases. Monitor all patients for hypertension and tachycardia.

Psychiatric Adverse Reactions Exacerbation of Pre-Existing Psychosis CNS stimulants may exacerbate symptoms of behavior disturbance and thought disorder in patients with a pre-existing psychiatric disorder.

Induction of a Manic Episod in Patients with Bipolar Disorder CNS stimulants may induce a manic or mixed episode in patients. Prior to initiating treatment, screen patients for risk factors for developing a manic episode (e.g., comorbid or history of depressive symptoms, or a family history of suicide, bipolar disorder, or depression).

New Psychotic or Manic Symptoms CNS stimulants, at recommended doses, may cause psychotic or manic symptoms (e.g., hallucinations, delusional thinking, or mania) in patients without a prior history of psychotic illness or mania. If such symptoms occur, consider discontinuing treatment with Quillivant XR. In a pooled analysis of multiple short-term, placebo-controlled studies of CNS stimulants, psychotic or manic symptoms occurred in approximately 0.1% of CNS stimulant-treated patients.

Long-Term Suppression of Growth CNS stimulants have been associated with weight loss and slowing of growth rate in pediatric patients. Closely monitor growth (weight and height) in pediatric patients treated with CNS stimulants, including Quillivant XR. Careful follow-up of weight and height in children ages 7 to 10 years who were randomized to either methylphenidate or nonmedication treatment groups over 14 months, as well as in naturalistic subgroups of newly methylphenidate-treated and nonmedication-treated children over 36 months (to the ages of 10 to 13 years), suggests that consistently medicated children (i.e., treatment for 7 days per week throughout the year) have a temporary slowing in growth rate on average, a total of about 2 cm less growth in height and 2.7 kg less growth in weight over 3 years), without evidence of growth rebound during this period of development. Published data are inadequate to determine whether chronic use of amphetamines may cause a similar suppression of growth; however, it is anticipated that they likely have this effect as well. Therefore, growth should be monitored during treatment with stimulants, and patients who are not growing or gaining height or weight as expected may need to have their treatment interrupted.

ADVERSE REACTIONS

Clinical Trials Experience Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. Clinical Trials Experience with methylphenidate products in children, adolescents, and adults with ADHD commonly reported (≥2% of the methylphenidate group and at least twice the rate of the placebo group) adverse reactions from placebo-controlled trials of methylphenidate products include: appetite decreased, weight decreased, nausea, abdominal pain, dysphoria, dry mouth, vomiting, insomnia, anxiety, nervousness, restlessness, affect lability, agitation, irritability, dizziness, vertigo, tremor, blurred vision, blood pressure increased, heart rate increased, tachycardia, palpitations, hyperthermia, and pyrexia. Clinical Trials Experience with Quillivant XR in children and adolescents with ADHD. There is limited experience with Quillivant XR in controlled clinical trials. Based on this limited experience, the adverse reaction profile of Quillivant XR appears similar to other methylphenidate extended-release products. The most common (≥2% in the Quillivant XR group and greater than placebo) adverse reactions reported in the Phase 3 controlled study conducted in 45 ADHD patients (ages 6-12 years) were affect lability, excitation, initial insomnia, tic, decreased appetite, vomiting, motion sickness, eye pain, and rash.

Table 2. Common Adverse Reactions occurring in ≥2% of subjects on Quillivant XR and greater than placebo during the controlled cross-over phase

<table>
<thead>
<tr>
<th>Adverse reaction</th>
<th>Quillivant XR (N=45)</th>
<th>Placebo (N=45)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Affect lability</td>
<td>9%</td>
<td>2%</td>
</tr>
<tr>
<td>Excitation</td>
<td>4%</td>
<td>0%</td>
</tr>
<tr>
<td>Initial insomnia</td>
<td>2%</td>
<td>0%</td>
</tr>
<tr>
<td>Tic</td>
<td>2%</td>
<td>0%</td>
</tr>
<tr>
<td>Vomiting</td>
<td>2%</td>
<td>0%</td>
</tr>
<tr>
<td>Motion sickness</td>
<td>2%</td>
<td>0%</td>
</tr>
<tr>
<td>Eye pain</td>
<td>2%</td>
<td>0%</td>
</tr>
<tr>
<td>Rash</td>
<td>2%</td>
<td>0%</td>
</tr>
</tbody>
</table>

Postmarketing Experience The following adverse reactions have been identified during post approval use of methylphenidate products. Because these reactions are reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency or establish a causal relationship to drug exposure. These adverse reactions are as follows:

Blood and Lymphatic System Disorders: Pancytopenia, Thrombocytopenia, Thrombocytopenic purpura
Cardiac Disorders: Angina pectoris, Bradycardia, Extrastyle, Supraventricular tachycardia, Ventricular extrasystole
Eye Disorders: Diplopia, Mydriasis, Visual impairment
General Disorders: Chest pain, Chest discomfort, Hyperventilation, Motion sickness
Hypersensitivity reactions such as angioedema, Anaphylactic reactions, Auricular swelling, Bullous conditions, Eosinophilic fasciitis, Urticaria
Puritus NEC, Rash, Eruptions, and Exanthemas NEC
Involuntary muscle contractions, Mania
Muscle twitching
Nervous System Disorders: Convulsion, Grand mal convulsion, Dyskinesia
Psychiatric Disorders: Disorientation, Hallucination, Hallucination auditory, Hallucination visual, Mania
Urogenital System: Priapism
Skin and Subcutaneous Tissue Disorders: Alopecia, Erythema
Vascular Disorders: Raynaud’s phenomenon

DRUG INTERACTIONS

MAO Inhibitors Do not administer Quillivant XR concomitantly with monoamine oxidase inhibitors or within 14 days after discontinuing MAOI treatment. Concomitant use of MAOIs and CNS stimulants can cause hypertensive crisis. Potential outcomes include death, stroke, myocardial infarction, aortic dissection, ophthalmological complications, eclampsia, pulmonary edema, and renal failure.

USE IN SPECIFIC POPULATIONS

Pregnancy Pregnancy Category C Risk Summary There are no adequate or well-controlled studies with Quillivant XR in pregnant women. Adverse pregnancy outcomes, including premature delivery and low birth weight, have been seen in mothers dependent on other stimulant products such as amphetamines. Methylphenidate showed some potential for teratogenicity when pregnant animals were treated during organogenesis: an increased incidence of fetal spina bifida in rabbits at 40 times the maximum recommended human dose (MRHD), on a mg/m² basis, and an increased incidence of fetal skeletal variations in rats at 7 times the MRHD. A decrease in body weight gain was seen in the offspring of rats treated with methylphenidate throughout organogenesis.

Because animal reproduction studies are not always predictive of human response, Quillivant XR should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Considerations Stimulant medications, such as Quillivant XR, cause vasodilatation and thereby decrease placental perfusion. Infants born to amphetamine-dependent mothers have an increased risk of premature delivery and low birth weight. Monitor infants for symptoms of withdrawal such as feeding difficulties, irritability, agitation, and excessive irritability and nervousness. Animal Data in studies conducted in rats and rabbits, methylphenidate was administered orally at doses of up to 75 and 200 mg/kg/day, respectively, during the period of organogenesis. Teratogenic effects (increased incidence of fetal spina bifida) were observed in rabbits at the highest dose, which is approximately 40 times the maximum recommended human dose (MRHD), on a mg/m² basis. The no effect level for embryofetal development in rabbits was 60 mg/kg/day (11 times the MRHD on a mg/m² basis). There was no evidence of specific teratogenic activity in rats, although increased incidences of fetal skeletal variations were seen at the highest dose level (7 times the MRHD on a mg/m² basis). Quillivant XR was also maternally toxic. The no effect level for embryofetal development in rats was 25 mg/kg/day (2 times the MRHD on a mg/m² basis). When methylphenidate was administered to rats throughout pregnancy and lactation at doses of up to 45 mg/kg/day, offspring body weight gain was decreased at the highest dose (4 times the MRHD on a mg/m² basis), but no other effects on postnatal
The P4P crossroads: Is hospital pharmacy leadership ready?

With the rollout of CMS’ Value-based Purchasing (VBP) Program and the Hospital Readmissions Reduction Program (HRRP) in 2012, hospitals are under the gun to attain higher quality standards or face the fallout of financial penalties. Many hospitals, including those that believe they were performing at high levels, were caught off guard to learn that their initial CMS performance reports pointed to penalty levels weighty enough to turn heads.

After the initial shock wore off, one of the first phone calls many CEOs made was to the pharmacy director seeking a plan of action to help improve performance. It’s no wonder. Many of the measures under regulatory scrutiny could be positively impacted with the right pharmacy directives and strategies.

The question is: Are pharmacy directors equipped and ready to face this challenge? The reality of how three initiatives under Title III of the Affordable Care Act — VBP, HRRP and the Hospital Acquired Conditions (HAC) — will impact bottom lines is beginning to come into focus. A typical 300-bed hospital with $50 million in annual CMS imputed payments could find that $3 million is potentially at risk by 2017.

**Strategies for competing**

Competition will be fierce. It’s the foundation upon which pay-for-performance programs are built. All scoring around VBP is relative to how one facility performs in relation to all others across the country. And there is little room for error.

For FFY13 scoring, process of care measures formed the primary basis of penalties, and hospitals generally had to be performing at 93% compliance with these quality measures just to be ranked as average. A score of 100% was often needed to be considered among top-tier facilities. Essentially, one missed opportunity to provide the proper care (e.g., medication, lab test, education) could drop a hospital out of the high-performance category.

Quillivant XR™ (methylphenidate HCl) Brief Summary continued...

