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Voice of the Pharmacist
DrugTopics.com
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CONTENT

CONTENT CHANNEL DIRECTOR Julia Talsma
440-891-2792 / jtalsma@advanstar.com

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

CONTENT EDITOR Mark Lowery
440-891-2705 / mlowery@advanstar.com

GROUP ART DIRECTOR Robert McGarr

ART DIRECTOR Lecia Landis

PUBLISHING AND SALES

EXECUTIVE VICE PRESIDENT Georgiann DeCenzo
440-891-2778 / gdecenzo@advanstar.com

VICE PRESIDENT, GROUP PUBLISHER Ken Sylvia
732-346-3017 / ksylvia@advanstar.com

GROUP PUBLISHER Mike Weiss
732-346-3071 / mweiss@advanstar.com

NATIONAL ACCOUNT MANAGER Mark Hildebrand
732-346-3006 / mhildebrand@advanstar.com

NATIONAL ACCOUNT MANAGER Rich Fiore
732-346-3014 / mfiore@advanstar.com

DIRECTOR, OF BUSINESS DEVELPMENT HEALTHCARE TECHNOLOGY SALES Margie Jaxel
732-346-3003 / mjaxel@advanstar.com

ACCOUNT MANAGER, DISPLAY/CLASSIFIED & HEALTHCARE TECHNOLOGY Patrick Carmody
440-891-2621 / pcarmody@advanstar.com

ACCOUNT MANAGER, CLASSIFIED/DISPLAY ADVERTISING Joan Maley
440-891-2722 / jmaley@advanstar.com

ACCOUNT MANAGER, RECRUITMENT ADVERTISING Joanna Shippoli
440-891-2615 / jshippoli@advanstar.com

BUSINESS DIRECTOR, EMEDIA Don Berman
212-951-6745 / dberman@advanstar.com

SPECIAL PROJECTS DIRECTOR Meg Benson
732-346-3039 / mbenson@advanstar.com

DIRECTOR OF MARKETING & RESEARCH SERVICES Gail Kaye
732-346-3042 / gkaye@advanstar.com

SALES SUPPORT Hannah Curis
732-346-3055 / hcuris@advanstar.com

REPRINT SERVICES
877-652-5295, ext. 121 / bkolb@wrightsmedia.com
Outside US, UK, direct dial: 281-419-5725, ext. 121

LIST ACCOUNT EXECUTIVE Renee Schuster
440-891-2613 / rschuster@advanstar.com

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

PRODUCTION

SENIOR PRODUCTION MANAGER Karen Lenzen
218-740-6371 / klenzen@media.advanstar.com

AUDIENCE DEVELOPMENT

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

DIRECTOR Christine Shappell
201-391-2359 / cshappell@advanstar.com

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

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NORTH OLMSTED, OHIO 44070
MAIN NUMBER: 440-243-8100
MAIN FAX NUMBER: 440-891-2735
CUSTOMER SERVICE: 877-922-2022
EMAIL: DRUGTOPICS@ADVANSTAR.COM

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Joe Loggia
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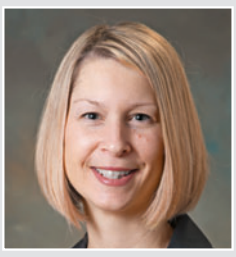
COVER STORY

Pharmacy in flux

Despite concerns over reimbursements, networks, and drug shortages, most pharmacists look forward to 2015. PAGE 44

PRESCRIBED READING



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First- and every-cycle Neulasta achieved:

- **94%** relative reduction in febrile neutropenia (17% placebo vs 1% Neulasta; $P < .001$)[1,2]
- **93%** relative reduction in febrile neutropenia–related hospitalization (14% placebo vs 1% Neulasta; $P < .001$)[1,2]
- **80%** relative reduction in febrile neutropenia–related IV anti-infective use (10% placebo vs 2% Neulasta; $P < .001$)[1,2]

Phase 3 study in patients with breast cancer receiving 100 mg/m^2 docetaxel for up to 4 cycles given placebo (n = 465) or Neulasta (n = 463); primary endpoint: incidence of febrile neutropenia.[1]

Febrile neutropenia = absolute neutrophil count (ANC) < 0.5 × 10^9/L and temperature ≥ 38.2°C.

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Help reduce the incidence of infection and protect your patients receiving myelosuppressive chemotherapy* from febrile neutropenia.

*Myelosuppressive chemotherapy regimens associated with a clinically significant risk of febrile neutropenia.

Neulasta® (pegfilgrastim) is administered by subcutaneous injection.

Neulasta is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anticancer drugs associated with a clinically significant incidence of febrile neutropenia.

Neulasta is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.

Important Safety Information

Do not administer Neulasta to patients with a history of serious allergic reactions to pegfilgrastim or filgrastim.

Splenic rupture, including fatal cases, can occur following the administration of Neulasta. Evaluate for an enlarged spleen or splenic rupture in patients who report left upper abdominal or shoulder pain after receiving Neulasta.

Acute respiratory distress syndrome (ARDS) can occur in patients receiving Neulasta. Evaluate patients who develop fever and lung infiltrates or respiratory distress after receiving Neulasta for ARDS. Discontinue Neulasta in patients with ARDS.

Serious allergic reactions, including anaphylaxis, can occur in patients receiving Neulasta. The majority of reported events occurred upon initial exposure. Allergic reactions, including anaphylaxis, can recur within days after the discontinuation of initial anti-allergic treatment. Permanently discontinue Neulasta in patients with serious allergic reactions.

Severe sickle cell crises can occur in patients with sickle cell disorders receiving Neulasta. Severe and sometimes fatal sickle cell crises can occur in patients with sickle cell disorders receiving filgrastim, the parent compound of pegfilgrastim.

The granulocyte colony-stimulating factor (G-CSF) receptor, through which pegfilgrastim and filgrastim act, has been found on tumor cell lines. The possibility that pegfilgrastim acts as a growth factor for any tumor type, including myeloid malignancies and myelodysplasia, diseases for which pegfilgrastim is not approved, cannot be excluded.

Bone pain and pain in extremity occurred at a higher incidence in Neulasta-treated patients as compared with placebo-treated patients.

Please see brief summary of Neulasta Prescribing Information on the adjacent page.

References: 1. Vogel C, et al. *J Clin Oncol.* 2005;23:1178-1184. **2.** Neulasta (pegfilgrastim) Prescribing Information. Thousand Oaks, CA: Amgen; 2011.

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Neulasta® (pegfilgrastim)

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BRIEF SUMMARY OF PRESCRIBING INFORMATION

Neulasta® (pegfilgrastim) injection, for subcutaneous use

INDICATIONS AND USAGE

Neulasta is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anticancer drugs associated with a clinically significant incidence of febrile neutropenia.

Neulasta is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.

CONTRAINDICATIONS

Do not administer Neulasta to patients with a history of serious allergic reactions to pegfilgrastim or filgrastim.

WARNINGS AND PRECAUTIONS

Splenic Rupture

Splenic rupture, including fatal cases, can occur following the administration of Neulasta. Evaluate for an enlarged spleen or splenic rupture in patients who report left upper abdominal or shoulder pain after receiving Neulasta.

Acute Respiratory Distress Syndrome

Acute respiratory distress syndrome (ARDS) can occur in patients receiving Neulasta. Evaluate patients who develop fever and lung infiltrates or respiratory distress after receiving Neulasta, for ARDS. Discontinue Neulasta in patients with ARDS.

Serious Allergic Reactions

Serious allergic reactions, including anaphylaxis, can occur in patients receiving Neulasta. The majority of reported events occurred upon initial exposure. Allergic reactions, including anaphylaxis, can recur within days after the discontinuation of initial anti-allergic treatment. Permanently discontinue Neulasta in patients with serious allergic reactions. Do not administer Neulasta to patients with a history of serious allergic reactions to pegfilgrastim or filgrastim.

Use in Patients With Sickle Cell Disorders

Severe sickle cell crises can occur in patients with sickle cell disorders receiving Neulasta. Severe and sometimes fatal sickle cell crises can occur in patients with sickle cell disorders receiving filgrastim, the parent compound of pegfilgrastim.

Potential for Tumor Growth Stimulatory Effects on Malignant Cells

The granulocyte-colony stimulating factor (G-CSF) receptor through which pegfilgrastim and filgrastim act has been found on tumor cell lines. The possibility that pegfilgrastim acts as a growth factor for any tumor type, including myeloid malignancies and myelodysplasia, diseases for which pegfilgrastim is not approved, cannot be excluded.

ADVERSE REACTIONS

The following serious adverse reactions are discussed in greater detail in other sections of the Brief Summary:

- Splenic Rupture [*See Warnings and Precautions*]
- Acute Respiratory Distress Syndrome [*See Warnings and Precautions*]
- Serious Allergic Reactions [*See Warnings and Precautions*]
- Use in Patients with Sickle Cell Disorders [*See Warnings and Precautions*]
- Potential for Tumor Growth Stimulatory Effects on Malignant Cells [*See Warnings and Precautions*]

The most common adverse reactions occurring in ≥ 5% of patients and with a between-group difference of ≥ 5% higher in the pegfilgrastim arm in placebo controlled clinical trials are bone pain and pain in extremity.

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 with rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

Neulasta clinical trials safety data are based upon 932 patients receiving Neulasta in seven randomized clinical trials. The population was 21 to 88 years of age and 92% female. The ethnicity was 75% Caucasian, 18% Hispanic, 5% Black, and 1% Asian. Patients with breast (n = 823), lung and thoracic tumors (n = 53) and lymphoma (n = 56) received Neulasta after nonmyeloablative cytotoxic chemotherapy. Most patients received a single 100 mcg/kg (n = 259) or a single 6 mg (n = 546) dose per chemotherapy cycle over 4 cycles.

The following adverse reaction data in Table 1 are from a randomized, double-blind, placebo-controlled study in patients with metastatic or non-metastatic breast cancer receiving docetaxel 100 mg/m^2 every 21 days. (Study 3). A total of 928 patients were randomized to receive either 6 mg Neulasta (n = 467) or placebo (n = 461). The patients were 21 to 88 years of age and 99% female. The ethnicity was 66% Caucasian, 31% Hispanic, 2% Black, and < 1% Asian, Native American or other.

Bone pain and pain in extremity occurred at a higher incidence in Neulasta-treated patients as compared with placebo-treated patients.

Table 1. Adverse Reactions With ≥ 5% Higher Incidence in Neulasta Patients Compared to Placebo in Study 3

System Organ Class Preferred Term	Placebo (N = 461)	Neulasta 6 mg SC on Day 2 (N = 467)
Musculoskeletal and connective tissue disorders		
Bone pain	26%	31%
Pain in extremity	4%	9%

Leukocytosis

In clinical studies, leukocytosis (WBC counts > 100 x 10^9/L) was observed in less than 1% of 932 patients with nonmyeloid malignancies receiving Neulasta. No complications attributable to leukocytosis were reported in clinical studies.

Immunogenicity

As with all therapeutic proteins, there is a potential for immunogenicity. Binding antibodies to pegfilgrastim were detected using a BIAcore assay. The approximate limit of detection for this assay is 500 ng/mL. Pre-existing binding antibodies were detected in approximately 6% (51/849) of patients with metastatic breast cancer. Four of 521 pegfilgrastim-treated subjects who were negative at baseline developed binding antibodies to pegfilgrastim following treatment. None of these 4 patients had evidence of neutralizing antibodies detected using a cell-based bioassay.

The detection of antibody formation is highly dependent on the sensitivity and specificity of the assay, and the observed incidence of antibody positivity in an assay may be influenced by several factors, including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies to Neulasta with the incidence of antibodies to other products may be misleading.

Postmarketing Experience

The following adverse reactions have been identified during post approval use of Neulasta. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. Decisions to include these reactions in labeling are typically based on one or more of the following factors: (1) seriousness of the reaction, (2) reported frequency of the reaction, or (3) strength of causal relationship to Neulasta.

Gastro-intestinal disorders: Splenic rupture [see *Warnings and Precautions*]

Blood and lymphatic system disorder: Sickle cell crisis [see *Warnings and Precautions*]

Hypersensitivity reactions: Allergic reactions/hypersensitivity, including anaphylaxis, skin rash, and urticaria, generalized erythema and flushing [see *Warnings and Precautions*]

Respiratory, thoracic, and mediastinal disorder: ARDS [see *Warnings and Precautions*]

General disorders and administration site conditions: Injection site reactions

Skin and subcutaneous tissue disorders: Sweet's syndrome, Cutaneous vasculitis

DRUG INTERACTIONS

No formal drug interaction studies between Neulasta and other drugs have been performed. Increased hematopoietic activity of the bone marrow in response to growth factor therapy may result in transiently positive bone-imaging changes. Consider these findings when interpreting bone-imaging results.

USE IN SPECIFIC POPULATIONS

Pregnancy

Pregnancy Category C

There are no adequate and well-controlled studies in pregnant women. Pegfilgrastim was embryotoxic and increased pregnancy loss in pregnant rabbits that received cumulative doses approximately 4 times the recommended human dose (based on body surface area). Signs of maternal toxicity occurred at these doses. Neulasta should be used during pregnancy only if the potential benefit to the mother justifies the potential risk to the fetus.

In animal reproduction studies, when pregnant rabbits received pegfilgrastim at cumulative doses approximately 4 times the recommended human dose (based on body surface area), increased embryolethality and spontaneous abortions occurred. Signs of maternal toxicity (reductions in body weight gain/food consumption) and decreased fetal weights occurred at maternal doses approximately equivalent to the recommended human dose (based on body surface area). There were no structural anomalies observed in rabbit offspring at any dose tested. No evidence of reproductive/developmental toxicity occurred in the offspring of pregnant rats that received cumulative doses of pegfilgrastim approximately 10 times the recommended human dose (based on body surface area).

Women who become pregnant during Neulasta treatment are encouraged to enroll in Amgen's Pregnancy Surveillance Program. Patients or their physicians should call 1-800-77-AMGEN (1-800-772-6436) to enroll.

Nursing Mothers

It is not known whether pegfilgrastim is secreted in human milk. Other recombinant G-CSF products are poorly secreted in breast milk and G-CSF is not orally absorbed by neonates. Caution should be exercised when administered to a nursing woman.

Pediatric Use

Safety and effectiveness of Neulasta in pediatric patients have not been established. The adverse reaction profile and pharmacokinetics of pegfilgrastim were studied in 37 pediatric patients with sarcoma. The mean (± standard deviation [SD]) systemic exposure ($AUC_{0\text{-inf}}$) of pegfilgrastim after subcutaneous administration at 100 mcg/kg was 22.0 (± 13.1) mcg·hr/mL in the 6 to 11 years age group (n = 10), 29.3 (± 23.2) mcg·hr/mL in the 12 to 21 years age group (n = 13), and 47.9 (± 22.5) mcg·hr/mL in the youngest age group (0 to 5 years, n = 11). The terminal elimination half-lives of the corresponding age groups were 20.2 (± 11.3) hours, 21.2 (± 16.0) hours, and 30.1 (± 38.2) hours, respectively. The most common adverse reaction was bone pain.

Geriatric Use

Of the 932 patients with cancer who received Neulasta in clinical studies, 139 (15%) were age 65 and over, and 18 (2%) were age 75 and over. No overall differences in safety or effectiveness were observed between patients age 65 and older and younger patients.

Renal Impairment

In a study of 30 subjects with varying degrees of renal dysfunction, including end stage renal disease, renal dysfunction had no effect on the pharmacokinetics of pegfilgrastim.Therefore, pegfilgrastim dose adjustment in patients with renal dysfunction is not necessary.

DOSAGE AND ADMINISTRATION

The recommended dosage of Neulasta is a single subcutaneous injection of 6 mg administered once per chemotherapy cycle in adults. Do not administer Neulasta between 14 days before and 24 hours after administration of cytotoxic chemotherapy.

Visually inspect parenteral drug products for particulate matter and discoloration prior to administration, whenever solution and container permit. Do not administer Neulasta if discoloration or particulates are observed.

NOTE: The needle cover on the single-use prefilled syringe contains dry natural rubber (latex); persons with latex allergies should not administer this product.

This product, its production, and/or its use may be covered by one or more US Patents, including US Patent Nos. 5,824,784; 5,582,823; 5,580,755, as well as other patents or patents pending.

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IN MY VIEW Daniel Shifrin, MS, RPh

A pharmacy irony: Remembering Mrs. C.

Several years ago, the head of my hospital's medical record department was performing an audit. She met with me about Mrs. C., a woman who had died of pancreatic cancer. She wanted to know the cost of a medication that Mrs. C. was receiving. I told her and asked whether she would also like the price of another drug.

She stated that she didn't need the price of that drug, because Mrs. C. had never received it. She thanked me and left the department.

Mrs. C. was on a monthly regimen; she was supposed to receive the same medication every month. For nine out of 10 months, she received the medication that the medical record department was inquiring about. However, in the fourth month of her therapy, on March 21, she received the wrong drug.

I knew that accidental administration of this drug, rather than the one prescribed, would not kill her. However, it was a medication error.

I considered my options. I could keep quiet and say nothing. Mrs. C. had not died from taking the wrong drug; she died as a result of complications of pancreatic cancer. Furthermore, reporting the error would create excessive paperwork and considerable aggravation, as well as heartache for those directly involved. I decided to say nothing.

The logic of the choice

Many hospitals claim they have a nonpunitive policy when it comes to medication errors. Hospitals want to know about unsafe practices in an attempt to prevent future problems. They encourage their staffs to report these situations without fear of retribution. The goal is to correct behaviors rather than punish.

These facilities review medication errors and near-misses. They follow strict guidelines to first evaluate the caregiver's action in order to determine if it was a system error. If the caregiver's action is deemed malicious or if the caregiver makes repeated mistakes, only then is punitive action taken. This process is known as "just culture."

Aftermath

Several months later, my boss called me to his office to show me a letter from Mrs. C.'s daughter. Her daughter wrote:

Mom looked forward to her monthly visits to the suite. Her biggest thrill was the birthday party that you gave her.

It made Mom feel wonderful. It was perhaps the only time that we left the chemo suite and went shopping instead of going home.

I told Mom that she should go home and rest like she usually did. But no, she stated that she felt well enough to go shopping that day.

This is how Mrs. C. should be remembered. Not as a medication-error statistic, not as one who might trigger job loss for others, but as an individual who touched every life she encountered.

She should be remembered for the stories she told, not for the root causes and algorithms that would have to be generated. She should be remembered for her smile and her caring heart, not for the miles of endless paperwork that someone would be forced to prepare. She should be remembered for the happiness she took from the party that we gave her. That was how she should be remembered.

After her treatment, we celebrated her birthday. She said she felt wonderful.

Remembering Mrs. C.

I reread the letter, and there it was.

Mrs. C. had a tough bout with pancreatic cancer. She was a brave woman, but after a treatment day, things were difficult. After receiving her treatment, Mrs. C. would go home, throw up, and collapse. She wouldn't eat for 24 hours. She'd be groggy, headachy, and in pain.

This happened every treatment day.

Except for one.

On that day, after her treatment, we celebrated her birthday, and Mrs. C. insisted on going shopping with her daughter. She said she felt wonderful, the best she'd ever felt.

Staff members had various reasons to remember Mrs. C.'s birthday. I have my own reason to remember it, as well.

In fact, it is a day I will always remember, because the best day of her life, ironically, was the day she received the wrong medication, the day of the medication error. Her birthday. DT

Daniel Shifrin *is a career service rep and pharmacy tech instructor in New Jersey. Contact him at rpdanny627@gmail.com.*

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CPE **CONTINUING EDUCATION**

MTM essentials for smoking cessation

By providing behavioral counseling along with pharmaceutical supervision, pharmacists can lend powerful support to patients who want to stop using tobacco. **PAGE 70**

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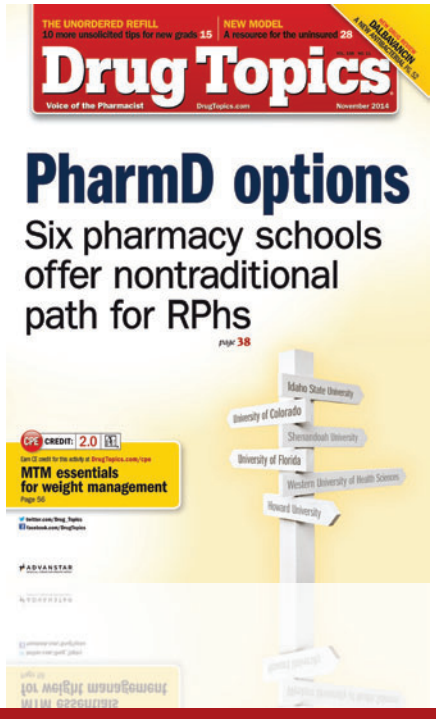

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DISPENSED AS WRITTEN Michael J. Schuh, BS, PharmD, MBA

Is fee for service dead?