- **Development:** Observed. The no effect level for pre- and postnatal development in rats was 15 mg/kg/day (equal to the MRHD on a mg/m² basis).
- **Nursing Mothers:** Methylphenidate is present in human milk. Long-term neurodevelopmental effects on infants from stimulant exposure are unknown. Because of the potential for serious adverse reactions in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.
- **Pediatric Use:** The safety and effectiveness of Quillivant XR have been established in pediatric patients ages 6 to 17 years. Use of Quillivant XR in pediatric patients 6 to 12 years of age is supported by adequate and well-controlled studies of Quillivant XR in younger pediatric patients and additional pharmacokinetic data in adolescents, along with safety information from other methylphenidate-containing products. The long-term efficacy of methylphenidate in pediatric patients has not been established. Safety and efficacy in pediatric patients below the age of 6 years have not been established. Long-Term Suppression of Growth: Growth should be monitored during treatment with stimulants, including Quillivant XR. Children who are not growing or gaining weight as expected may need to have their treatment interrupted (see Warnings and Precautions).
- **Juvenile Animal Data:** Rats treated with methylphenidate early in the postnatal period through sexual maturation demonstrated a decrease in spontaneous locomotor activity in adulthood. A deficit in acquisition of a specific learning task was observed in females only. The doses at which these findings were observed are at least 6 times the maximum recommended human dose (MRHD) on a mg/m² basis. In the study conducted in young rats, methylphenidate was administered orally at doses of up to 100 mg/kg/day for 9 weeks, starting early in the postnatal period (postnatal day 7) and continuing through sexual maturity (postnatal week 10). When these animals were tested as adults (postnatal weeks 13-14), decreased spontaneous locomotor activity was observed in males and females previously treated with 50 mg/kg/day (approximately 6 times the maximum recommended human dose [MRHD] on a mg/m² basis) or greater, and a deficit in the acquisition of a specific learning task was observed in females exposed to the highest dose (12 times the MRHD on a mg/m² basis). The no effect level for juvenile neurobehavioral development in rats was 5 mg/kg/day (half the MRHD on a mg/m² basis). The clinical significance of the long-term behavioral effects observed in rats is unknown.
- **Geriatric Use:** Quillivant XR has not been studied in patients over the age of 65 years.
- **DRUG ABUSE AND DEPENDENCE:** Controlled Substance Quillivant XR contains methylphenidate, a Schedule II controlled substance. Abuse CNS stimulants including Quillivant XR, other methylphenidate-containing products, and amphetamines have a high potential for abuse. Abuse is characterized by impaired control over drug use, compulsive use, continued use despite harm, and craving. Signs and symptoms of CNS stimulant abuse include increased heart rate, respiratory rate, blood pressure, and/or sweating, dilated pupils, hyperactivity, restlessness, insomnia, decreased appetite, loss of coordination, tremors, flushed skin, vomiting, and/or abdominal pain. Anxiety, psychosis, hostility, aggression, suicidal or homicidal ideation have also been observed. Abusers of CNS stimulants may chew, snort, inject, or use other unapproved routes of administration which can result in overdose and death (see Overdosage). To reduce the abuse of CNS stimulants including Quillivant XR, assess the risk of abuse prior to prescribing. After prescribing, keep careful prescription records, educate patients and their families about abuse and on proper storage and disposal of CNS stimulants, monitor for signs of abuse while on therapy, and re-evaluate the need for Quillivant XR use.
- **Dependence/Tolerance:** Tolerance (a state of adaptation in which exposure to a drug results in a reduction of the drug’s desired and/or undesired effects over time) can occur during chronic therapy with CNS stimulants including Quillivant XR. Dependence Physical dependence (a state of adaptation manifested by a withdrawal syndrome produced by abrupt cessation, rapid dose reduction, or administration of an antagonist) can occur in patients treated with CNS stimulants including Quillivant XR. Withdrawal symptoms after abrupt cessation following prolonged high-dosage administration of CNS stimulants include extreme fatigue and depression.
- **OVERDOSAGE:** Signs and Symptoms Signs and symptoms of acute methylphenidate overdose, resulting principally from overstimulation of the CNS and from excessive sympathomimetic effects, may include the following: nausea, vomiting, diarrhea, restlessness, anxiety, agitation, tremors, hyperreflexia, muscle twitching, convulsions (may be followed by coma), euphoria, confusion, hallucinations, delirium, sweating, flushing, headache, hyperpyrexia, tachycardia, palpitations, cardiac arrhythmias, hypertension, hypotension, tachypnea, mydriasis, and dryness of mucous membranes.
- **Management of Overdose:** Consult with a Certified Poison Control Center for up-to-date guidance and advice on the management of overdose with methylphenidate (1-800-222-1222.) Provide supportive care, including close medical supervision and monitoring. Treatment should consist of those general measures employed in the management of overdosage with any drug. Consider the possibility of multiple drug overdosage. Ensure an adequate airway, oxygenation, and ventilation. Monitor cardiac rhythm and vital signs. Use supportive and symptomatic measures.
**Smoking cessation aid may increase risk of cardiovascular events**

The smoking cessation aid varenicline (Chantix, Pfizer) may increase the risk of cardiovascular events in adults with cardiovascular disease, according to a recent FDA safety announcement.

FDA first notified the public about a possible increased risk of cardiovascular adverse events with varenicline in its June 2011 Drug Safety Communication. FDA required the manufacturer to conduct meta-analysis to further evaluate the cardiovascular safety of the drug.

The recent announcement follows the results of the meta-analysis of 15 Pfizer-sponsored, randomized double-blind, placebo-controlled clinical trials that included 7,002 patients, which was conducted to assess the occurrence and timing of major adverse cardiovascular events.

**A slight increased risk**

Researchers found that, within 30 days of treatment, patients taking varenicline were slightly more likely than patients taking placebo to experience a major adverse event, reported as a combined outcome of cardiovascular-related death, nonfatal heart attack, and nonfatal stroke (varenicline, 0.31% [13/4190]; placebo, 0.21% [6/2812]). FDA notes that the events were uncommon in both groups, and the increased risk was not statistically significant; however multiple data analyses consistently demonstrated a higher occurrence of these events in patients taking varenicline.

**Chantix label updated**

FDA reports that the Warnings and Precautions section of the Chantix label has been updated to include the results of the new data.

"It is important to note that smoking is a major risk factor for cardiovascular disease, and Chantix is effective in helping patients to quit smoking and abstain from it for as long as one year. The health benefits of quitting smoking are immediate and substantial," according to FDA. But, the Agency advises healthcare professionals to weigh risks of treatment against the benefits for each patient.

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**Heparin container labels must clearly state the total drug strength, according to FDA**

Heparin container and carton labels must now clearly state the total drug strength, according to an FDA Drug Safety Communication.

This label change will require manufacturers of Heparin Lock Flush Solution, USP and Heparin Sodium Injection, USP to clearly state the strength of the entire container of the medication followed by how much of the medication is in 1 mL. These modifications will eliminate the need for healthcare professionals to calculate the total amount of heparin medication in a product containing more than 1 mL, thereby reducing the risk of miscalculations that may result in medication errors.

**Background information**

"In 2003, the United States Pharmacopeia's (USP) Safe Medication Use Expert Committee became aware of medication errors involving the expression of strength in the labeling for all injectable products. Containers labeled with the strength per mL were often misunderstood as the total drug content, which could result in dosing errors with serious consequences to patients," according to FDA's statement.

Heparin is used to prevent blood clots from forming in people who have certain medical conditions or who are undergoing certain medical procedures that may increase the chance that clots will form, or to stop the growth of clots that have already formed in the blood vessels and to prevent blood clots from forming in catheters that are left in veins over a period of time.

There will be a transition period before and after the official implementation date on May 1, 2013, during which both the current heparin container labels and the revised heparin container labels will be available in the marketplace. To minimize the potential for medication errors, users should consider separating the supplies of “current” and “revised” labeled heparin, and use all of the supplies of the “current” heparin before using products with the “revised” container label.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

Complete and submit the report online.

Download a form or call (800) 332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to (800) FDA-0178.
To effectively devise strategies for competing in a new “Pay for Performance” era, pharmacies must understand where they can have the most impact. Conducting a gap analysis around the key performance measures and determining the most effective care delivery models is critical. These initiatives will also need to be backed by flexible IT structures that provide the necessary tools for driving improvements in patient outcomes and clinical intelligence reporting.

The impact—2014 and beyond
Thresholds and benchmarks for process of care measures under VBP are so high that they leave very little room for error or improvement. As more focus is placed on the patient experience and outcomes measures (where current performance scores lag), hospitals will have more opportunity to make improvements and rise to the top.

Primary performance measure sets for FFY14 will expand from the FFY13 “process of care” focus to include a more holistic view of performance — process of care (45%), patient experience (30%), and outcomes (25%). This shift increases the potential impact of pharmacy initiatives to impact of overall care since the focus will be more around outcomes and eventually efficiency (cost) measures and less on ensuring a single step in the care delivery.

The risk associated with the readmissions reduction program will escalate quickly following its 2012 introduction. Covering readmissions for heart failure, myocardial infarction, and pneumonia and impacting 1% of payout in 2012, the program will increase to 2% in 2013 and 3% in 2014. Conditions covered will expand to chronic obstructive pulmonary disease, coronary bypass grafting, percutaneous transluminal coronary angioplasty, and other vascular procedures by 2014.

Of 3,400 hospitals falling under HRRP in its first year, 65.5% were penalized, representing $280 million in penalties. Unlike the VBP program, there is no reward for having lower than expected readmissions rates, but as readmission rates begin to drop around the United States, it will become increasingly difficult to ensure your hospital is on the right side of the penalty equation.

Pay-for-performance initiatives have the potential to elevate the role of the
pharmacy department in driving performance improvement through initiatives that optimize medication use, enhance patient education, and prevent outlier events such as adverse drug events. While the pharmacy has sometimes struggled to demonstrate the value of the clinical services it provides, there is now a structure that supports a business plan for demonstrating how these initiatives impact care and the bottom line.

Consider this simple four-part analysis for positioning pharmacy services:

- **Establish current gaps** in care by reviewing the data. Determine which services would be most valuable in closing these gaps at your organization.
- **Rank each opportunity** for improvement by the impact that pharmacists can have on improving performance and reducing readmissions.
- **Consider all options** for care delivery models and determine the most effective approach within the framework of hospital workflows. Also consider what current activities that are not delivering high value should be eliminated!
- **Consider the sustainability** of the final strategy. What are the diverse sources of value that will support the service (e.g., decreased readmission, increased HCAHPS scores, reimbursable clinical visits, or discharge prescription services)?

When conducting this analysis, many pharmacy directors will find that high thresholds minimize the potential for improving process of care measures even though the pharmacy department’s ability to impact this part of the VBP equation is high.

Surgical Care Improvement Project (SCIP) and other “Core Measure” outcomes can be greatly impacted through pharmacy systems and processes that ensure every patient gets proper care. That said, the patient experience measures that revolve around HCAHPS scores often provide more opportunity for improvement because of the much larger gap between the threshold and benchmark.

The question then becomes: “Does it make more sense to focus resources on improving a performance measure by .04%, or will resources be better used in taking a HCAHPS score from 30% to 80% to lead the pack?” Based on this type of analysis, many hospitals are looking at HCAHPS scores first.

The pharmacy department at Minnesota-based Fairview Health Services, a health system encompassing seven hospitals and more than 40 primary health clinics, is leading the charge to impact pain management HCAHPS scores.

The organization first appointed a pain stewardship pharmacist charged with monitoring daily reports for all patients on oral long-acting opioids, fentanyl and methadone, as well as checking current medication profiles against patient history.

Interventions include an “opioid review” note that is documented by the pain stewardship pharmacist and a plan of transition to oral medications that includes a weaning of acute pain medications for continuity of care. These initiatives have resulted in an increase in pharmacist consults.

Other hospitals are focusing on patient education to boost HCAHPS and hopefully reduce readmissions. Using pharmacists to provide medication and patient education to boost HCAHPS and hopefully reduce readmissions.

The role of technology

While process and workflow strategies will go a long way toward raising the bar on quality standards, it will take a solid foundation of technology, automation, and clinical decision support (CDS) to truly impact quality measures.

Electronic medical records (EMR) are a critical first step, but the current reach of CDS in these applications can be somewhat limited in that it is not able to consider all existing relevant contextual patient data. Most alerts appear one time — at the time of order entry — with no additional follow-up to take into account the dynamic nature of patient care. Alert fatigue further reduces effectiveness of the tools.

When rules-based, advanced surveillance technology is combined with robust CDS solutions, hospitals can achieve much richer aggregation of patient data covering the overall scope of care and ultimately rendering an alert that is more relevant to the patient’s true condition. Smart logic built into these applications can be used to develop rules that enable real-time and ongoing monitoring of patient care to impact performance.

Currently most performance data and reports lag weeks if not months behind actual care delivery and provide little value around impacting patient care and driving continuous quality improvement.

West Florida Hospital (WFH), a 531-bed acute care hospital in Pensacola, Fla., realized a 100% increase in pharmacy-driven interventions upon deploying surveillance technology and reaped the benefits associated with better care delivery as well as chalked up monthly savings of $6,300 around renal dosing adjustments and $11,800 for antibiotic-related interventions.

Currently, WFH’s entire renal dosing program is driven by the technology, and the hospital’s Antimicrobial Management Program uses the surveillance technology to monitor appropriate use of high-cost antibiotics as well as patients on antibiotics for more than 10 days. Rules-based monitoring also aids WFH in its efforts to track CMS Core Measures performance for acute myocardial infarction, heart failure, diabetes, and pneumococcal and influenza vaccinations.

**Conclusion**

It’s a new day for the pharmacy as regulatory and reimbursement pressures open the door for pharmacy management to take the lead in strategically positioning hospitals for the performance expectations of the future. Are you ready?

Steve Riddle, PharmD, BCPS, FASHP, is vice president of Clinical Affairs with Pharmacy OneSource, part of Wolters Kluwer Health. He can be reached at steve.riddle@pharmacyonesource.com
FDA has recently approved rivaroxaban (Xarelto, Janssen Pharmaceuticals) for treatment of acute deep vein thrombosis (DVT) and pulmonary embolism and for prevention of recurrences. These indications are in addition to the drug’s previous approvals for prevention of thromboembolism and stroke in patients with nonvalvular atrial fibrillation and for DVT prevention in patients undergoing joint surgery.

The approval was based mainly on results from three trials with a total of 9,478 patients randomized to rivaroxaban, placebo, or enoxaparin (Lovenox, Sanofi-Aventis) combined with a vitamin K antagonist such as warfarin (Coumadin, Bristol-Myers Squibb). Those trials showed that rivaroxaban was as effective as the enoxaparin and vitamin K antagonist combination for treating DVT and pulmonary embolism. A placebo-controlled trial showed that 1.3% of patients taking rivaroxaban had recurrent thromboembolic events compared with 7.1% of those assigned to placebo.

The studies also indicated that rivaroxaban has a lower risk of bleeding events. For example, in the EINSTEIN-PE trial, reported earlier this year in the New England Journal of Medicine and at the American College of Cardiology's annual meeting, 1.1% of patients on rivaroxaban were treated with vitamin K antagonists for early discontinuation compared with 2.2% with enoxaparin (P=.003).

A major advantage of rivaroxaban, an oral Factor Xa inhibitor, is that it doesn’t require monitoring of coagulation activity. Its major adverse event is increased risk of bleeding, as is the case with all other anticoagulants.


**Study: No aspirin for stent patients on oral anticoagulants**

A study presented at the European Society of Cardiology 2012 Congress indicates that patients treated with oral anticoagulants who are receiving stents do not need the addition of aspirin to their drug regimen.

The trial showed a large reduction in overall bleeding in patients receiving dual therapy with oral anticoagulants and clopidogrel compared with those receiving triple therapy including aspirin. Efficacy was not compromised and there actually appeared to be lower rates of ischemic events and a significant reduction in all-cause mortality.

The trial included 573 patients already treated with oral anticoagulants for atrial fibrillation or mechanical valves and undergoing coronary stenting were prospectively randomized to two groups: one given additional clopidogrel only (double therapy group), or a second given additional clopidogrel and aspirin (triple therapy group). Each was followed for one year.

The data presented showed cumulative incidence of bleeding in the triple therapy group to be 44.9%, whereas the double therapy group had an incidence of bleeding of 19.5%. The cumulative mortality was 6.4% for the triple therapy group versus 2.6% for the anticoagulant/clopidogrel group.


**Aspirin offers some benefit for preventing VTE recurrence**

Low-dose aspirin may benefit patients who have completed an initial course of anticoagulation therapy for venous thromboembolism, a recent study indicates.

Although the researchers found that aspirin did not significantly reduce the recurrence of venous thromboembolism compared with placebo, they did find that aspirin provided a net clinical benefit.

The investigators randomly assigned 822 patients who had completed initial anticoagulant therapy after a first episode of unprovoked VTE to receive 100 mg of aspirin daily or placebo for up to 4 years. The primary outcome was a recurrence of venous thromboembolism.

During a median follow-up period of 37.2 months, venous thromboembolism recurring in 73 of 411 patients assigned to placebo and in 57 of 411 assigned to aspirin (P=.09). Aspirin reduced the rate of the secondary outcomes (myocardial infarction, stroke, or cardiovascular death) by 34% (P=.01).

The rate of venous thromboembolism, myocardial infarction, stroke, major bleeding, or death from any cause was reduced by 33% (P=.01). There was no significant difference in the rates of bleeding.

WHAT YOU NEED TO KNOW

PRESCRIBED FOR CHILDREN 6 MONTHS OF AGE AND OLDER

• No Contraindications
• Sklice Lotion should be used in the context of an overall lice management program

IMPORTANT SAFETY INFORMATION FOR SKLICE LOTION

• The most common adverse reactions (incidence <1%) were conjunctivitis, ocular hyperemia, eye irritation, dandruff, dry skin, and skin burning sensation

PROVEN EFFECTIVE IN TWO CLINICAL TRIALS

• Patients received a single 10-minute treatment and were instructed not to nit comb
• 14 days after treatment, no live lice were observed in 76.1% (54/71) and 71.4% (50/70) of patients

10-MINUTE TREATMENT

• No nit combing required
  —However, a fine-tooth comb or special nit comb may be used to remove dead lice and nits
• To prevent accidental ingestion, adult supervision is required for pediatric application. Avoid contact with eyes.


Your choice matters.
Order a tube of Sklice Lotion for your pharmacy today.
INDICATION
Sklice Lotion is a pediculicide indicated for the topical treatment of head lice infestations in patients 6 months of age and older.

ADJUNCTIVE MEASURES
Sklice Lotion should be used in the context of an overall lice management program:
• Wash (in hot water) or dry-clean all recently worn clothing, hats, used bedding and towels
• Wash personal care items such as combs, brushes and hair clips in hot water
A fine-tooth comb or special nit comb may be used to remove dead lice and nits.

IMPORTANT SAFETY INFORMATION FOR SKLICE LOTION
In order to prevent accidental ingestion, Sklice Lotion should only be administered to pediatric patients under the direct supervision of an adult.

The most common adverse reactions (incidence <1%) were conjunctivitis, ocular hyperemia, eye irritation, dandruff, dry skin, and skin burning sensation.

Please see brief summary of full prescribing information on the following page.

For more information, please visit www.Skllice.com/HCP.

NDC: 49281-183-71

Two randomized, double-blind, vehicle-controlled trials in patients 6 months of age and older with head lice infestations. The primary endpoint was assessed as the proportion of patients who were free of live lice at day 2 and through day 8 to the final evaluation 14 (+2) days following a single application.

SKLICE® (Ivermectin) Lotion, 0.5% for topical use

Brief Summary of Prescribing Information

1 INDICATIONS AND USAGE

1.1 Indication
SKLICE® Lotion is indicated for the topical treatment of head lice infestations in patients 6 months of age and older.

1.2 Adjunctive Measures
SKLICE Lotion should be used in the context of an overall lice management program:
- Wash (in hot water) or dry-clean all recently worn clothing, hats, used bedding and towels.
- Wash personal care items such as combs, brushes and hair clips in hot water.
- A fine-tooth comb or special nit comb may be used to remove dead lice and nits.

2 DOSAGE AND ADMINISTRATION

For topical use only. SKLICE Lotion is not for oral, ophthalmic, or intravaginal use.
Apply SKLICE Lotion to dry hair in an amount sufficient (up to 1 tube) to thoroughly coat the hair and scalp. Leave SKLICE Lotion on the hair and scalp for 10 minutes, and then rinse off with water.
The tube is intended for single use; discard any unused portion.
Avoid contact with eyes.

4 CONTRAINDICATIONS
None.

5 WARNINGS AND PRECAUTIONS

5.1 Ingestion in Pediatric Patients
In order to prevent ingestion, SKLICE Lotion should only be administered to pediatric patients under the direct supervision of an adult.

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience
Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.
The data described below reflect exposure to a single 10 minute treatment of SKLICE Lotion in 379 patients, ages 6 months and older, in placebo-controlled trials. Of these subjects, 47 subjects were age 6 months to 4 years, 179 subjects were age 4 to 12 years, 56 subjects were age 12 to 18 years and 97 subjects were age 16 or older. Adverse reactions, reported in less than 1% of subjects treated with SKLICE Lotion, include conjunctivitis, ocular hyperemia, eye irritation, dandruff, dry skin, and skin burning sensation.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy
Pregnancy Category C

There are no adequate and well-controlled studies with SKLICE Lotion in pregnant women. SKLICE Lotion should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

No comparisons of animal exposure with human exposure are provided due to the low systemic exposure noted in the clinical pharmacokinetic study (see Clinical Pharmacology (12.3) in the full prescribing information). Human Data

There are published reports of oral ivermectin use during human pregnancy. In an open label study, 397 women in their second trimester of pregnancy were treated with ivermectin tablets and albendazole at the labeled dose rate for soil-transmitted helminths and compared with a pregnant, non-treated population. No differences in pregnancy outcomes were observed between treated and untreated populations.

Animal Data

Systemic embryofetal development studies were conducted in mice, rats and rabbits. Oral doses of 0.1, 0.2, 0.4, 0.8, and 1.6 mg/kg/day ivermectin were administered during the period of organogenesis (gestational days 6–15) to pregnant female mice. Maternal death occurred at 0.4 mg/kg/day and above. Cleft palate occurred in the fetuses from the 0.4, 0.8, and 1.6 mg/kg/day groups. Exencephaly was seen in the fetuses from the 0.8 mg/kg group. Oral doses of 2.5, 5, and 10 mg/kg/day ivermectin were administered during the period of organogenesis (gestational days 8–17) to pregnant female rats. Maternal death and pre-implantation loss occurred at 10 mg/kg/day. Cleft palate and wavy ribs were seen in fetuses from the 10 mg/kg/day group. Oral doses of 1.5, 3, and 6 mg/kg/day ivermectin were administered during the period of organogenesis (gestational days 6–18) to pregnant female rabbits. Maternal toxicity and abortion occurred at 6 mg/kg/day. Cleft palate and clubbed forepaws occurred in the fetuses from the 3 and 6 mg/kg groups. These teratogenic effects were found only at or near doses that were maternally toxic to the pregnant female. Therefore, ivermectin does not appear to be selectively fetotoxic to the developing fetus.

8.3 Nursing Mothers

Following oral administration, ivermectin is excreted in human milk in low concentrations. This has not been evaluated following topical administration. Caution should be exercised when SKLICE Lotion is administered to a nursing woman.

8.4 Pediatric Use

The safety and effectiveness of SKLICE Lotion have been established for pediatric patients 6 months of age and older [see Clinical Pharmacology (12.3) in the full prescribing information and Clinical Studies (14) in the full prescribing information].
The safety of SKLICE Lotion has not been established in pediatric patients below the age of 6 months. SKLICE Lotion is not recommended in pediatric patients under 6 months of age because of the potential increased systemic absorption due to a high ratio of skin surface area to body mass and the potential for an immature skin barrier and risk of ivermectin toxicity.

8.5 Geriatric Use

Clinical studies of SKLICE Lotion did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients.

10 OVERDOSAGE

In incidental or significant exposure to unknown quantities of veterinary formulations of ivermectin in humans, either by ingestion, inhalation, injection, or exposure to body surfaces, the following adverse effects have been reported most frequently: rash, edema, headache, dizziness, asthenia, nausea, vomiting, and diarrhea. Other adverse effects that have been reported include: seizure, ataxia, dyspnea, abdominal pain, paresthesia, urticaria, and contact dermatitis.

In case of accidental poisoning, supportive therapy, if indicated, should include parenteral fluids and electrolytes, respiratory support (oxygen and mechanical ventilation if necessary) and pressor agents if clinically significant hypotension is present. Induction of emesis and/or gastric lavage as soon as possible, followed by purgatives and other routine anti-poison measures, may be indicated if needed to prevent absorption of ingested material.

Distributed by:
Sanofi Pasteur Inc.
Switzerland, PA 18370

Manufactured by:
DPT Laboratories LTD
San Antonio, TX 78215
129685

U.S. Patent No. 6,103,248 and other patents pending.

IVE-BPLR-SA-FEB12 Revised: February 2012
FDA approves oral disease-modifying drug for multiple sclerosis

On September 12, 2012, FDA approved teriflunomide (Aubagio, Genzyme, a Sanofi-Aventis company), a pyrimidine synthesis inhibitor, for the treatment of patients with relapsing forms of multiple sclerosis (MS). This is the second oral disease-modifying treatment approved for MS with the first being fingolimod (Gilenya, Novartis) approved in 2010.

In a clinical trial, the relapse rate was 30% lower for individuals who received teriflunomide than for those taking placebo.

Patients considering taking teriflunomide should be evaluated for liver function before starting and periodically during treatment as this drug has a risk of liver toxicity. In addition, teriflunomide is labeled as pregnancy category X, so all women of childbearing age must have a negative pregnancy test prior to starting this drug treatment and must continue to use birth control while taking this agent.