Healthcare is evolving into an interdisciplinary approach, enabling teammate providers with different training and expertise to care for patients to produce the best patient outcomes. Institutions are using transitions-of-care billing codes, and more settings are moving toward a form of payment based on diagnosis-related groups (DRG), which associate costs with the care of a patient with a particular diagnosis, cared for by an interdisciplinary team.

So fee for service (FFS) is dead! Pharmacists are on the team! We don't have to worry about billing for pharmacist services in this new utopia, right? Not quite.

Where will the $$ come from?

How will the team pharmacist be paid? Current Procedural Terminology (CPT) codes for DRG and non-MTM services are directed toward payment of federally recognized providers and for current overhead costs incurred by the "team" that currently receives federal recognition. The pharmacist is not officially on this team.

Many commercial carriers follow CMS guidelines for group-care payment, and the pharmacist salary isn't accounted for there, either. Because pharmacists aren't included in the payment calculation and are viewed as nonproviders, the bucket of DRG money has to be split further. In a financial sense, pharmacists either become administrative overhead, take away from the fixed payment already determined without their participation, or, in an inpatient setting, are supported by the doses of meds dispensed in the central pharmacy.

Revenue creation

Pharmacists have no ability to bring money in. This puts us at the disadvantage of having to justify our existence with the more nebulous "cost avoidance" argument: We will decrease costs just by being there. Easy argument, right? Proven in the literature, right? In the eyes of those paying that salary, not necessarily.

In the outpatient setting, if you can obtain a contract with a self-insured entity, you can use the Asheville Project to make the cost-avoidance argument. But it's not so easy to get those contracts.

In nongovernmental ambulatory care and community pharmacy, we still have to fall back on revenue creation. For now, low-level Medicare CPT codes, Medicare Part D plans, and MTM CTP codes will have to do.

At this time, however, the lowest "incident to" CPT code doesn't cover the cost of pharmacist services; the Part D plans and other forms of payment structured for pharmacy benefit managers (PBMs) are inadequate; and many payers still do not recognize MTM CPT codes monetarily if a pharmacist performs the services.

By the way, much of community pharmacy payment for MTM services is also based on cost avoidance. The problem is, someone other than the pharmacist is getting most of those saved dollars.

Only one way

It gets worse. The team scenario mainly pertains to large teaching, academic, or government facilities that might have the funds to support an extra administrative healthcare cost on the team. But most patients who would benefit from pharmacists services are located somewhere else: in the community; in a small community hospital; in a long-term-care facility; or even in team-utilization facilities on other medical services.

Pharmacist services have to be paid for. The easiest and only direct way to account for them to administrative and managerial decision-makers is through revenue streams — read FFS. It is the only way for us to bridge the gap between the current world of payment for services and the coming world of team-based care.

To get there from here may take years. In the meantime, provider substitutes for pharmacists will be used, such as PAs, ARNPs, and others such as RNs who *are* federally recognized providers.

Will pharmacist provider status be a cure-all for pharmacist payment problems? It depends. It depends on whether future CPT and other billing codes include the extra pharmacist provider. It depends on how well pharmacists will be able to use existing and future codes to cover their costs to the system.

We must keep in mind that we are grossly outnumbered by practitioners in the medical and nursing professions, and that the political war chests of other professional organizations are highly funded; we will have to be more professionally and politically active to achieve our professional goals. We have to concern ourselves not only with provider status but with how we can earn our place at the table now.

Is fee for service dead? Not on your professional life. DT

Michael Schuh *is a clinical MTM pharmacist in Jacksonville, Fla. Contact him at mschuhrx1@gmail.com.*

Inter@ctive

TRENDING NOW

PharmD options limited for RPhs

For registered pharmacists who want to return to school but need to keep working, six pharmacy programs offer a nontraditional path. Highlights include didactic and experiential learning requirements and how long the programs will take to complete.

http://drugtopics.com/PharmDoptions

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A few recent tweets and retweets from and about *Drug Topics*

Tim Barrick
@Kookaburra3
Development of #opioids that are harder to abuse helps address #prescriptiondrugabuse in the US. ow.ly/ERgpm

Zyp Czyk
@ZypCzyk
#FDA provides more guidance for "outsourcing facilities." bit.ly/1thcgbr

Damian Espinasse
@DamienSF
#WAG, #pharmacist liable for #HIPPA violation. bit.ly/1rjqYUg

SAMPIG: J Perepelkin
@RxInterestgroup
@ShopprsDrugMart study to test transitional care model. drugtopics.modernmedicine.com/drug-topics/ne… via @Drug_Topics

Drug Topics App

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SEE AND HEAR PHARMACISTS, INDUSTRY LEADERS, AND PHARMACY ADVOCATES DISCUSS NEWS AND ISSUES OF IMPORTANCE TO PHARMACISTS. EXCLUSIVE VIDEOS ONLY AVAILABLE THROUGH *Drug Topics*.

Using social media responsibly

Jessica Skelley, PharmD, BCACP, McWhorter School of Pharmacy, Samford University, outlines the pitfalls pharmacies should avoid while using social media.

Medication adherence in America

When it comes to taking medication properly, Americans 40 and older earn avesrage grades, according to a patient survey by the National Community Pharmacists Association. B. Douglas Hoey, NCPA CEO, discusses the survey.

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Voices

Follow the money

Re: "Generic drug price hikes cause hardships for pharmacies, patients" [Julia Talsma, November 21, *www.drugtopics.com*]:

In any other industry this would be considered PRICE-GOUGING, so why is the pharmaceutical industry allowed to continue with such unreasonable increases?

In most cases, I do not approve of government regulation, but it seems the industry refuses to regulate itself in this case.

The statement that "it is unclear what factors are driving the ... continued price increases" is not that difficult to answer. It is what drives most corporate decisions — greed.

Marilyn Coffman
POSTED AT *WWW.DRUGTOPICS.COM*

Guess who (really) pays?

One of the biggest reasons for generic drug price increases is the kickbacks that generic drug manufacturers have to pay pharmacy benefit managers (PBMs), discount drug cards, chain drugstores, and the federal government. This also holds true for brand-name manufacturers having to pay kickbacks. These kickbacks increase the cost of prescription drugs to every man, woman and child in the world!

John Patton
POSTED AT *WWW.DRUGTOPICS.COM*

And guess who gets?

Perhaps some of you have forgotten how our government works!

In this free economy, we do not have price controls.

In order for the healthcare bill to pass, it had to have the backing of the pharmaceutical manufacturers. The brand-name manufacturers, generic manufacturers, PBMs and insurance industries pour billions of dollars yearly into Washington. Why would you expect those receiving those dollars to cut them off by seeking to serve the taxpayers and voters of this country with price controls or regulations?

Congress has passed laws requiring the brand-name manufacturers to pay rebates on brand-name medications sold through Medicare, and now it is after the generic manufacturers to do the same. The manufacturers would not have supported Obamacare if price controls had been a part of the bill, and the bill could not have passed without their support. The manufacturers are only paying themselves off for their support of the bill.

If you have not been asleep, you should also know that the bill was passed without those passing it having read it.

The American population has just reelected back into office the majority of those who have been depleting your wallets for years. Evidently our population has not seen the need to elect a new crop of criminals and thieves, and enjoys being taken advantage of.

We do not have a budget.

If you in your business had employees who did not perform up to your expectations, would you keep them and hire more like them so you could lose money and your business too? The American public has done just this and has yet to realize that the money that the government spends is *their* money.

Most of us in the frontline of healthcare who actually take care of patients work hard and long, and do more and more for less and less.

We all need to do a better job of explaining to the general population who we are and what we do, and work toward change for a better society for our children and grandchildren, and those who will follow us as healthcare providers.

Ed Hackney
ATLANTA, GA.

It's not just generics

Re: "Senate hearing will explore soaring prices of generic drugs" [Mark Lowery, November 14, *www.drugtopics.com*]:

Why limit it to generic manufacturers? Lantus, Levemir, and Humalog alone have gone up as much as 47% over the last 14 months.

Doug Bennett
POSTED AT *WWW.DRUGTOPICS.COM*

You think?

Wonder if these price increases have anything to do with the ACA. Remember the drug companies made a deal with the government back in 2009?

Also, was it really because of unsafe practices that those manufacturers were shut down, or is Big Brother using the FDA the way it uses the IRS?

Why do we have to wait until 2016 to have the generic pricing problems fixed? They didn't take that long to pass the ACA. Why are we quietly standing by and watching?

Randall Davis
POSTED AT *WWW.DRUGTOPICS.COM*

Who needs a hearing?

Because "Greed is Good." I don't think Congress, especially the Senate, needs to hold a hearing on this. Anyway, it might detract from the time they need to count all their cash coming from Big Pharma PAC's.

Anonymous
POSTED AT *WWW.DRUGTOPICS.COM*

What would you call it?

Re: "Pharmacists on pharmacy: *Drug Topics* readers speak out" [November 19; *www.drugtopics.com*]:

In regard to gouging by compounding pharmacies, what do you call drug companies that charge almost $1,000 for a bottle of 30 tablets of a drug — cost-effective prescribing?

The insurance companies will hem and haw a bit, but will pay if the coding is right. It seems more like a bias. Or maybe Big Pharma, insurance companies, and the glorious FDA are in cahoots. I have seen a lot over 40+ years to make me doubt the big pharmaceutical companies and the FDA.

As for the insurance companies, they strain to swallow a gnat and swallow the camel with ease.