Efficacy
FDA approval for teriflunomide was based on the data from the Teriflunomide Multiple Sclerosis Oral (TEMSO) trial, a phase 3 study that enrolled 1088 patients with relapsing forms of MS. Patients were randomized to receive teriflunomide at a dose of 7 mg, 14 mg, or placebo. Neurological examinations were performed every 12 weeks until 108 weeks and at unscheduled visits for suspected relapse. MRI was also performed at screening and at weeks 24, 48, 72, and 108.

The primary end point was the annualized relapse rate (ARR) which was significantly reduced by 31% in patients treated with 7 mg or 14 mg of teriflunomide compared with the placebo-treated patients. There was also a statistically significant reduction in the time to disability progression, sustained for 12 weeks, by 30% in the 14-mg dose group compared to placebo.

MRI outcomes demonstrated a significantly lower change in total lesion volume from baseline in the 7-mg and 14-mg groups compared with the placebo group.

Safety
The most common adverse reactions for teriflunomide in the 14-mg and 7-mg groups, respectively, during the clinical trials were headache (19% and 22%), ALT increase (14% and 12%), alopecia (13% and 10%), diarrhea (18% and 15%), influenza (12% and 9%), nausea (14% and 9%), and paresthesia (10% and 9%). Alopecia was the most common cause of discontinuation in the clinical trials.

Teriflunomide carries a black-box warning of the risk of hepatotoxicity and teratogenicity. Because fatal liver failure has been reported in patients treated with leflunomide, a similar risk is expected with teriflunomide. Clinicians should evaluate patients’ liver function within 6 months before teriflunomide initiation and monitor ALT levels monthly for 6 months after starting the drug.

Based on animal trials, teriflunomide may cause major birth defects if used during pregnancy. It is contraindicated in pregnant women or women of childbearing age who are not using reliable contraception.

Dosage
The recommended dose of teriflunomide is 7 mg or 14 mg orally once daily, with or without food. Within 6 months of initiating therapy, the clinician should obtain transaminase, bilirubin levels, and a complete blood count. Patients should also be screened for latent tuberculosis infection with a tuberculin skin test prior to initiation of therapy. Blood pressure should also be checked prior to treatment and periodically during treatment. Due to prolonged elimination of teriflunomide (8 months to 2 years) upon treatment discontinuation, accelerated elimination procedures including administration of cholestyramine 8 g every 8 hours for 11 days or 50 g of oral activated charcoal powder every 12 hours for 11 days can be used.

Diana M. Sobieraj is assistant professor of Pharmacy Practice, University of Connecticut School of Pharmacy, Storrs, Conn.
Macrovascular and microvascular complications of diabetes mellitus

Jiehyun Lee, PharmD
POSTDOCTORAL FELLOW, UNIVERSITY OF CONNECTICUT SCHOOL OF PHARMACY, STORRS, CONN.

Devra K. Dang, PharmD, BCPS, CDE
ASSOCIATE CLINICAL PROFESSOR, UNIVERSITY OF CONNECTICUT SCHOOL OF PHARMACY, STORRS, CONN.

Abstract
Diabetes causes acute complications, such as hyperglycemic crises. It is the progressive long-term complications of diabetes, however, that bring devastating and life-threatening consequences to patients with diabetes. The long-term complications are divided into microvascular and macrovascular complications, both resulting from cellular damages inflicted by chronic hyperglycemia. Appropriate screenings and treatment of these complications must take place in a timely manner to prevent worsening of the complications.

Faculty: Jiehyun Lee, PharmD, and Devra K. Dang, PharmD, BCPS, CDE
Dr. Lee is a post-doctoral fellow at the University of Connecticut School of Pharmacy, Storrs, Conn. Dr. Dang is associate clinical professor at the University of Connecticut School of Pharmacy, Storrs, Conn.

Faculty Disclosure: Dr. Lee and Dr. Dang have no actual or potential conflict of interest associated with this article.

Disclosure of Discussions of Off-Label and Investigational Uses of Drugs: This activity may contain discussion of unlabeled/unapproved use of drugs. The content and views presented in this educational program are those of the faculty and do not necessarily represent those of Drug Topics or University of Connecticut School of Pharmacy. Please refer to the official prescribing information for each product for discussion of approved indications, contraindications, and warnings.

EDUCATIONAL OBJECTIVES

Goal: To assist pharmacists in recognizing significant complications associated with diabetes to help prevent the development or progression of complications and improve diabetes care.

After participating in this activity, pharmacists will be able to:
- Recognize macrovascular and microvascular complications associated with diabetes mellitus
- Identify goals of therapy and drug and non-drug treatment options to decrease the risk of macrovascular and microvascular complications in patients with diabetes mellitus
- Recommend appropriate medications for treating macrovascular and microvascular complications of uncontrolled diabetes

The University of Connecticut School of Pharmacy is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Pharmacists are eligible to participate in the knowledge-based activity, and will receive up to 0.2 CEUs (2 contact hours) for completing the activity, passing the quiz with a grade of 70% or better, and completing an online evaluation. Statements of credit will be sent to CPE Monitor.

ACPE #0009-9999-13-001-H01-P

Grant Funding: As of September 17, 2012, funding for this activity is as follows:
An independent medical education grant from Abbott Laboratories.
This activity is supported by an independent educational grant from Boehringer Ingelheim Pharmaceuticals, Inc., which was made possible in part, through a collaboration with Eli Lilly and Company.
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Merk Sharp & Dohme Corp.
sanofi-aventis U.S.

Activity Fee: There is no fee for these activities.

Initial release date: 1/10/2013
Expiration date: 1/10/2015

To obtain immediate CPE credit, take the test online at www.drugtopics.com/cpe. Just click on the link in the yellow box that can be found under Free CPE Activities, which will take you to the CPE site. For first-time users, please complete the registration page. For those already registered, log in, find, and click on this lesson. Test results will be displayed immediately. Complete the evaluation form, and all credits will be sent to CPE Monitor.

For questions concerning the online CPE activities, e-mail: cpehelp@advanstar.com.
Medication Therapy Management (MTM) in Patients with Diabetes CPE Series

Welcome to a new Medication Therapy Management (MTM) in Patients with Diabetes CPE Series, which has been designed for pharmacists who take care of patients with diabetes. Beginning in September 2012 and continuing through March 2013, pharmacists can earn up to 14 hours of CPE credit with 7 monthly knowledge-based activities from the University of Connecticut School of Pharmacy and Drug Topics. This month, the professional development activity will cover macrovascular and microvascular complications of diabetes mellitus, and in February 2013, the focus will be psychosocial considerations in the management of the disease. In March 2013, the last knowledge-based activity will enable greater understanding of drug-induced hyper- and hypoglycemia, nonprescription medications, and complementary and alternative medicine for diabetes care. The MTM CPE Series will also be offering application-based and practice-based activities for an additional 9 CPE credits. Online interactive case-based studies will be available with 1 hour of CPE credit, starting in February 2013 and continuing through April 2013.

The MTM CPE Series will conclude with a live meeting at the University of Connecticut School of Pharmacy in May 2013, offering application of MTM concepts to the patient with diabetes and motivational interviewing skills development for health behavior change in diabetes management.

Diabetes mellitus is the 7th leading cause of death in the United States and doubles the risk for death among patients with diabetes compared to persons of similar age without diabetes. Uncontrolled hyperglycemia can lead to acute complications of diabetes such as diabetic ketoacidosis and hyperglycemic hyperosmolar syndrome. It is often the long-term complications of uncontrolled hyperglycemia that put patients with diabetes at significant risk for death.

Long-term complications of diabetes are divided into microvascular and macrovascular complications. The microvascular complications include retinopathy, nephropathy, and neuropathy. Macrovascular complications include cardiovascular disease (CVD) such as ischemic heart disease, cerebrovascular disease, peripheral arterial disease, chronic heart failure, and cardiomyopathy. The damaging effects of chronic hyperglycemia on the vasculature are the underlying causes for morbidity and mortality in patients with diabetes. It is crucial for healthcare professionals to understand the close relationship between diabetes and its vascular complications to prevent them.

Pathophysiology of microvascular complications

Hyperglycemia is closely associated with cellular dysfunction and activation. Hyperglycemia triggers proinflammatory responses and other forms of cellular activation from endothelial cells, leading to overall vasculature damage. Several biochemical pathways have been postulated to trigger the cellular responses and cause the microvascular complications. These include polyol accumulation, formation of advanced glycation end products, oxidative stress, and activation of protein kinase C. Future treatment options for diabetes may target these pathways.

Microvascular complications

Diabetic retinopathy. Diabetic retinopathy is the most common microvascular complication of diabetes, contributing to over 10,000 cases of blindness per year. Almost all patients with type 1 diabetes and approximately 60% of those with type 2 diabetes will develop some degree of retinopathy within 20 years of diagnosis. The prevalence of retinopathy at clinical diagnosis of diabetes is approximately 21% in the United States, and clinically significant retinopathy can be detected as early as 7 years before the diagnosis.

Diabetic retinopathy results from microangiopathy affecting retinal vasculature. Two underlying pathologic mechanisms are microvascular leakage and microvascular occlusion. Diabetic retinopathy is clinically divided into 2 major stages: nonproliferative diabetic retinopathy (NPDR), also known as background retinopathy, and proliferative diabetic retinopathy (PDR). NPDR is further subdivided into mild, moderate, and severe levels. The retinopathy stages correspond to certain findings on dilated ophthalmoscopy (Table 1). Diabetes patients with significant macular edema and PDR generally require treatment with laser photocoagulation to prevent progression to blindness. For vitreous hemorrhage and active progressive PDR, vitrectomy surgery may be required to improve visual acuity.

Most diabetes patients with detectable retinopathy are asymptomatic until the damage to their eyes is severe enough to cause vision changes. Symptomatic patients may complain of blurry vision, floaters, night time vision impairment, and partial vision loss, all indicating clinically significant retinal damage. Because of the asymmetric nature of diabetic retinopathy and the effectiveness of laser photocoagulation at specific stages of retinopathy, the American Diabetes Association (ADA) recommends an annual dilated eye examination by an ophthalmologist or optometrist for all diabetes patients. The eye exam has additional benefits as it can detect other ophthalmic complications that are more common in older patients, such as cataract, glaucoma, and age-related macular degeneration.

In addition to surgical treatments, medical management of diabetic retinopathy includes glycemic control and blood pressure control to prevent the development or progression of diabetic retinopathy. Two randomized clinical trials, the United Kingdom Prospective Diabetes Study (UKPDS) and the Diabetes Control and Complications Trial (DCCT), demonstrated the importance of glycemic control in preventing diabetic retinopathy.

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Table 1

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<tr>
<th>Stage</th>
<th>Description</th>
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<tr>
<td>Background</td>
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<td>Proliferative</td>
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DrugTopics.com

January 2013

DRUG TOPICS 45
In UKPDS 3,867 newly diagnosed patients with type 2 diabetes were randomized to intensive treatment with a sulfonylurea or insulin or to conventional treatment with dietary therapy. Over 10 years the patients receiving intensive treatment showed a significant 25% risk reduction in microvascular end points, mostly due to fewer cases of retinal photocoagulation, when compared to those who received conventional treatment. In addition, a prospective observational study of UKPDS found that each 1% reduction in glycosylated hemoglobin (A1C) level was associated with a 37% decrease in microvascular end points.

DCCT compared intensive insulin treatment (injection 3 or 4 times daily) to conventional insulin treatment (twice-daily injection) in patients with type 1 diabetes. During a mean follow-up of 6 years, the intensive treatment group showed a 34% reduction in progression of retinopathy and a 54% reduction in the risk of progression. The Epidemiology of Diabetes Interventions and Complications (EDIC) study also showed a 39% and 54% reduction in the incidence of microalbuminuria for the intensive therapy group. The EDIC study also compared to results for the conventional insulin treatment group. The UKPDS also showed a 37% decrease in visual acuity when compared to a blood pressure target of less than 180/105 mm Hg. Other clinical trials have demonstrated the association between blood pressure control and reduction in the incidence or progression of diabetic retinopathy.

**Diabetic nephropathy.** Diabetic nephropathy is the leading cause of kidney failure in the United States, accounting for 44% of all new cases of kidney failure in 2008. In the UKPDS the incidence of microalbuminuria was 2.0% per year and the prevalence of microalbuminuria was 24.9% 10 years after the diagnosis of type 2 diabetes. In addition, approximately 7% of patients with type 2 diabetes already had microalbuminuria at the time of diagnosis. The cumulative incidence of microalbuminuria in patients with type 1 diabetes was 12.6% over 7.3 years, according to the European Diabetes (EURODIAB) Prospective Complications Study. A prospective, population-based study also suggested that diabetic nephropathy was significantly associated with cardiovascular mortality.

Pathogenic mechanism of diabetic nephropathy involves glomerular basement membrane thickening, diffuse mesangial sclerosis, microaneurysm, hyaline degeneration, and hyaline arteriosclerosis. Mesangial expansion and glomerular basement membrane thickening are commonly seen in diabetes patients with varying degrees of nephropathy.

**Diabetic nephropathy** is categorized into 2 stages based on urinary albumin excretion: microalbuminuria and macroalbuminuria, also known as proteinuria or overt diabetic nephropathy. These terms are often mistakenly interpreted as the differing sizes of albumin molecules. The terms microalbuminuria and macroalbuminuria, however, are in fact referring to the quantity of urinary albumin excreted, and the ADA now recommends the term “increased urinary albumin excretion” over the terms microalbuminuria and macroalbuminuria (Table 2). The ADA recommends albumin measurement in a spot urine sample to obtain urinary albumin-to-creatinine ratio, which should be done annually in patients with type 1 diabetes with diabetes duration of 5 years or longer and in all patients with type 2 diabetes starting at the time of diagnosis. Alternatively, semiquantitative dipstick measurements may be used to test for proteinuria. Although these diagnostic tools and criteria may detect early signs of diabetic nephropathy, the risk for developing diabetic nephropathy and CVD begins even when diabetes patients have normal urinary albumin excretion.

Similar to diabetic retinopathy, glycemic control and blood pressure control are the main ways to prevent diabetic nephropathy. In the DCCT, the intensive insulin treatment group experienced a 39% and 54% reduction in the incidence of microalbuminuria and macroalbuminuria, respectively, compared to results for the conventional insulin treatment group. The EDIC study also demonstrated that benefits of the intensive treatment on preventing diabetic nephropathy persisted 4 years after the end of DCCT even though the difference in A1C was no longer significant between the intensive treatment group and the conventional treatment group. The UKPDS also showed a 34% risk reduction in the progression of albuminuria for the intensive therapy group.

Other prospective randomized studies have also demonstrated that glycemic control can delay the rate of progression from microalbuminuria to macroalbuminuria in patients with type 1 or type 2 diabetes. Thus, strict glycemic control (A1C <7%) is still recommended for most patients with diabetes to prevent microvascular complications. However, as will be discussed later in this article, the A1C goal needs to be individualized according to patient characteristics, and a less-stringent A1C goal may be appropriate in certain patients.

### Table 1

**Diabetic Retinopathy Disease Severity Scale**

<table>
<thead>
<tr>
<th>Disease severity level</th>
<th>Findings observable on dilated ophthalmoscopy</th>
</tr>
</thead>
<tbody>
<tr>
<td>No apparent retinopathy</td>
<td>No abnormalities</td>
</tr>
<tr>
<td>Mild NPDR</td>
<td>Microaneurysms only</td>
</tr>
<tr>
<td>Moderate NPDR</td>
<td>More than just microaneurysms but less than severe NPDR</td>
</tr>
<tr>
<td>Severe NPDR</td>
<td>Any of the following: more than 20 intraretinal hemorrhages in each of 4 quadrants; definite venous beading in 2+ quadrants; prominent intraretinal microvascular abnormalities in 1+ quadrant; And no signs of PDR</td>
</tr>
<tr>
<td>PDR</td>
<td>One or more of the following: neovascularization, vitreous/preretinal hemorrhage</td>
</tr>
</tbody>
</table>

Abbreviations: NPDR, nonproliferative diabetic retinopathy; PDR, proliferative diabetic retinopathy. Source: Ref 4

46 Drug Topics January 2013 DrugTopics.com
In the UKPDS blood pressure control also reduced the risk for the development of microalbuminuria.\textsuperscript{1,3} Other numerous studies showed that treatment of hypertension, irrespective of the agent used, produced beneficial effects on albuminuria in patients with type 1 and type 2 diabetes.\textsuperscript{19} In particular, renin-angiotensin-aldosterone system blockade plays an important role in the prevention and treatment of diabetic nephropathy. In patients with type 2 diabetes, both ACE inhibitors and angiotensin receptor blockers (ARB) have been shown to reduce the risk of development and progression of diabetic nephropathy significantly by up to 70%.\textsuperscript{22,24} In addition, ACE inhibitors increase the chances of regression to normal urinary albumin excretion.\textsuperscript{19} The renoprotective effects of ACE inhibitors and ARBs are independent of their blood-pressure-lowering effects and related to decreased intraglomerular pressure and passage of proteins into the proximal tubule.

Combination treatment of an ACE inhibitor plus an ARB has been shown to produce synergistic effects on urinary albumin excretion in some studies.\textsuperscript{19,25} However, the National Kidney Foundation’s 2012 Kidney Disease Outcomes Quality Initiative Clinical Practice Guidelines for Diabetes and Chronic Kidney Disease recommend against dual therapy with an ACE inhibitor and an ARB in diabetes due to the risk of increased adverse events (e.g. hyperkalemia, impaired kidney function) with combination therapy despite a reduction in observed albuminuria. Combination therapy with an ACE inhibitor or ARB with the renin inhibitor aliskiren is also contraindicated in diabetes patients according to the FDA due to the risk of renal impairment, hypotension, and hyperkalemia.\textsuperscript{25}

**Diabetic neuropathy.** Diabetic neuropathy is characterized by progressive nerve damage affecting both divisions of the peripheral nervous system, the somatic and autonomic systems. According to the Centers for Disease Control and Prevention, approximately 60% to 70% of patients with diabetes have mild-to-severe forms of nervous system damage.\textsuperscript{1} A prospective study of patients with type 1 diabetes reported that the overall prevalence of diabetic neuropathy ranged from 18% to 58% at baseline.\textsuperscript{26} In patients with type 2 diabetes the overall prevalence was 28% according to a population-based study.\textsuperscript{27}

**Diabetic neuropathy is defined as** "the presence of symptoms and/or signs of peripheral nerve dysfunction in people with diabetes after the exclusion of other causes."\textsuperscript{28} It carries considerable morbidity and mortality. Diabetic neuropathy is the leading cause of lower-extremity amputations, being implicated in more than 60% of nontraumatic lower-limb amputations in patients with diabetes.\textsuperscript{1} More than 80% of amputations follow a foot ulcer or injury, which may be due to nerve damage from diabetes.\textsuperscript{29}

Numerous classifications of diabetic neuropathy are available for the variety of syndromes within the peripheral nervous system. According to the ADA, diabetic neuropathy can be divided into 3 main categories: sensory neuropathies, focal and multifocal neuropathies, and autonomic neuropathy. Multiple subcategories exist within each category.\textsuperscript{29}

Acute sensory neuropathy is a rare type of sensory neuropathy following periods of glycemic fluctuation. It has an acute onset of severe sensory symptoms, especially at night time. Chronic sensorimotor distal symmetric polyneuropathy (DPN), however, is the most common form of diabetic neuropathy. Up to 50% of patients with DPN may complain of burning, tingling, stabbing, deep aching, or electrical pain, which often worsens at night.\textsuperscript{29} The symptoms commonly manifest in the feet and lower limbs, but can also be present in the hands. This classic pattern of symmetrical sensory loss is called the “stocking-glove” distribution.\textsuperscript{30}

In more advanced cases of DPN patients may simply feel numbness, which then can potentially lead to painless foot injury or ulceration.\textsuperscript{29} Other forms of neuropathy, such as chronic inflammatory demyelinating polyneuropathy, vitamin B\textsubscript{12} deficiency, hypothyroidism, and uremia, must be ruled out first before making a diagnosis of DPN. Of note, long-term use of metformin can cause vitamin B\textsubscript{12} deficiency, which may be confused with diabetic neuropathy.\textsuperscript{31}

A careful clinical examination should be done for all patients with diabetes to diagnose DPN. Annual screening should be performed by assessing pinprick, temperature, and vibration perception, 10-g monofilament pressure sensation, and ankle reflexes.\textsuperscript{29} Abnormalities in more than one of these tests have greater than 87% sensitivity in detecting DPN.\textsuperscript{29} In particular, the 10-g monofilament sensation test is a strong predictor of future foot ulcer risk.\textsuperscript{32} Examination of the feet for ulcers, calluses, and deformity should also be performed.\textsuperscript{29} In addition, all patients with diabetes should be educated on how to perform daily self-monitoring of their feet, proper selection of footwear, and proper skin and nail care for foot.\textsuperscript{8} See the October 2012 Drug Topics continuing education article in this diabetes series for additional information on patient education about foot care.\textsuperscript{33}

**The renoprotective effects of ACE inhibitors and ARBs are independent of their blood-pressure lowering effects.**

Focal and multifocal neuropathies represent another category of diabetic neuropathy and are more common in older patients with type 2 diabetes.\textsuperscript{30} This category includes focal limb, cranial, truncal, and proximal motor neuropathy.\textsuperscript{29} Focal limb

### TABLE 2

**DEFINITIONS OF ABNORMALITIES IN URINARY ALBUMIN EXCRETION**

<table>
<thead>
<tr>
<th>Category</th>
<th>Spot urine collection (µg/mg creatinine)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>&lt;30</td>
</tr>
<tr>
<td>Increased urinary albumin excretion</td>
<td>≥30</td>
</tr>
</tbody>
</table>

Diagnosis of increased urinary albumin excretion should only be made based on a positive reading for 2 out of 3 samples collected over a 3- to 6-month period as other factors such as exercise, fever, and marked hypertension may elevate urinary albumin excretion. Source: Ref 12

DrugTopics.com January 2013 DRUG TOPICS 47
neuropathy (mononeuropathy) is often, but not always, due to nerve entrapment. Carpal tunnel syndrome, an example of nerve entrapment, occurs in up to 20% of diabetes patients. Cranial neuropathies are rare. Truncal neuropathies (thoracolumbar radiculoneuropathy) may present with girdle-like pain over the abdominal wall with spontaneous resolution within 4-6 months. Proximal motor neuropathy (amyotrophy) is characterized by relatively acute onset of unilateral or asymmetrically bilateral, severe pain with muscle wasting, and weakness in the thighs.

Autonomic neuropathy carries significant morbidity and even mortality in diabetes patients. Three common organ systems affected by diabetic autonomic neuropathy are the gastrointestinal, genitourinary, and cardiovascular systems. Neurologic dysfunction can manifest as gastroparesis, constipation, erectile dysfunction, bladder dysfunction, exercise intolerance, resting tachycardia, and orthostatic hypotension. Cardiovascular autonomic neuropathy may bring life-threatening consequences to diabetes patients such as silent myocardial ischemia and even sudden cardiac death.

Glycemic control is an important way to prevent the development and progression of diabetic neuropathy. The DCCT study showed that improved glycemic control reduced the risk of diabetic neuropathy in patients with type 1 diabetes. Many epidemiologic studies have suggested that glycemic control helps prevent diabetic neuropathy in patients with type 2 diabetes as well. Many drugs have been studied for the treatment of the symptoms of chronic somnolent or neuropathic pain. Tricyclic antidepressants, selective serotonin reuptake inhibitors, serotonin-norepinephrine reuptake inhibitors, anticonvulsants, opioids, topical capsaicin, and the lidocaine patch have been clinically used to provide symptomatic relief from DPN pain. Only duloxetine and pregabalin, however, have FDA’s approved indication for the treatment of DPN. Multiple national and international guidelines on the pharmacological treatment of painful DPN exist, and with various differences in their recommendations. The majority of the guidelines do recommend serotonin-norepinephrine reuptake inhibitors (either duloxetine or both duloxetine and venlafaxine), tricyclic antidepressants, or the alpha2-delta ligands pregabalin and gabapentin as first or second-line treatment. Pharmacologic treatment options for painful DPN should be carefully chosen and evaluated as these can cause significant side effects and drug interactions. For example, even though the majority of guidelines recommend tricyclic antidepressants as a first-line treatment option, significant cardiac and anticholinergic side effects can occur with this drug class. No pharmacologic agent currently available can modify the natural history of DPN. Thus, treatment should focus on glycemic control to prevent the onset and progression of diabetic neuropathy.