Anonymous
POSTED AT *WWW.DRUGTOPICS.COM*

PBMs again

I am appalled at the way pharmacies are being underpaid by PBMs. When reimbursements below cost (RBC) occur, there is very little a pharmacy can do to fix the problem. The PBMs make you fill out a form and they review it, and if they feel it does need an adjustment they will adjust it on the next fill — and will not go retroactive, so you lose on that fill.

Then there is a hidden DIR fee for preferred pharmacies done on the back end of claims that don't appear on adjudicated claim fields. They show up later on the remittance advices. So you can never really figure out the true reimbursements.

I want everyone in the country to know that the PBMs are going to be the end of pharmacy if they can get away with RBCs.

Gary Einsidler, RPh
BOSTON, MASS.

It could happen to you

I recently read the articles on e-Rx issues published online in June 2014 ["Electronic prescriptions: Return to sender," The Cynical Pharmacist, June 10; "E-Prescribing: The end of prescription errors? Hardly," Tom Hanson, June 11] and thought I would share an issue that was not mentioned.

Surescripts and pharmacy management systems (EnterpriseRx) call it "looping." It happened to me, and there was no simple resolution for the issue.

The doctor transmitted an e-Rx and my pharmacy received it. Somehow the *exact same* e-Rx kept showing up on my pharmacy system every 10 seconds, and it would not stop.

I called Surescripts and they told me the looping occurred from the doctor's computer and they could not stop it. I called EnterpriseRx and they claimed they didn't have control and could not shut my system down to disconnect and stop receiving any eRx. I called all over, even to the doctor's private lines, and couldn't reach her.

Surescripts *finally* got hold of the doctor and got the looping to stop. But before that happened, it went on for hours, and I couldn't get any valid new e-Rx for my pharmacy.

I also had to pay for every single looping e-Rx that came to my pharmacy. I was out a couple hundred dollars. Surescripts and EnterpriseRx refused to pick up the tab.

This could happen again to me or any other pharmacy. Hopefully someone from Surescripts or EnterpriseRx has found a solution for this by now.

It is so unfair for us to get charges for the e-Rxs — and assuming that the doctors are not compensated for transmitting them.

Kevin Dang, PharmD
SAN JOSE, CALIF.

Now for something completely different

Re: "Washington pharmacists fighting Plan B mandate" [Mark Lowery, Dec. 2, *www.drugtopics.com*];

Maybe the state of Washington should mandate that CVS pharmacies sell tobacco.

Bill Sarraf
POSTED AT *WWW.DRUGTOPICS.COM*

Beg to differ

Posted November 30 re: "E-cigs: Healthy tobacco alternative? Definitely not" [Madeleine Bile, Student Corner, September]:

I really wish this author had spent a little more time researching this topic. Her article pretty much looks like what you'd find if you googled "E-cigs bad."

She also refers to what is exhaled as "second-hand smoke." The exhalant of e-cigs is water vapor.

As a pharmacist and former 20-year smoker, I have not touched a regular "analog" cigarette in two-and-a-half years since I started using electronic cigarettes. I also have no problem recommending them to current smokers.

The accidental poisoning of young children with the nicotine liquid is no different from a parent leaving gummy vitamins out where a child can get them and overdose. If we used this excuse to say that e-cigs are dangerous and should not be used, than I need to walk out and pull all the yummy childrens vitamins off the shelf.

I do agree that more research needs to be done, but there is no reason to paint such a broad picture and say that they are not beneficial in helping people quit smoking. I am proof that they do work.

Anonymous
POSTED AT *WWW.DRUGTOPICS.COM*

Continued on pg. 18

Voices

Continued from pg. 17

Supplemental info

Re: "Can dietary supplements help manage type 2 diabetes?" [Mark Lowery, Diabetes Supplement, November]:

I don't have a lot of time for a blow-by-blow extirpation of all the assumptions, misdirections, and generalities expressed in this article, but I have to say something to help balance this one-sided attack on all that is non-Pharma.

First of all, some people (maybe a lot of people) are chromium-deficient. So exploring this with a lab test might reveal those patients who would benefit from 500 to 1,000 mcg of chromium with each meal. Try it. It works. There IS evidence for this.

Second: Berberine has been shown in studies to be equal to metformin for reducing blood sugar. It has an added benefit of controlling yeast overgrowth in the gut, which is a primary driver of carbohydrate cravings. This is the *gut-brain connection* that you may have heard about. Try 500 mg PO BID and get back to me.

Third: Magnesium's role in glucose metabolism is well known. It is also well established that somewhere between 60% and 75% of the population is magnesium-deficient. Ask for an RBC Magnesium Level on a lab slip to deterimine the extent of the nutritional deficiency.

The overuse of diuretics (hey! they don't work for hypertension — stop using them!),the (over?)-consumption of caffeine, and the low mineral content of our processed-food diet contribute to this deficiency.

The problem is that most pharmacists don't understand that the salt form of the magnesium makes all the difference in bowel tolerance. In fact, so many doctors are misinformed that they have scared my patients about taking magnesium. I tell them that all they have heard is wrong.

If a knowledgeable pharmacist or doctor were to recommend an amino acid chelate (like Mg glycinate or Mg threonate or Mg maleate) and give half a dose in the morning and two-thirds of a dose in the afternoon, there wouldn't be any issues with loose stools and the patients would sleep better, have stronger bones, less anxiety, and better blood sugars. Most people have a 1,200-mg elemental magnesium deficit.

How about Vanadium? See chromium above.

What about advanced glycation end products (HbA1c and fructosamine levels)? These are the major contributors to erectile dysfunction, hypertension, Alzheimer's disease, coronary heart failure, stroke, macular degeneration, renal failure, cataracts, atherosclerosis, etc., etc. And peripheral neuropathy.

(Also see "Advanced lipoxidation end-products," *http://www.ncbi.nlm.nih.gov/pubmed/23767955*.)

Are there any pharmaceutical agents addressing this problem? Are pharmacy school students taught about this pathology? Are there any supplements that address advanced glycoxidation and lipoxidation end products (AGEs and ALEs)?

Turns out there are! L-carnosine, alpha lipoic acid, berberine, benfotiamine, pyridoxine-5-phosphate, methyl-B12, biotin, d-chiro inositol (this one is really good for Polycystic Ovarian Syndrome), cinnamon(!), Yerba mate tea, etc., all reduce the formation of AGEs, RAGEs, and ALEs.

Lastly: Antioxidants. Do they have a role? Or have they, too, been relegated to the used car lot? Read the literature on PubMed (mounds of it) that supports the use of antioxidants in the treatment and mitigation of diabetes and its sequelae.

Pharmacists shouldn't ignore the evidence about supplements in the treatment and mitigation and reversal of diabetes so as to accommodate their patients' misguided attempts to self-treat their diabetes.

They should use that evidence to support and promote the health of these better-informed patients who realize that a lifetime of metformin, insulin, and bad dietary advice will just put them in their graves faster.

Diabetes is a curable disease, but drugs won't cure it.

Mark Burger

POSTED AT *WWW.DRUGTOPICS.COM*

Correction: *In the article "What's on the horizon for diabetes therapy?" (Diabetes Supplement, November), there was an error in Table 2, which noted phase 3 compounds in development. The linagliptin/pioglitazone fixed-dose combination (Boehringer Ingelheim, Eli Lilly) has been discontinued in the United States.* Drug Topics *regrets the error.*

Correction: *"PharmD Options," the November cover story, stated that international students in the Shenandoah University Non-traditional Doctor of Pharmacy Pathway program might have to take an additional rotation to gain more experience working in a "retail setting" in the United States. The article should have stated "retail or hospital pharmacy setting."* Drug Topics *regrets the error.*

Correction: *A news item about insulin detemir [rDNA origin] injection (Levemir FlexTouch) (July, p. 25), listed an incorrect URL for the product. The correct URL is* www.levemirpro.com. Drug Topics *regrets the error.*

We want to hear from you

Printed and e-mailed letters should be brief and include the writer's name, address, daytime phone number, and date of the issue you are referencing: Editor, ***Drug Topics***, 24950 Country Club Blvd., Suite 200, North Olmsted, OH 44070-5351. E-mail address: drugtopics@advanstar.com. Letters may be edited for length, style, content, and clarity at our discretion.

IN MY VIEW Kelly Howard, BS, PharmD, BCPS

Warm fuzzies in the pharmacy: The importance of being liked

The importance of being well liked? Really? Yes, really. Learn from my mistakes – it is not only important, but absolutely necessary to be well liked by your co-workers and supervisors. That is, if you want to have a successful career.

Obviously, from our patients' perspective, our warmth and responsiveness as people and the way we engage with them is crucial as well, but that's a different article.

What I'm talking about here is the spate of recent research suggesting that your chance of being hired or promoted is directly proportional to the degree to which your supervisors and co-workers find you tolerable, likable, and enjoyable to work with.

What didn't work

In my previous job, I made the grievous error of believing that if I willingly worked unpaid overtime, initiated effective clinical programs, and produced stellar patient satisfaction scores, then I didn't need to repair a broken relationship with my supervisor or expend a lot of effort to get the new administration to like me.

As I said, that was my previous job. I'm not there anymore, so obviously, I was wrong.

You can be the smartest clinical pharmacist or the most efficient community pharmacist in the history of your company, but if your co-workers think you're a jerk or your manager misperceives your lack of interest in her personal life as rude, than your tenure is likely to be short, or at the very least you won't find a lot of raises or promotions coming your way.

Is this unfair? Possibly. Is it a concrete fact of life? Absolutely.

Perception is key

As demonstrated throughout season after season of the television show "American Idol," we Americans will fight for people we like, whether or not those individuals have any real discernible talent.

The same is largely true in the American workplace. Employees who are well-liked are more likely to receive assistance from co-workers, be promoted, and have their mistakes forgiven.

This is not to say that I think we should be abandoning substance in favor of style. My point is that we need to recognize the importance of how we are perceived by our co-workers and manager.

Engage, participate, connect

Having thoroughly learned the importance of likability at my last job, I have devoted significant energy to increasing my congeniality factor in my current job.

I genuinely like and respect my current co-workers, and to a greater degree than I did my previous co-workers, but maybe that's simply the result of my own increased efforts to be a better co-worker.