**Macrovascular complications**

Macrovascular complications such as myocardial infarction (MI), stroke, and peripheral artery disease are major consequences of diabetes. Patients with diabetes are at 2- to 4-fold increased risk for developing CVD. The macrovascular complications are responsible for approximately 80% of mortality in diabetes patients. Although patients with diabetes commonly experience and complain of microvascular complications, the greatest cause of death in people with diabetes is CVD.

The main pathologic mechanism of diabetic macrovascular complications is the development of atherosclerosis – the excessive accumulation of lipids, inflammatory cells, and connective tissue in the vessel wall. Atherosclerotic plaques are formed in response to endothelial cell dysfunction and activation as described previously. The plaques grow silently over decades and eventually occlude the vessel lumen causing ischemia to target tissues. Although this form of vessel occlusion causes considerable discomfort (e.g., angina pectoris), clinical cardiovascular events commonly occur when a thrombus (blood clot) is formed due to the plaque deterioration or rupture, leading to rapid and complete cessation of blood supply to target tissues.

Subsequent observational follow-up data of the landmark studies DCCT and UKPDS showed significant benefits of intensive therapy over conventional therapy on CVD. The DCCT/EDIC study research group followed 93% of the original cohort from DCCT for a mean duration of 17 years and found that intensive treatment reduced the risk of any CVD event by 42% and the risk of nonfatal MI, stroke, or death from CVD by 57%. The UKPDS demonstrated a nonsignificant 16% reduction in the risk of MI. In posttrial monitoring of 3,277 patients from UKPDS over 10 years, the intensive therapy
The benefits of metformin in CVD were also observed in UKPDS, with a 39% reduction in MI in the metformin group compared to the dietary therapy group. A prospective observational study of UKPDS also found that each 1% reduction in A1C was associated with a 1% reduction in A1C levels between the intensive therapy group and the conventional therapy group. It should be noted that baseline differences in mean A1C levels were lost by 1 year. A prospective observational study of UKPDS also found that each 1% reduction in A1C was associated with a 14% reduction in MI and a 12% reduction in stroke. The benefits of metformin in CVD were also observed in UKPDS, with a 39% reduction in MI in the metformin group compared to the dietary therapy group.

As these two landmark studies had no glycemic threshold further research was warranted, especially in patients with type 2 diabetes. Several large, long-term trials took place in response, including Action to Control Cardiovascular Risk in Diabetes (ACCORD), Action in Diabetes and Vascular Disease: Preterax and Diamicron Modified-Release Controlled Evaluation (ADVANCE), and Veterans Affairs Diabetes Trial (VADT). All of these studies enrolled older type 2 diabetes patients. A detailed description of these three studies is available in the Drug Topics November 2012 continuing education article.

The ACCORD study looked at over 10,000 type 2 diabetes patients with either history of CVD or significant CVD risk and randomized them to intensive glycemic control (goal A1C <6%) or standard glycemic control (goal A1C 7.0%-7.9%). Both groups were treated with multiple diabetes medications, but 35% of the participants were already treated with insulin at baseline. The mean duration of diabetes was 10 years. The glycemic control portion of the ACCORD study was stopped early due to an increased rate of all-cause mortality and cardiovascular deaths in the intensive control group. A clear explanation for the mortality findings could not be found. Severe hypoglycemia was associated with higher mortality than those without it in both groups.

The ADVANCE study looked at over 11,000 patients with type 2 diabetes from Europe, Australia/New Zealand, Canada, and Asia. The participants were randomized to intensive glycemic control (primary therapy with glargine [a sulfonylurea] and additional medications with a target A1C ≤6.5%) or standard therapy (any diabetes medications except glargine with a target set according to “local guidelines”). Baseline characteristics of the patient population were similar to those of the ACCORD study, except that the participants of ADVANCE were slightly older and had an average duration of diabetes 2 years shorter, lower baseline A1C, and almost no use of insulin at baseline. The median A1C was 6.3% in the intensive therapy group and 7.0% in the standard therapy group. Despite the difference in A1C levels, no significant difference was found between the 2 groups in the macrovascular outcome (hazard ratio=0.94, 95% CI, 0.84-1.06; P=.32).

The VADT was a much smaller randomized, controlled trial compared to ACCORD and ADVANCE, including 1,791 military veterans. Participants of VADT were randomized to intensive glycemic control (goal <6%) or standard glycemic control (planned A1C difference of 1.5% between the 2 groups). Both groups used multiple and similar diabetes medications to achieve the glycemic goals. Median A1C level within the first 6 months of the study was 6.9% in the intensive group and 8.4% in the standard group. However, the intensive group showed no significant reduction in CVD events. In fact, more CVD deaths were found in the intensive group.

### Patients may better realize the importance of treatment adherence when you point out that their current symptoms (e.g. painful peripheral neuropathy or erectile dysfunction) are likely due to uncontrolled hyperglycemia. Think of patients whom you can help to connect their current symptoms with complications of diabetes.
compared to the standard group, although the difference was not statistically significant.43 Exploratory analyses of VAADT also found a close association between severe hypoglycemia and CVD mortality.36

Results from these 3 studies did not lead to any changes in glycemic control goals, but they provided additional clarification to the current ADA guideline. A subsequent meta-analysis, including these three trials and two others, found that intensive glycemic control was associated with a statistically significant 17% risk reduction in nonfatal MI and 15% risk reduction in coronary heart disease but not in the risk of stroke or all-cause mortality.44 It has been suggested that, based on subgroup analyses from the three studies described above, clinicians can consider a more intensive glycemic goal than the general goal of <7% may be appropriate.36

Management of macrovascular complications not only involves achieving glycemic control but also needs to include management of other CVD risk factors such as hypertension, dyslipidemia, and obesity. Collectively these CVD risk factors have been called the metabolic syndrome. The components of metabolic syndrome are elevated blood glucose level, raised blood pressure, elevated triglyceride levels, low high-density lipoprotein cholesterol levels, and central obesity (Table 3).45 The metabolic syndrome has direct correlation to CVD outcomes and increases the risk for CVD by 2-fold over the next 5 to 10 years.45 Early detection and management of these CVD risk factors are crucial in diabetes management to prevent macrovascular events. The benefits of lipid and blood pressure lowering in decreasing CVD risk have been substantiated by many studies in patients with diabetes. Table 4 summarizes the general management of blood pressure and lipids, including the new systolic blood pressure goal according to the ADA.46 For hypertension management, an ACE inhibitor or an ARB should be included in the antihypertensive regimen as these agents have been shown to be more effective in reducing CVD risk for diabetes patients than any other antihypertensive agents.46 Patients on these medications should have their kidney function and serum potassium level monitored. According to the ADA, statin therapy should also be initiated for lipids management, regardless of baseline low-density lipoprotein cholesterol levels. Of all the medications for dyslipidemia, statins are the only agents that have clinical evidence for decreasing CVD mortality in diabetes patients. Of note, the bile acid sequestrant colesvelem has an FDA-approved indication for type 2 diabetes,46 ACE inhibitors, ARBs, and statins are all contraindicated in pregnancy.

Because of plaque erosion and rupture, patients with diabetes are at increased risk of thrombotic CVD.2 Aspirin therapy decreases the risk for CVD events but only in certain diabetes patients.8 The recommendation for aspirin therapy was changed with the ADA Standards of Care guidelines in 2010. Prior to 2010, the ADA recommendation was that aspirin therapy as a primary prevention strategy for preventing CVD be considered for all diabetes patients older than 40 years.47 However, the recommendation was subsequently changed based on more recent research data that cast doubts on the efficacy of aspirin for primary prevention in diabetes patients. The efficacy depends on a patient’s underlying CVD risk, which must be weighted against the risk of gastrointestinal bleeding. The current criteria for aspirin therapy are listed in Table 5.8 In addition, patients with diabetes are encouraged to stop smoking or not begin smoking given that smoking increases the risk of CVD dramatically. Patients should be educated to know their “diabetes ABCs” – their A1C, blood pressure, and cholesterol goal and current values.48 Nonpharmacologic treatments such as dietary therapy, weight management, and physical activity can lead to the achievement of glycemic, blood pressure, and lipid goals and help prevent diabetic complications. A detailed discussion of medical nutrition therapy and physical activity for diabetes patients can be found in the Drug Topics October 2012 continuing education article in this diabetes series.33

**Conclusion**

Clinical evidence and science have proved clear relationships between diabetes and vascular complications. The impact of vascular complications is well understood among healthcare professionals. As a complex metabolic disease, diabetes requires more than just glycemic control to prevent and manage vascular complications.

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**TABLE 5: AMERICAN DIABETES ASSOCIATION ASPIRIN THERAPY CRITERIA**

<table>
<thead>
<tr>
<th>Consider aspirin therapy (75–162 mg/day) as primary prevention strategy in those with type 1 or type 2 diabetes at increased cardiovascular risk (10-year risk &gt;10%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Men &gt;50 years or women &gt;60 years of age AND at least 1 additional major CVD risk factor:</strong></td>
</tr>
<tr>
<td>o Family history of CVD</td>
</tr>
<tr>
<td>o Hypertension</td>
</tr>
<tr>
<td>o Smoking</td>
</tr>
<tr>
<td>o Dyslipidemia</td>
</tr>
<tr>
<td>o Albuminuria</td>
</tr>
<tr>
<td>Avoid aspirin therapy in patients at low CVD risk (10-year risk &lt;5%): men &lt;50 years or women &lt;60 years of age and no major additional CVD risk factors</td>
</tr>
<tr>
<td>For men &lt;50 years or women &lt;60 years of age with multiple other CVD risk factors (10-year CVD risk 5-10%), clinical judgment is required.</td>
</tr>
</tbody>
</table>

**Source:** Ref 8

Abbreviations: CVD, cardiovascular disease.
TEST QUESTIONS

1. Which is NOT a microvascular complication of diabetes?
   a. Retinopathy
   b. Myopathy
   c. Nephropathy
   d. Neuropathy

2. Which is NOT an example of diabetic macrovascular complications?
   a. Peripheral artery disease
   b. Myocardial infarction (MI)
   c. Stroke
   d. Chronic kidney disease

3. How early may clinically significant diabetic retinopathy be detected in a patient with diabetes?
   a. 5 years before diagnosis of diabetes
   b. 6 years before diagnosis of diabetes
   c. 7 years before diagnosis of diabetes
   d. 8 years before diagnosis of diabetes

4. How often does a patient with diabetes need a dilated eye exam?
   a. Twice a year
   b. Once a year
   c. Every other year
   d. Every 5 years

5. In terms of albumin-to-creatinine ratio, which of these ranges is considered normal urinary albumin excretion?
   a. <30 µg/mg
   b. 30-299 µg/mg
   c. 300-499 µg/mg
   d. >500 µg/mg

6. Which should be a part of the medication regimen for a patient with diabetes and nephropathy?
   a. Thiazide diuretic
   b. Angiotensin-converting enzyme inhibitor
   c. Calcium channel blocker
   d. Beta blocker

7. How often should a patient with diabetes and nephropathy be screened for nephropathy with urinary albumin excretion measurement?
   a. Twice a year
   b. Once a year
   c. Every other year
   d. Every 5 years

8. Which 2 drugs are FDA approved for diabetic peripheral neuropathic pain?
   a. Pregabalin and duloxetine
   b. Pregabalin and amitriptyline
   c. Gabapentin and duloxetine
   d. Gabapentin and fluoxetine

9. Which may result from diabetic autonomic neuropathy?
   a. Silent MI
   b. Foot amputation
   c. Carpal tunnel syndrome
   d. Infection

10. What is the typical clinical presentation of chronic sensorimotor distal symmetric polyneuropathy?
    a. Constipation
    b. Pain, tingling, and/or numbness in feet and ankles
    c. Erectile dysfunction
    d. Bladder dysfunction

11. In terms of A1C, which should be the general goal of glycemic control in patients with diabetes according to the ADA?
    a. <6%
    b. <6.5%
    c. <7%
    d. <8%

12. Which one of these four antihypertensive medications is a preferred agent in patients with diabetes and hypertension?
    a. Valsartan
    b. Hydrochlorothiazide
    c. Amiodipine
    d. Clonidine

13. Which is NOT a component of metabolic syndrome?
    a. Central obesity
    b. Raised blood pressure
    c. Raised low-density lipoprotein (LDL) cholesterol
    d. Elevated blood glucose

14. According to the 2013 ADA Standards of Medical Care in Diabetes, what is the goal blood pressure for patients with diabetes?
    a. <120/80 mm Hg
    b. <130/80 mm Hg
    c. <140/80 mm Hg
    d. <140/90 mm Hg

15. What is the goal LDL cholesterol level in patients with diabetes and no overt cardiovascular disease (CVD)?
    a. <70 mg/dL
    b. <80 mg/dL
    c. <100 mg/dL
    d. <130 mg/dL

16. According to the ADA, aspirin therapy is NOT indicated for which individuals with diabetes?
    a. 65-year-old male with microalbuminuria
    b. 55-year-old male with hypertension
    c. 57-year-old female with osteoporosis
    d. 62-year old female with dyslipidemia

17. Which antilipid agent has been shown to reduce CVD mortality in a patient with diabetes?
    a. Fenofibrate
    b. Niacin
    c. Fish oil
    d. Atorvastatin

18. Which antilipid agent also has an FDA-approved indication for the treatment of type 2 diabetes?
    a. Colesevelam
    b. Fenofibrate
    c. Niacin
    d. Omega-3 fatty acid

19. Blood pressure control is beneficial for which two microvascular complications of diabetes?
    a. Retinopathy and nephropathy
    b. Retinopathy and neuropathy
    c. Neuropathy and nephropathy
    d. Neuropathy and myopathy

20. Which is NOT a major risk factor in aspirin therapy criteria for a patient with diabetes who meets the age cut off?
    a. Smoking
    b. Dyslipidemia
    c. Carpal tunnel syndrome
    d. Albuminuria
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The deadly outbreak of fungal meningitis has resulted in a public health crisis. More than 500 individuals across 19 states have become infected by contaminated vials of injectable steroid drug from the New England Compounding Center (NECC). Dozens have died.

From a legal and regulatory point of view, the crisis has exposed a void in the world of drug manufacturing versus compounding pharmacy to which few pay attention, although there has been significant litigation in this area even before this latest crisis.

Traditional compounding pharmacy practices involve admixing or altering prescription ingredients to make custom medications that fit the needs of an individual patient, whether sterile or non-sterile products. These pharmacies have historically fallen under the jurisdiction of the state pharmacy boards.

In 1997, Congress attempted to clarify the role of FDA in the oversight of compounding pharmacies as a part of the FDA Modernization Act. However, before the law was to take effect, seven compounding pharmacies sued to block its enactment. Since then, the law, as well as FDA’s existing authority to regulate compounding pharmacies under the Federal Food, Drug and Cosmetic Act, became mired in litigation and uncertainty. To attempt to remedy some of the ambiguity, FDA issued guidelines in 2002 to try to draw a line between manufacturing and traditional compounding.

The tragedy has caused legislators to call for Congressional hearings on the issue of pharmacy compounding. Congressman Ed Markey of Massachusetts is quoted as stating: “A state’s ability to protect patients is limited only to activities that take place within its borders. Because the new age of compounding pharmacies involves shipping drugs across state lines, the federal government — specifically the FDA — needs the authority to ensure that patients that rely on compounded drugs are kept safe. The FDA has said clearly that it needs new authority to effectively protect patients and oversee these companies. This authority can only be provided by Congress.”

Although Markey believes that traditional small compounding pharmacies should continue to operate as they currently do, and should continue to be regulated by the states as long as they use safe drugs, undertake safe practices, and get valid prescriptions for the drugs they make, he is proposing new legislation that is intended to address when a pharmacy should be regulated by FDA when it engages in certain drug preparation activities.

In general, the NECC crisis has fed federal legislators and regulators calling for greater accountability of certain compounding pharmacies. Some examples include:

1. Registration with FDA as drug manufacturers,
2. FDA inspections of compounding pharmacies at any time,
3. Transparency to the public, with appropriate labeling of compounded drugs, and
4. Mandatory reporting to the FDA when adverse reactions occur so patients aren’t given drugs that are known to have caused health problems.

Although it is well known at this time that both federal and state investigation and inquiry have been undertaken against NECC, recent reports indicate that a grand jury has been convened to assess any criminal culpability of individuals associated with NECC.

This article is not intended as legal advice and should not be used as such. When legal questions arise, pharmacists should consult with attorneys familiar with the relevant drug and pharmacy laws.

Ned Milenkovich is a member at McDonald Hopkins, LLC, and chairs its drug and pharmacy practice group. He is also Vice-Chairman of the Illinois State Board of Pharmacy. Contact Ned at 312-642-1480 or at nmilenkovich@mcdonaldhopkins.com.
New formulas fight seasonal cold, flu symptoms to help you breathe easier

MIRANDA HESTER, CONTENT COORDINATOR

The mix of cold temperatures and holiday burn-out may send patients on the hunt for relief from coughs, colds, and sore throats. Fortunately, a number of companies have introduced new products and formulas in liquid and caplet forms to address just these symptoms.

Last year, Mucinex introduced its Fast-Max line in liquid form. The company now offers the line in caplet form. Fast-Max Cold, Flu, & Sore Throat works to relieve headache, fever, sore throat; break up mucus; relieve congestion; and control cough. The active ingredients are acetaminophen, dextromethorphan, guaifenesin, and phenylephrine.

Fast-Max Cold & Sinus relieves headache and fever, and breaks up mucus to relieve nasal and chest congestion. The product contains acetaminophen, dextromethorphan, guaifenesin, and phenylephrine.

Fast-Max Severe Congestion & Cold controls coughs, breaks up mucus, and provides relief for congestion as well as headaches and fevers. All three formulations are available in 20- and 30-count packages.

Easing cold, flu symptoms
For adults and children 12 years and over, Robitussin’s Peak Cold Daytime Cold+Flu is a non-drowsy formula that helps relieve cough, congestion, fever, body aches, and sore throat. The 20 liquid-filled capsules contain acetaminophen, dextromethorphan, and phenylephrine. A nighttime version is also available, which contains acetaminophen, dextromethorphan, and doxylamine succinate. The newest product in the line, Mucus + Chest Congestion, uses guaifenesin to loosen phlegm and help make coughs more productive. The syrup is safe for adults and children over 12 years.

Children’s remedies
Mucinex also has expanded its children’s line. Children’s Cold, Cough, and Sore Throat Liquid soothes sore throat, suppresses coughs, and works to relieve congestion. The product comes in Mixed Berry and contains acetaminophen, dextromethorphan, guaifenesin, and phenylephrine.

A Children’s Multi-Symptom Cold & Fever Liquid breaks up mucus, reduces fevers, relieves congestion, and soothes coughs. Coming in a Berry Blast flavor, the product’s active ingredients are acetaminophen, dextromethorphan, guaifenesin, and phenylephrine.

Robitussin’s Mucus+Chest Congestion is safe for adults and children over 12 years old.

PHOTOS COURTESY OF ROBITUSSIN

Continued on pg. 56
At NACDS, total means...

baby care  **consumer goods**  photo/video
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transportation  e-commerce  electronic data interchange
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cosmetics & fragrances  home health care  diagnostics
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pharmaceuticals  oral care  equipment  personal care

...TOTAL

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Little Remedies and Prestige Brands have released **Honey Elixir** to help soothe the coughs and sore throats of children. The product contains no alcohol, saccharin, gluten, or dyes. Children over one year old can use the product safely.

Luden's, another Prestige Brands product line, has introduced **Moisture Drops**. Each Moisture Drop provides relief from sore throats. Coming in a Kiwi-Strawberry flavor, the drops contain pectin.

Pedia-Care, also from Prestige Brands, has introduced **Children’s Cold & Flu Hydration**. Each packet helps restore equilibrium after stomach upset related to illness. Packets come in grape flavor and are best mixed with cold water.

Chloraseptic has introduced **Warming Sore Throat Spray** to join the lozenges that it released last year. The spray provides relief for sore throats. It contains phenol but has no alcohol, sugar, or aspirin. The spray comes in honey lemon, cherry, menthol, or soothing citrus.

**Cooling lozenges**

Cepacol has launched a **Sensations line**, which is available in three different formulations: Hydra, Cooling, and Warming. The Hydra formulation helps soothe sore throat, mouth irritation, and canker sore pain. The lozenges contain benzocaine and come in Citrus Splash.

Cooling lozenges provide relief for sore throat, canker sore pain, and mouth irritation, while delivering a cooling sensation. The lozenges come in an Ice Cool flavor and contain benzocaine and menthol. Patients who prefer a warming sensation with their sore throat, canker sore, and mouth irritation relief can try the Warming lozenges.

**Fighting flu-like symptoms**

Boiron is launching its best-selling product for flu-like symptoms, **Oscillococcinum in a 30-dose package**. This new item will help retailers attract loyal shoppers. Within the box, handy break-away 3-dose packs support stocking Oscillococcinum in purses, at work, in toiletry travel totes, and elsewhere to take quick action at the first signs of symptoms.

In addition, the lower cost per dose removes possible price-based hesitations by consumers. The 30-dose package cuts cost per dose in half to $1 per dose. Suggested retail price is $29.99 for the 30 doses, compared to $11.99 for the 6-dose package and $18.99 for the 12-dose package. Consumers can visit Oscillo.com for a coupon or to find the nearest retail store.