For me, this has been less about buying their affections with fat and sugar (although I have been shameless about bringing baked goods) and more about simply being a good person.

Maybe I would prefer working through lunch alone at my desk instead of eating with my fellow pharmacists family-style every day at noon, but those lunches have provided countless opportunities for me to connect with and learn more about my co-workers, and I'm ultimately the better for it.

Sure, nobody is thrilled to be forced to look at 412 pictures of a co-worker's new baby, but if others look willingly at pictures of your family, you should return the favor.

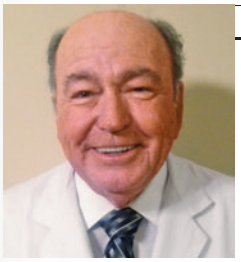
These are the personal interactions that connect us to our co-workers, hold us accountable to one another in the workplace, and ultimately make the pharmacy a happier place for everyone.

You get what you give

In hindsight, I see that no amount of personality coaching, ingratiating behavior, or forced socializing could have changed my fate at my previous job. I will never be a pharmacist who prioritizes profit margins over patient care, so I would never have fit the administration's ideal.

However, the four years I toiled away at that hospital might ultimately have been more pleasant and more fairly compensated if I had simply taken the chip off my shoulder and made an effort to be more huggable. DT

Kelly Howard *is a freelance pharmacist living and working in Southeastern North Carolina. Contact her to talk about your own HQ at* kelly@gottsman.org *or* www.thefreelancepharmacist.com.



IN MY VIEW Truman Lastinger, RPh

Pharmacist's story is the saga of an era

Truman Lastinger is a walking history of pharmacy practice. He spent 58 years in retail pharmacy, 50 of them as an RPh, and did more to bring healthcare services to his rural Georgia community than he is likely to admit. He has, however, recorded many of his memories of causes championed and patients helped in a new book, titled "Farming to Pharmacy: Memories of a Sharecropper's Son." Below, he tells us how it all began.

Being born in 1937 to a sharecropper did not lend itself to getting a college education. Sharecropping existed with, and then replaced, slavery after the Civil War. The only thing the sharecropper had was a mule and a little furniture. His family existed at the whim of the landowner.

At 15 years of age I got tired of working on farms and went to town, Moultrie, Ga., to see if I could find a job. I went almost all the way around the courthouse square, going into every office and store. There were six drugstores around that square, serving about 25,000 people. All the stores seemed to be doing a good business, and everyone had a lunch hour.

I got hired in the fourth drugstore I went into. They needed a soda jerk. The owner's wife asked me to write down my name and the name of the store. When she saw she could read my writing, she told him to hire me.

After I spent a week or so in the soda fountain, the boss took me into the back of the store and put me to pouring and labeling wets, and measuring and labeling drys. It was here that I discovered some peculiar names for drugs. Acetylated salicylic acid (aspirin), phenylazodiamino pyridine (pyridium), acetylated para amino phenol (APAP, which became Tylenol), were some that caught my eye. I got hooked on pharmacy.

Off to pharmacy school

My boss told me to apply for pharmacy school. When I told him that I couldn't afford it, he said that he would pay my tuition if I came back and worked for him. I was excited and applied. I was accepted by The University of Georgia, Auburn University in Alabama, and Southern College of Pharmacy in Atlanta. I told my girlfriend I was going to pharmacy school.

Then my boss had a heart attack and drowned at Daytona Beach. Suddenly I was back where I started. My girlfriend insisted that I could work my way through school and said she would help.

We got married and went to Atlanta, where I entered Southern College of Pharmacy. I chose it because I could find a job in Atlanta. It took us eight hard years and overcoming many obstacles, but we finally made it.

My first drugstore

We moved back to South Georgia and finally opened our own drugstore. I remembered how things were done in Moultrie, and practiced the way they did.

Many of my pharmacy neighbors and I served as primary healthcare providers to the county. People with small problems we treated with OTC meds and meds we made up. We made eyedrops, lozenges, douche powders, toothpaste, and poultices. We used sulfur and cream of tarter lozenges for skin problems. I mixed insulins, administered B_{12} injections, and gave allergy shots. Quite often a doctor would call me and ask me to go to the store and administer a tetanus shot, and to let him know if the patient needed stitches.

Public service

I went to the school board and explained that many of our families could not afford to pay a doctor $4 or $5 dollars when their children had a problem that kept them out of school. The board agreed to accept my written notes, ensuring that no child would have to be absent without cause.

The health department administered inoculations and began to pass out certain medications. Among these were birth-control drugs. I went to the health department and volunteered my time to oversee the distribution of oral medications. I wound up running a birth-control clinic once a week. At these clinics I would counsel and dispense birth-control drugs. When the patients came back the next month I would discuss side effects with them. Sometimes we had to change birth-control methods, due to their reactions.

The University of Georgia Pharmacy School put on a drug-testing continuing education program. I attended, because some drugs had begun to show up in our county. I brought the equipment back and told the police and sheriff's departments that I could quickly give them testing results for suspected drugs. This would give them cause to charge someone until the state crime lab provided the official results. Both departments used this service until drug tests became available.

During the Sixties there was a nationwide effort to inoculate the entire U.S.

Continued on pg. 49

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JANUARY 2015

INTRODUCING

Hysingla™ ER

(Hydrocodone Bitartrate) CII

EXTENDED-RELEASE TABLETS

Visit HysinglaER.com to get the latest information

WARNING: ADDICTION, ABUSE, AND MISUSE; LIFE-THREATENING RESPIRATORY DEPRESSION; ACCIDENTAL INGESTION; NEONATAL OPIOID WITHDRAWAL SYNDROME; AND CYTOCHROME P450 3A4 INTERACTION

Addiction, Abuse, and Misuse
HYSINGLA ER exposes patients and other users to the risks of opioid addiction, abuse, and misuse, which can lead to overdose and death. Assess each patient's risk prior to prescribing HYSINGLA ER, and monitor all patients regularly for the development of these behaviors or conditions *[see Warnings and Precautions (5.1)]*.

Life-Threatening Respiratory Depression
Serious, life-threatening, or fatal respiratory depression may occur with use of HYSINGLA ER. Monitor for respiratory depression, especially during initiation of HYSINGLA ER or following a dose increase. Instruct patients to swallow HYSINGLA ER tablets whole; crushing, chewing, or dissolving HYSINGLA ER tablets can cause rapid release and absorption of a potentially fatal dose of hydrocodone *[see Warnings and Precautions (5.2)]*.

Accidental Ingestion
Accidental ingestion of even one dose of HYSINGLA ER, especially by children, can result in a fatal overdose of hydrocodone *[see Warnings and Precautions (5.2)]*.

Neonatal Opioid Withdrawal Syndrome
Prolonged use of HYSINGLA ER during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening if not recognized and treated, and requires management according to protocols developed by neonatology experts. If opioid use is required for a prolonged period in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available *[see Warnings and Precautions (5.3)]*.

Cytochrome P450 3A4 Interaction
The concomitant use of HYSINGLA ER with all cytochrome P450 CYP3A4 inhibitors may result in an increase in hydrocodone plasma concentrations, which could increase or prolong adverse drug effects and may cause potentially fatal respiratory depression. In addition, discontinuation of a concomitantly used cytochrome P450 3A4 inducer may result in an increase in hydrocodone plasma concentration. Monitor patients receiving HYSINGLA ER and any CYP3A4 inhibitor or inducer *[see Warnings and Precautions (5.11), Drug Interactions (7.1), and Clinical Pharmacology (12.3)]*.

Please read Brief Summary of Full Prescribing Information on the following pages, including Boxed Warning.

PURDUE

A8970-APP-A 11/2014

Hysingla™ ER

(Hydrocodone Bitartrate) II

EXTENDED-RELEASE TABLETS

BRIEF SUMMARY OF PRESCRIBING INFORMATION (For complete details please see the Full Prescribing Information and Medication Guide.)

WARNING: ADDICTION, ABUSE, AND MISUSE; LIFE-THREATENING RESPIRATORY DEPRESSION; ACCIDENTAL INGESTION; NEONATAL OPIOID WITHDRAWAL SYNDROME; AND CYTOCHROME P450 3A4 INTERACTION

Addiction, Abuse, and Misuse

HYSINGLA™ ER exposes patients and other users to the risks of opioid addiction, abuse, and misuse, which can lead to overdose and death. Assess each patient's risk prior to prescribing HYSINGLA ER, and monitor all patients regularly for the development of these behaviors or conditions *[see Warnings and Precautions (5.1)]*.

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4 CONTRAINDICATIONS

HYSINGLA ER is contraindicated in patients with: • Significant respiratory depression • Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment • Known or suspected paralytic ileus and gastrointestinal obstruction • Hypersensitivity to any component of HYSINGLA ER or the active ingredient, hydrocodone bitartrate

5 WARNINGS AND PRECAUTIONS **5.1 Addiction, Abuse, and Misuse** HYSINGLA ER contains hydrocodone, a Schedule II controlled substance. As an opioid, HYSINGLA ER exposes users to the risks of addiction, abuse, and misuse *[see Drug Abuse and Dependence (9.1)]*. As extended-release products such as HYSINGLA ER deliver the opioid over an extended period of time, there is a greater risk for overdose and death due to the larger amount of hydrocodone present. Although the risk of addiction in any individual is unknown, it can occur in patients appropriately prescribed HYSINGLA ER and in those who obtain the drug illicitly. Addiction can occur at recommended doses and if the drug is misused or abused. Assess each patient's risk for opioid addiction, abuse, or misuse prior to prescribing HYSINGLA ER, and monitor all patients receiving HYSINGLA ER for the development of these behaviors or conditions. Risks are increased in patients with a personal or family history of substance abuse (including drug or alcohol addiction or abuse) or mental illness (e.g., major depression). The potential for these risks should not, however, prevent the prescribing of HYSINGLA ER for the proper management of pain in any given patient. Abuse or misuse of HYSINGLA ER by crushing, chewing, snorting, or injecting the dissolved product will result in the uncontrolled delivery of the hydrocodone and can result in overdose and death *[see Drug Abuse and Dependence (9.1), and Overdosage (10)]*. Opioid agonists are sought by drug abusers and people with addiction disorders and are subject to criminal diversion. Consider these risks when prescribing or dispensing HYSINGLA ER. Strategies to reduce these risks include prescribing the drug in the smallest appropriate quantity and advising the patient on the proper disposal of unused drug *[see Patient Counseling Information (17)]*. Contact local state professional licensing board or state controlled substances authority for information on how to prevent and detect abuse or diversion of this product. **5.2 Life-Threatening Respiratory Depression** Serious, life-threatening, or fatal respiratory depression has been reported with the use of modified-release opioids, even when used as recommended. Respiratory depression from opioid use, if not immediately recognized and treated, may lead to respiratory arrest and death. Management of respiratory depression may include close observation, supportive measures, and use of opioid antagonists, depending on the patient's clinical status *[see Overdosage (10.2)]*. Carbon dioxide (CO_2) retention from opioid-induced respiratory depression can exacerbate the sedating effects of opioids. While serious, life-threatening, or fatal respiratory depression can occur at any time during the use of HYSINGLA ER, the risk is greatest during the initiation of therapy or following a dose increase. Closely monitor patients for respiratory depression when initiating therapy with HYSINGLA ER and following dose increases. To reduce the risk of respiratory depression, proper dosing and titration of HYSINGLA ER are essential *[see Dosage and Administration (2.1, 2.2)]*. Overestimating the HYSINGLA ER dose when converting patients from another opioid product can result in fatal overdose with the first dose. Accidental ingestion of even one dose of HYSINGLA ER, especially by children, can result in respiratory depression and death due to an overdose of hydrocodone. **5.3 Neonatal Opioid Withdrawal Syndrome** Prolonged use of HYSINGLA ER during pregnancy can result in withdrawal signs in the neonate. Neonatal opioid withdrawal syndrome, unlike opioid withdrawal syndrome in adults, may be life-threatening if not recognized and requires management according to protocols developed by neonatology experts. If opioid use is required for a prolonged period in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available. Neonatal opioid withdrawal syndrome presents as irritability, hyperactivity and abnormal sleep pattern, high pitched cry, tremor, vomiting, diarrhea and failure to gain weight. The onset, duration, and severity of neonatal opioid withdrawal syndrome vary based on the specific opioid used, duration of use, timing and amount of last maternal use, and rate of elimination of the drug by the newborn. **5.4 Interactions with Central Nervous System Depressants** Hypotension, profound sedation, coma, respiratory depression, and death may result if HYSINGLA ER is used concomitantly with alcohol or other central nervous system (CNS) depressants (e.g., sedatives, anxiolytics, hypnotics, neuroleptics, other opioids). When considering the use of HYSINGLA ER in a patient taking a CNS depressant, assess the duration use of the CNS depressant and the patient's response, including the degree of tolerance that has developed to CNS depression. Additionally, evaluate the patient's use of alcohol or illicit drugs that cause CNS depression. If the decision to begin HYSINGLA ER is made, start with a lower HYSINGLA ER dose than usual (i.e., 20-30% less), monitor patients for signs of sedation and respiratory depression, and consider using a lower dose of the concomitant CNS depressant *[see Drug Interactions (7.2)]*. **5.5 Use in Elderly, Cachectic, and Debilitated Patients** Life-threatening respiratory depression is more likely to occur in elderly, cachectic, or debilitated patients as they may have altered pharmacokinetics or altered clearance compared to younger, healthier patients. Monitor such patients closely, particularly when initiating and titrating HYSINGLA ER and when HYSINGLA ER is given concomitantly with other drugs that depress respiration *[see Warnings and Precautions (5.2)]*. **5.6 Use in Patients with Chronic Pulmonary Disease** Monitor patients with significant chronic obstructive pulmonary disease or cor pulmonale, and patients having a substantially decreased respiratory reserve, hypoxia, hypercapnia, or preexisting respiratory depression for respiratory depression, particularly when initiating therapy and titrating with HYSINGLA ER, as in these patients, even usual therapeutic doses of HYSINGLA ER may decrease respiratory drive to the point of apnea *[see Warnings and Precautions (5.2)]*. Consider the use of alternative non-opioid analgesics in these patients if possible. **5.7 Use in Patients with Head Injury and Increased Intracranial Pressure** In the presence of head injury, intracranial lesions or a preexisting increase in intracranial pressure, the possible respiratory depressant effects of opioid analgesics and their potential to elevate cerebrospinal fluid pressure (resulting from vasodilation following CO_2 retention) may be markedly exaggerated. Furthermore, opioid analgesics can produce effects on pupillary response and consciousness, which may obscure neurologic signs of further increases in intracranial pressure in patients with head injuries. Monitor patients closely who may be susceptible to the intracranial effects of CO_2 retention, such as those with evidence of increased intracranial pressure or impaired consciousness. Opioids may obscure the clinical course of a patient with a head injury. Avoid the use of HYSINGLA ER in patients with impaired consciousness or coma. **5.8 Hypotensive Effect** HYSINGLA ER may cause severe hypotension including orthostatic hypotension and syncope in ambulatory patients. There is an added risk to individuals whose ability to maintain blood pressure has been compromised by a depleted blood volume, or after concurrent administration with drugs such as phenothiazines or other agents which compromise vasomotor tone. Monitor these patients for signs of hypotension after initiating or titrating the dose of HYSINGLA ER. In patients with circulatory shock, HYSINGLA ER may cause vasodilation that can further reduce cardiac output and blood pressure. Avoid the use of HYSINGLA ER in patients with circulatory shock. **5.9 Gastrointestinal Obstruction, Dysphagia, and Choking** In the clinical studies with specific instructions to take HYSINGLA ER with adequate water to swallow the tablet, 11 out of 2476 subjects reported difficulty swallowing HYSINGLA ER. These reports included esophageal obstruction, dysphagia, and choking, one of which had required medical intervention to remove the tablet *[see Adverse Reactions (6)]*. Instruct patients not to pre-soak, lick, or otherwise wet HYSINGLA ER tablets prior to placing in the mouth, and to take one tablet at a time with enough water to ensure complete swallowing immediately after placing in the mouth *[see Patient Counseling Information (17)]*. Patients with underlying gastrointestinal disorders such as esophageal cancer or colon cancer with a small gastrointestinal lumen are at greater risk of developing these complications. Consider use of an alternative analgesic in patients who have difficulty swallowing and patients at risk for underlying gastrointestinal disorders resulting in a small gastrointestinal lumen. **5.10 Decreased Bowel Motility** HYSINGLA ER is contraindicated in patients with known or suspected gastrointestinal obstruction, including paralytic ileus. Opioids diminish propulsive peristaltic waves in the gastrointestinal tract and decrease bowel motility. Monitor for decreased bowel motility in post-operative patients receiving opioids. The administration of HYSINGLA ER may obscure the diagnosis or clinical course in patients with acute abdominal conditions. Hydrocodone may cause spasm of the sphincter of Oddi. Monitor patients with biliary tract disease, including acute pancreatitis. **5.11 Cytochrome P450 CYP3A4 Inhibitors and Inducers** Since the CYP3A4 isoenzyme plays a major role in the metabolism of HYSINGLA ER, drugs that alter CYP3A4 activity may cause changes in clearance of hydrocodone which could lead to changes in hydrocodone plasma concentrations. The clinical results with CYP3A4 inhibitors show an increase in hydrocodone plasma concentrations and possibly increased or prolonged opioid effects, which could be more pronounced with concomitant use of CYP3A4 inhibitors. The expected clinical result with CYP3A4 inducers is a decrease in hydrocodone plasma concentrations, lack of efficacy or, possibly, development of an abstinence syndrome in a patient who had developed physical dependence to hydrocodone. If co-administration is necessary, caution is advised when initiating HYSINGLA ER treatment in patients currently taking, or discontinuing, CYP3A4 inhibitors or inducers. Evaluate these patients at frequent intervals and consider dose adjustments until stable drug effects are achieved *[see Drug Interactions (7.1)]*. **5.12 Driving and Operating Machinery** HYSINGLA ER may impair the mental and physical abilities needed to perform potentially hazardous activities such as driving a car or operating machinery. Peak blood levels of hydrocodone may occur 14 – 16 hours (range 6 – 30 hours) after initial dosing of HYSINGLA ER tablet administration. Blood levels of hydrocodone, in some patients, may be high at the end of 24 hours after repeated-dose administration. Warn patients not to drive or operate dangerous machinery unless they are tolerant to the effects of HYSINGLA ER and know how they will react to the medication *[see Clinical Pharmacology (12.3)]*. **5.13 Interaction with Mixed Agonist/Antagonist Opioid Analgesics** Avoid the use of mixed agonist/antagonist analgesics (i.e., pentazocine, nalbuphine, and butorphanol) in patients who have received, or are receiving, a course of therapy with a full opioid agonist analgesic, including HYSINGLA ER. In these patients, mixed agonist/antagonist analgesics may reduce the analgesic effect and/or may precipitate withdrawal symptoms. **5.14 QTc Interval Prolongation** QTc prolongation has been observed with HYSINGLA ER following daily doses of 160 mg *[see Clinical Pharmacology (12.2)]*. This observation should be considered in making clinical decisions regarding patient monitoring when prescribing HYSINGLA ER in patients with congestive heart failure, bradyarrhythmias, electrolyte abnormalities, or who are taking medications that are known to prolong the QTc interval. HYSINGLA ER should be avoided in patients with congenital long QT syndrome. In patients who develop QTc prolongation, consider reducing the dose by 33 – 50%, or changing to an alternate analgesic.