**Chloraseptic has introduced Warming Sore Throat Spray. It contains phenol, but has no alcohol, sugar, or aspirin. The spray comes in honey lemon, cherry, menthol, or soothing citrus.**

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**Advertiser Index**

| Corporate | Roxane Laboratories 5 |
| Corporate | United Drugs 21a*, 37a* |
| Corporate | Live Oak Bank 9 |
| Excederin Migraine | Novartis Consumer 03a* |
| Fenofibrate | Teva Pharmaceuticals USA CV2 |
| Lice Shield | Lomenread 7 |
| Master Brand | Mylan Pharmaceuticals Inc CV4 |
| Oscillococcinum | Boiron 23 |
| Pharmaceutical Care Management Association (PCMA) | Pharmaceutical Care Management Association (PCMA) CV3 |
| Quillivant | Pfizer inc 33-35 |
| Sklice | Sanofi Pasteur 40-42 |
| Total Store Expo | NACDS 55 |
| Vascepa | Amarin Pharma Inc 17-18 |

*Indicates a demographic advertisement.
**New products**

**New generics**

Greenstone LLC, the generic pharmaceutical subsidiary of Pfizer, has received FDA approval of its *diclofenac/misoprostol tablets* in dosage strengths of 50 and 75 mg. The company’s diclofenac sodium/misoprostol tablets product is the authorized generic of, and equivalent to Arthrotec. Greenstone also received FDA approval of its *phenytoin tablets*, USP in the dosage strength of 50 mg. Its phenytoin tablets product is the authorized generic of, and equivalent to Dilantin Infatabs. (http://greenstonellc.com)

**New drugs**

FDA has approved *Fulyzaq* (crofelemer, Salix Pharmaceuticals and Napo Pharmaceuticals Inc.) 125-mg delayed-release tablets, a botanical prescription drug for the treatment of the symptoms of diarrhea in HIV/AIDS patients taking antiretroviral therapy. Many HIV/AIDS patients experience diarrhea and discontinue or switch their antiretroviral therapies. Fulyzaq can be used by HIV/AIDS patients whose diarrhea is not caused by an infection from a virus, bacteria, or parasite, according to FDA. Fulyzaq is administered twice daily to manage watery diarrhea due to the loss of electrolytes and water in the gastrointestinal tract. The safety and efficacy of Fulyzaq were established in a clinical trial of 374 HIV-positive patients who were taking antiretroviral therapy and had prolonged diarrhea of a month or more. Approximately 18% of patients who took Fulyzaq experienced a clinical response compared with only 8% of placebo-treated patients. Common side effects of the botanical drug in the clinical trial were upper respiratory tract infection, bronchitis, cough, flatulence, and increased liver enzyme bilirubin. (www.salix.com)

*Sirturo* (bedaquiline, Janssen Therapeutics, a division of Janssen Products LP) was FDA-approved for the treatment of adults with multi-drug resistant pulmonary tuberculosis (TB) when other alternatives are not available. *Mycobacterium tuberculosis* causes one of the world’s deadliest infections. For individuals who develop multi-drug resistant TB because *M. tuberculosis* becomes resistant to isoniazid and rifampin, Sirturo may be used but not without risks, according to Edward Cox, MD, MPH, director of the Office of Antimicrobial Products in the FDA’s Center for Drug Evaluation and Research. Sirturo’s label includes a Boxed Warning about the risk of QT prolongation, which could lead to an abnormal and potentially lethal heart rhythm. Nine patients who received the drug died compared to two patients receiving placebo during clinical trials. The manufacturer will distribute the drug through a single source and provide educational materials to ensure its appropriate use. It was approved following two phase 2 trials, demonstrating quicker resolution time compared to placebo for the patients’ sputum to be free of *M. tuberculosis*. Common side effects of Sirturo included nausea, joint pain, and headache. (www.janssentherapeutics.com)

FDA approved *Eliquis* (apixaban, Bristol-Myers Squibb), a factor Xa inhibitor anticoagulant, which is indicated to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation. In a clinical trial of more than 18,000 patients with atrial fibrillation not caused by cardiac valve disease, Eliquis was more effective than warfarin in the reduction of stroke. Patients who receive Eliquis or other FDA-approved anticoagulants at increased risk for bleeding, including life-threatening and fatal bleeding. Eliquis must be dispensed with a patient Medication Guide, which includes instructions about its safe use. Healthcare professionals must counsel patients about the signs and symptoms of possible bleeding. The recommended dose is 5 mg orally twice daily. However, in patients with two of the following characteristics (aged 80 years and older, body weight ≤60 kg, or serum creatinine ≥1.5 mg/dL), reduce the dose to 2.5 mg orally twice daily. (www.bms.com)

*Adasuve* (loxapine, Alexza Pharmaceuticals) inhalation powder for oral inhalation use was FDA-approved for the acute treatment of agitation associated with schizophrenia or bipolar I disorder in adults. The Adasuve label includes a Boxed Warning alerting patients and healthcare providers about the risk of potentially lethal bronchospasm and increased mortality in the elderly with dementia-related psychosis. The typical antipsychotic must be administered as a single dose in a 24-hour period by a healthcare professional within an enrolled healthcare facility. Adasuve is available as a 10-mg unit in a single-use inhaler and only through a Risk Evaluation and Mitigation Strategy (REMS) program. The drug is contraindicated for patients with asthma or chronic obstructive pulmonary disease, or other lung disease associated with bronchospasm; for patients with acute respiratory signs and symptoms; and a known hypersensitivity to loxapine or amoxapine. The most common adverse
reactions compared to placebo were dysgeusia, sedation, and throat irritation. ([www.adasuve.com](http://www.adasuve.com))

FDA approved Varizig, a varicella zoster immune globulin (VZIG) preparation, manufactured by Gencieve Corporation, for reducing the severity of varicella zoster virus (VZV) infections in high-risk individuals. It should be administered within four days after exposure. Varizig is the only FDA-approved immune globulin for VZV after exposure that is available in the United States. The preparation had been approved as an orphan drug by FDA and received a priority review. Varizig is administered in two or more injections, depending on the weight of the recipient, according to FDA. It is approved for immunocompromised children and adults, newborns, pregnant women, premature infants, children younger than 1 year old, and adult with no immunity to VZV. The most common adverse effects from Varizig were injection-site pain and headache. ([www.cangene.com](http://www.cangene.com))

Another drug, which received priority review and is now FDA-approved, is Iclusig (ponatinib, ARIAD Pharmaceuticals). Iclusig is indicated for the treatment of adults with chronic myeloid leukemia (CML) and Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL), two rare blood and bone marrow diseases. The drug blocks certain proteins that promote the development of cancerous cells. Iclusig is taken once daily to treat patients with chronic, accelerated, and blast phases of CML and Ph+ ALL whose leukemia is resistant or intolerant to tyrosine kinase inhibitors (TKIs). Ponatinib targets CML cells that have a specific mutation, known as T315I, which makes these cells resistant to currently approved TKIs. Iclusig’s label includes a Boxed Warning that the drug can cause blood clots and liver toxicity. The most common side effects reported during clinical trials included hypertension, rash, abdominal pain, fatigue, headache, dry skin, constipation, fever, joint pain, and nausea. ([www.ariad.com](http://www.ariad.com))

FDA approved Gattex (teduglutide) for injection, NPS Pharmaceuticals) for the treatment of adults with short bowel syndrome (SBS) who require additional nutrition from intravenous feeding. Gattex, a recombinant analog of human glucagon-like peptide 2, is injected once daily to help improve the absorption of fluids and nutrients in the intestine. It is the third drug approved by FDA for this indication. The drug was approved with a REMS program, which included a communication plan and training for prescribers. Patients taking Gattex have a potential increased risk of developing cancer and polyps in the intestine, obstructions to the intestine, gallbladder disease, biliary tract disease, and pancreatic disease. The FDA is requiring a postmarket study of SBS patients treated with the drug in a routine clinical setting to continue to evaluate the potential increased risk of developing colorectal cancer and other conditions. The most common side effects associated with Gattex in clinical trials were abdominal pain, injection site reactions, nausea, headaches, abdominal distension, and upper respiratory tract infection. Walgreens Infusion Services has recently been selected as a provider of Gattex. ([www.npsp.com/Gattex](http://www.npsp.com/Gattex))

FDA approved Juxtapid (lomitapide, Aegerion Pharmaceuticals) as an orphan drug to reduce low-density lipoprotein (LDL) cholesterol, total cholesterol, apolipoprotein B, and non-high-density lipoprotein (non-HDL) cholesterol in patients with homozygous familial hypercholesterolemia (HoFH). It is an adjective treatment for use with a low-fat diet and other lipid-lowering treatments. This rare cholesterol disorder is inherited and causes abnormally high levels of circulating LDL cholesterol. In the United States, approximately one in 1 million individuals have the disease. Juxtapid’s safety and efficacy were evaluated in a clinical trial of 29 patients with the disorder. For those who could tolerate the treatment, LDL levels dropped by approximately one-half during the first 26 weeks of treatment. Juxtapid’s label includes a Boxed Warning about a serious risk of liver toxicity because of its association with liver enzyme abnormalities and accumulation of fat in the liver. It also interacts with several other medications. Juxtapid was approved with a REMS program that includes elements to ensure safe use, such as prescriber and pharmacy certification and documentation of safe-use conditions to accompany each new prescription. FDA has required three postmarketing studies for the drug. The most common adverse effects were diarrhea, nausea, vomiting, indigestion, and abdominal pain. ([www.aegerion.com](http://www.aegerion.com))

**New indication**

FDA has expanded the use of Tamifu, (oseltamivir phosphate, Genentech/Roche) to children as young as 2 weeks old who have flu symptoms that have been present for 2 days or less. Tamifu, an influenza neuraminidase inhibitor, was first approved in 1999, and can be used prophylactically in patients 1 year and older. It is available in capsule form and as an oral suspension. For individuals who cannot swallow pills, the oral suspension should be used. If the oral suspension is not available, the capsule can be opened and mixed with sweetened liquid for administration. However, if the appropriate strength is not available, a pharmacist can compound an emergency supply of suspension from Tamifu 75-mg capsules, according to the package insert.

Tamifu is contraindicated in individuals with a hypersensitivity to the drug. The most common side effects have been nausea and vomiting. ([www.tamifu.com](http://www.tamifu.com))
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Healthcare provider status for pharmacists is long overdue

Pharmacists are often underutilized because they are not recognized as healthcare providers under the Social Security Act. As a result pharmacists cannot be fully compensated by Medicare and Medicaid for all their capabilities, which if completely incorporated could improve patient health outcomes.

That’s why it is heartening to read U.S. Surgeon General Regina Benjamin’s letter supporting the conclusions of Improving Patient and Health System Outcomes through Advanced Pharmacy Practice - A Report to the U.S. Surgeon General, 2011. Dr. Benjamin agrees with the report’s finding that “recognition of pharmacists as healthcare providers, clinicians, and an essential part of the healthcare team is appropriate given the level of care they provide in many healthcare settings.”

The Surgeon General makes the case for this designation by pointing out that pharmacists currently work with physicians and clinicians under collaborative practice agreements in 43 states and in federal health programs in “performing patient assessments and developing therapeutic plans; utilizing authorities to initiate, adjust, or discontinue medications; ordering, interpreting, and monitoring appropriate laboratory tests; providing care coordination and other healthcare services for wellness and prevention; and developing partnerships with the patients for ongoing and follow-up care.”

As the nation’s chief health advocate and doctor, the Surgeon General certainly crosses the independence and credibility threshold because her words carry weight. For example, the tobacco industry is still reeling from the fallout (i.e., major class action lawsuits, stringent regulations, reduction in the percentage of smokers, etc.) that occurred from the warning regarding the dangers associated with smoking from U.S. Surgeon General Luther Terry in 1964. Hopefully, history repeats itself in our case.

With this federally recognized designation, pharmacists could finally be recognized for the valuable work they do and for their dedication to their patients. When I engage independent community pharmacists on this issue, they welcome the additional responsibility and the extra scrutiny that recognition brings, because they know the tangible results they can deliver. For example, our members’ patient-focused business model is ideally situated to put a big dent in the up to $290 billion a year that is wasted on care due to the improper use of medications. Independent community pharmacies can and should become active participants in new collaborative healthcare models such as accountable care organizations and medical homes. Our members can fill the need of an overstressed healthcare system by treating patients for their minor healthcare needs.

Independent community pharmacists already enjoy the trust of patients. For example, according to the annual honesty and ethical standards survey by Gallup, pharmacists came in second among all professions. That is not a one-time occurrence, but a long-standing trend. Pharmacists’ standing in the 2012 survey marked an all-time high.

The National Community Pharmacists Association will work tirelessly over the next year with Congress, the states, payers, and other healthcare practitioners to ensure that they understand the value pharmacists bring to healthcare through examples such as what happened with the Asheville Project and with Smith Drug Company. In both instances pharmacists were incorporated into the healthcare team to help patients maximize their health outcomes. Not only were patients healthier, but the costs were reduced in comparison to previous years when the role of pharmacists weren’t part of the unique, but effective approach. Not only are the results impressive, but they will serve as a real-world example to rebut the inevitable push-back.

The reason provider designation has proved elusive is a fear of the costs the healthcare system will incur. Any front-end costs will pale in comparison to the savings that will accrue on the back end.

Having inundated the decision makers with the overwhelming evidence of why and how pharmacists can do more, we should finally see the long overdue change to the Social Security Act that needs to occur by passing legislation in the U.S. Congress. Then finally, the cutting-edge contributions that pharmacists can provide will be tapped. Everyone will benefit as a result.

Donnie Calhoun, PD, RPh, is the National Community Pharmacists Association president and a pharmacy owner in Anniston, Ala.
OVERVIEW

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