6 ADVERSE REACTIONS The following serious adverse reactions are described elsewhere in the labeling: • Addiction, Abuse, and Misuse *[see Warnings and Precautions (5.1)]* • Life-Threatening Respiratory Depression *[see Warnings and Precautions (5.2)]* • Neonatal Opioid Withdrawal Syndrome *[see Warnings and Precautions (5.3)]* • Interactions with Other CNS Depressants *[see Warnings and Precautions (5.4)]* • Hypotensive Effects *[see Warnings and Precautions (5.8)]* • Gastrointestinal Effects *[see Warnings and Precautions (5.9, 5.10)]* **6.1 Clinical Trial 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. A total of 1,827 patients were treated with HYSINGLA ER in controlled and open-label chronic pain clinical trials. Five hundred patients were treated for 6 months and 364 patients were treated for 12 months. The clinical trial population consisted of opioid-naïve and opioid-experienced patients with persistent moderate to severe chronic pain. The common adverse reactions (≥2%) reported by patients in clinical trials comparing HYSINGLA ER (20-120 mg/day) with placebo are shown in Table 2 below:

Table 2: Adverse Reactions Reported in ≥2% of Patients during the Open-Label Titration Period and Double-Blind Treatment Period: Opioid-Naïve and Opioid-Experienced Patients

	Open-label Titration Period	Double-blind Treatment Period	
MedDRA Preferred Term	(N=905) (%)	Placebo (N=292) (%)	HYSINGLA ER (N=296) (%)
Nausea	16	5	8
Constipation	9	2	3
Vomiting	7	3	6
Dizziness	7	2	3
Headache	7	2	2
Somnolence	5	1	1
Fatigue	4	1	1
Pruritus	3	<1	0
Tinnitus	2	1	2
Insomnia	2	2	3
Decreased appetite	1	1	2
Influenza	1	1	3

The adverse reactions seen in controlled and open-label chronic pain studies are presented below in the following manner: most common (≥5%), common (≥1% to <5%), and less common (<1%).

The most common adverse reactions (≥5%) reported by patients treated with HYSINGLA ER in the chronic pain clinical trials were constipation, nausea, vomiting, fatigue, upper respiratory tract infection, dizziness, headache, somnolence.

The common (≥1% to <5%) adverse events reported by patients treated with HYSINGLA ER in the chronic pain clinical trials organized by MedDRA (Medical Dictionary for Regulatory Activities) System Organ Class were:

Ear and labyrinth disorders	tinnitus
Gastrointestinal disorders	abdominal pain, abdominal pain upper, diarrhea, dry mouth, dyspepsia, gastroesophageal reflux disease
General disorders and administration site conditions	chest pain, chills, edema peripheral, pain, pyrexia

Infections and infestations	bronchitis, gastroenteritis, gastroenteritis viral, influenza, nasopharyngitis, sinusitis, urinary tract infection
Injury, poisoning and procedural complications	fall, muscle strain
Metabolism and nutrition disorders	decreased appetite
Musculoskeletal and connective tissue disorders	arthralgia, back pain, muscle spasms, musculoskeletal pain, myalgia, pain in extremity
Nervous system disorders	lethargy, migraine, sedation
Psychiatric disorders	anxiety, depression, insomnia
Respiratory, thoracic and mediastinal disorders	cough, nasal congestion, oropharyngeal pain
Skin and subcutaneous tissue disorders	hyperhidrosis, pruritus, rash
Vascular disorders	hot flush, hypertension

Other less common adverse reactions that were seen in <1% of the patients in the HYSINGLA ER chronic pain clinical trials include the following in alphabetical order: abdominal discomfort, abdominal distention, agitation, asthenia, choking, confusional state, depressed mood, drug hypersensitivity, drug withdrawal syndrome, dysphagia, dyspnea, esophageal obstruction, flushing, hypogonadism, hypotension, hypoxia, irritability, libido decreased, malaise, mental impairment, mood altered, muscle twitching, edema, orthostatic hypotension, palpitations, presyncope, retching, syncope, thinking abnormal, thirst, tremor, and urinary retention.

7 DRUG INTERACTIONS 7.1 Drugs Affecting Cytochrome P450 Isoenzymes *Inhibitors of CYP3A4* Co-administration of HYSINGLA ER with ketoconazole, a strong CYP3A4 inhibitor, significantly increased the plasma concentrations of hydrocodone. Inhibition of CYP3A4 activity by inhibitors, such as macrolide antibiotics (e.g., erythromycin), azole-antifungal agents (e.g., ketoconazole), and protease inhibitors (e.g., ritonavir), may prolong opioid effects. Caution is advised when initiating therapy with, currently taking, or discontinuing CYP3A4 inhibitors. Evaluate these patients at frequent intervals and consider dose adjustments until stable drug effects are achieved *[see Clinical Pharmacology (12.3)]*. *Inducers of CYP3A4* CYP3A4 inducers may induce the metabolism of hydrocodone and, therefore, may cause increased clearance of the drug which could lead to a decrease in hydrocodone plasma concentrations, lack of efficacy or, possibly, development of a withdrawal syndrome in a patient who had developed physical dependence to hydrocodone. If co-administration with HYSINGLA ER is necessary, monitor for signs of opioid withdrawal and consider dose adjustments until stable drug effects are achieved *[see Clinical Pharmacology (12.3)]*. **7.2 Central Nervous System Depressants** The concomitant use of HYSINGLA ER with other CNS depressants including sedatives, hypnotics, tranquilizers, general anesthetics, phenothiazines, other opioids, and alcohol can increase the risk of respiratory depression, profound sedation, coma and death. Monitor patients receiving CNS depressants and HYSINGLA ER for signs of respiratory depression, sedation and hypotension. When combined therapy with any of the above medications is considered, the dose of one or both agents should be reduced *[see Warnings and Precautions (5.4)]*. **7.3 Interactions with Mixed Agonist/Antagonist and Partial Agonist Opioid Analgesics** Mixed agonist/antagonist analgesics (i.e., pentazocine, nalbuphine, and butorphanol) and partial agonist analgesics (buprenorphine) may reduce the analgesic effect of HYSINGLA ER or precipitate withdrawal symptoms in these patients. Avoid the use of mixed agonist/antagonist and partial agonist analgesics in patients receiving HYSINGLA ER. **7.4 MAO Inhibitors** HYSINGLA ER is not recommended for use in patients who have received MAO inhibitors within 14 days, because severe and unpredictable potentiation by MAO inhibitors has been reported with opioid analgesics. No specific interaction between hydrocodone and MAO inhibitors has been observed, but caution in the use of any opioid in patients taking this class of drugs is appropriate. **7.5 Anticholinergics** Anticholinergics or other drugs with anticholinergic activity when used concurrently with opioid analgesics may increase the risk of urinary retention or severe constipation, which may lead to paralytic ileus. Monitor patients for signs of urinary retention and constipation in addition to respiratory and central nervous system depression when HYSINGLA ER is used concurrently with anticholinergic drugs. **7.6 Strong Laxatives** Concomitant use of HYSINGLA ER with strong laxatives (e.g., lactulose), that rapidly increase gastrointestinal motility, may decrease hydrocodone absorption and result in decreased hydrocodone plasma levels. If HYSINGLA ER is used in these patients, closely monitor for the development of adverse events as well as changing analgesic requirements.

8 USE IN SPECIFIC POPULATIONS 8.1 Pregnancy *Pregnancy Category C Risk Summary* There are no adequate and well-controlled studies of HYSINGLA ER use during pregnancy. Prolonged use of opioid analgesics during pregnancy may cause neonatal opioid withdrawal syndrome. In animal reproduction studies with hydrocodone in rats and rabbits no embryotoxicity or teratogenicity was observed. However, reduced pup survival rates, reduced fetal/pup body weights, and delayed ossification were observed at doses causing maternal toxicity. In all of the studies conducted, the exposures in animals were less than the human exposure (see Animal Data). HYSINGLA ER should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. *Clinical Considerations* Fetal/neonatal adverse reactions Prolonged use of opioid analgesics during pregnancy for medical or nonmedical purposes can result in physical dependence in the neonate and neonatal opioid withdrawal syndrome shortly after birth. Observe newborns for symptoms of neonatal opioid withdrawal syndrome, such as poor feeding, diarrhea, irritability, tremor, rigidity, and seizures, and manage accordingly *[see Warnings and Precautions (5.3)]*. *Data* Animal Data No evidence of embryotoxicity or teratogenicity was observed after oral administration of hydrocodone throughout the period of organogenesis in rats and rabbits at doses up to 30 mg/kg/day (approximately 0.1 and 0.3-fold, respectively, the human hydrocodone dose of 120 mg/day based on AUC exposure comparisons). However, in these studies, reduced fetal body weights and delayed ossification were observed in rat at 30 mg/kg/day and reduced fetal body weights were observed in in rabbit at 30 mg/kg/day (approximately 0.1 and 0.3-fold, respectively, the human hydrocodone dose of 120 mg/day based on AUC exposure comparisons). In a pre- and post-natal development study pregnant rats were administered oral hydrocodone throughout the period of gestation and lactation. At a dose of 30 mg/kg/day decreased pup viability, pup survival indices, litter size and pup body weight were observed. This dose is approximately 0.1-fold the human hydrocodone dose of 120 mg/day based on AUC exposure comparisons. **8.2 Labor and Delivery** Opioids cross the placenta and may produce respiratory depression in neonates. HYSINGLA ER is not recommended for use in women immediately prior to and during labor, when use of shorter acting analgesics or other analgesic techniques are more appropriate. HYSINGLA ER may prolong labor through actions which temporarily reduce the strength, duration and frequency of uterine contractions. However, this effect is not consistent and may be offset by an increased rate of cervical dilatation, which tends to shorten labor. **8.3 Nursing Mothers** Hydrocodone is present in human milk. Because of the potential for serious adverse reactions in nursing infants, a decision should be made whether to discontinue nursing or to discontinue HYSINGLA ER, taking into account the importance of the drug to the mother. Infants exposed to HYSINGLA ER through breast milk should be monitored for excess sedation and respiratory depression. Withdrawal symptoms can occur in breast-fed infants when maternal administration of an opioid analgesic is stopped, or when breast-feeding is stopped. **8.4 Pediatric Use** The safety and effectiveness of HYSINGLA ER in pediatric patients have not been established. Accidental ingestion of a single dose of HYSINGLA ER in children can result in a fatal overdose of hydrocodone *[see Warnings and Precautions (5.2)]*. HYSINGLA ER gradually forms a viscous hydrogel (i.e., a gelatinous mass) when exposed to water or other fluids. Pediatric patients may be at increased risk of esophageal obstruction, dysphagia, and choking because of a smaller gastrointestinal lumen if they ingest HYSINGLA ER *[see Warnings and Precautions (5.9)]*. **8.5 Geriatric Use** In a controlled pharmacokinetic study, elderly subjects (greater than 65 years) compared to young adults had similar plasma concentrations of hydrocodone *[see Clinical Pharmacology (12.3)]*. Of the 1827 subjects exposed to HYSINGLA ER in the pooled chronic pain studies, 241 (13%) were age 65 and older (including those age 75 and older), while 42 (2%) were age 75 and older. In clinical trials with appropriate initiation of therapy and dose titration, no untoward or unexpected adverse reactions were seen in the elderly patients who received HYSINGLA ER. Hydrocodone may cause confusion and oversedation in the elderly. In addition, because of the greater frequency of decreased hepatic, renal, or cardiac function, concomitant disease and concomitant use of CNS active medications, start elderly patients on low doses of HYSINGLA ER and monitor closely for adverse events such as respiratory depression, sedation, and confusion. **8.6 Hepatic Impairment** No adjustment in starting dose with HYSINGLA ER is required in patients with mild or moderate hepatic impairment. Patients with severe hepatic impairment may have higher plasma concentrations than those with normal hepatic function. Initiate therapy with 1/2 the initial dose of HYSINGLA ER in patients with severe hepatic impairment and monitor closely for adverse events such as respiratory depression *[see Clinical Pharmacology (12.3)]*. **8.7 Renal Impairment** No dose adjustment is needed in patients with mild renal impairment. Patients with moderate or severe renal impairment or end stage renal disease have higher plasma concentrations than those with normal renal function. Initiate therapy with 1/2 the initial dose of HYSINGLA ER in these patients and monitor closely for adverse events such as respiratory depression *[see Clinical Pharmacology (12.3)]*.

9 DRUG ABUSE AND DEPENDENCE 9.1 Controlled Substance HYSINGLA ER contains hydrocodone bitartrate, a Schedule II controlled substance with a high potential for abuse similar to fentanyl, methadone, morphine, oxycodone, and oxymorphone. HYSINGLA ER can be abused and is subject to misuse, abuse, addiction and criminal diversion. The high drug content in the extended-release formulation adds to the risk of adverse outcomes from abuse and misuse. **9.2 Abuse** All patients treated with opioids require careful monitoring for signs of abuse and addiction, because use of opioid analgesic products carries the risk of addiction even under appropriate medical use. Drug abuse is the intentional non-therapeutic use of an over-the-counter or prescription drug, even once, for its rewarding psychological or physiological effects. Drug abuse includes, but is not limited to the following examples: the use of a prescription or over-the-counter drug to get "high," or the use of steroids for performance enhancement and muscle build up. Drug addiction is a cluster of behavioral, cognitive, and physiological phenomena that develop after repeated substance use and include: a strong desire to take the drug, difficulties in controlling its use, persisting in its use despite harmful consequences, a higher priority given to drug use than to other activities and obligations, increased tolerance, and sometimes a physical withdrawal. "Drug-seeking" behavior is very common to addicts and drug abusers. Drug seeking tactics include, but are not limited to, emergency calls or visits near the end of office hours, refusal to undergo appropriate examination, testing or referral, repeated claims of "loss" of prescriptions, tampering with prescriptions and reluctance to provide prior medical records or contact information for other treating physician(s). "Doctor shopping" (visiting multiple prescribers) to obtain additional prescriptions is common among drug abusers, people with untreated addiction, and criminals seeking drugs to sell. Preoccupation with achieving adequate pain relief can be appropriate behavior in a patient with poor pain control. Abuse and addiction are separate and distinct from physical dependence and tolerance. Physicians should be aware that addiction may not be accompanied by concurrent tolerance and symptoms of physical dependence in all addicts. In addition, abuse of opioids can occur in the absence of true addiction. HYSINGLA ER can be diverted for non-medical use into illicit channels of distribution. Careful record-keeping of prescribing information, including quantity, frequency, and renewal requests, as required by law, is strongly advised. Proper assessment of the patient, proper prescribing practices, periodic re-evaluation of therapy, and proper dispensing and storage are appropriate measures that help to limit abuse of opioid drugs. Abuse may occur by taking intact tablets in quantities greater than prescribed or without legitimate purpose, by crushing and chewing or snorting the crushed formulation, or by injecting a solution made from the crushed formulation. The risk is increased with concurrent use of HYSINGLA ER with alcohol or other central nervous system depressants. *Risks Specific to Abuse of HYSINGLA ER* HYSINGLA ER is for oral use only. Abuse of HYSINGLA ER poses a risk of overdose and death.. Taking cut, broken, chewed, crushed, or dissolved HYSINGLA ER increases the risk of overdose and death. With parenteral abuse, the inactive ingredients in HYSINGLA ER can result in death, local tissue necrosis, infection, pulmonary granulomas, and increased risk of endocarditis and valvular heart injury. Parenteral drug abuse is commonly associated with transmission of infectious diseases, such as hepatitis and HIV. Abuse Deterrence Studies *Summary* The *in vitro* data demonstrate that HYSINGLA ER has physical and chemical properties that are expected to deter intranasal and intravenous abuse. The data from the clinical abuse potential studies, along with support from the *in vitro* data, also indicate that HYSINGLA ER has physicochemical properties that are expected to reduce intranasal abuse and oral abuse when chewed. However, abuse of HYSINGLA ER by the intravenous, intranasal, and oral routes is still possible. Additional data, including epidemiological data, when available, may provide further information on the impact of HYSINGLA ER on the abuse liability of the drug. Accordingly, this section may be updated in the future as appropriate. HYSINGLA ER contains hydrocodone, an opioid agonist and Schedule II controlled substance with an abuse liability similar to other opioid agonists, legal or illicit, including fentanyl, hydromorphone, methadone, morphine, oxycodone, and oxymorphone. HYSINGLA ER can be abused and is subject to misuse, addiction, and criminal diversion *[See Warnings and Precautions (5.1) and Drug Abuse and Dependence (9)]*. **9.3 Dependence** Both tolerance and physical dependence can develop during chronic opioid therapy. Tolerance is the need for increasing doses of opioids to maintain a defined effect such as analgesia (in the absence of disease progression or other external factors). Tolerance may occur to both the desired and undesired effects of drugs, and may develop at different rates for different effects. Physical dependence results in withdrawal symptoms after abrupt discontinuation or a significant dose reduction of a drug. Withdrawal also may be precipitated through the administration of drugs with opioid antagonist activity, e.g., naloxone, nalmefene, or mixed agonist/antagonist analgesics (pentazocine, butorphanol, nalbuphine). Physical dependence may not occur to a clinically significant degree until after several days to weeks of continued opioid usage. HYSINGLA ER should be discontinued by a gradual downward titration *[see Dosage and Administration (2.6)]*. If HYSINGLA ER is abruptly discontinued in a physically dependent patient, an abstinence syndrome may occur. Some or all of the following can characterize this syndrome: restlessness, lacrimation, rhinorrhea, yawning, perspiration, chills, piloerection, myalgia, mydriasis, irritability, anxiety, backache, joint pain, weakness, abdominal cramps, insomnia, nausea, anorexia, vomiting, diarrhea, increased blood pressure, respiratory rate, or heart rate. Infants born to mothers physically dependent on opioids will also be physically dependent and may exhibit respiratory difficulties and withdrawal symptoms *[see Warnings and Precautions (5.3) and Use in Specific Populations (8.3)]*.

10 OVERDOSAGE 10.1 Symptoms Acute overdosage with opioids is often characterized by respiratory depression, somnolence progressing to stupor or coma, skeletal muscle flaccidity, cold and clammy skin, constricted pupils, and, sometimes, pulmonary edema, bradycardia, hypotension, and death. Marked mydriasis rather than miosis may be seen due to severe hypoxia in overdose situations *[see Clinical Pharmacology (12.2)]*. **10.2 Treatment** In the treatment of HYSINGLA ER overdosage, primary attention should be given to the re-establishment of a patent airway and institution of assisted or controlled ventilation. Employ other supportive measures (including oxygen and vasopressors) in the management of circulatory shock and pulmonary edema accompanying overdose as indicated. Cardiac arrest or arrhythmias will require advanced life support techniques. The opioid antagonist naloxone hydrochloride is a specific antidote against respiratory depression that may result from opioid overdosage. Nalmefene is an alternative opioid antagonist, which may be administered as a specific antidote to respiratory depression resulting from opioid overdose. Since the duration of action of HYSINGLA ER may exceed that of the antagonist, keep the patient under continued surveillance and administer repeated doses of the antagonist according to the antagonist labeling, as needed, to maintain adequate respiration. Opioid antagonists should not be administered in the absence of clinically significant respiratory or circulatory depression. Administer opioid antagonists cautiously to persons who are known, or suspected to be, physically dependent on HYSINGLA ER. In such cases, an abrupt or complete reversal of opioid effects may precipitate an acute abstinence syndrome. In an individual physically dependent on opioids, administration of the usual dose of the antagonist will precipitate an acute withdrawal syndrome. The severity of the withdrawal syndrome produced will depend on the degree of physical dependence and the dose of the antagonist administered. If a decision is made to treat serious respiratory depression in the physically dependent patient, administration of the antagonist should be initiated with care and by titration with smaller than usual doses of the antagonist.

CAUTION
DEA FORM REQUIRED

Healthcare professionals can telephone Purdue Pharma's Medical Services Department (1-888-726-7535) for information on this product.

Purdue Pharma L.P.
Stamford, CT 06901-3431

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VIEW FROM THE ZOO David Stanley, RPh

Doing well by doing good

A brilliant maneuver puts one drugstore chain ahead of the pack

Sometimes there's nothing like a good cop show on TV, and as the deadline for this month's column approaches, I've wasted most of the afternoon remembering some of my favorites. There was a time in the '90s when I never missed an episode of a series most famous for pushing the boundaries of what broadcast television would tolerate in terms of nudity and salty language. It wasn't seeing an occasional bare bottom or hearing words usually reserved for the locker room that drew me to the show, though. It was the writing.

If you paid attention, there was always a larger theme to the week's cases, as in the episode when a suspect's parents turned him in solely to collect reward money to feed their drug habit, while another was shielded from the police because his friends truly — and incorrectly, as it turned out — believed him to be innocent.

A situation in which the right thing was done for a bad reason and the wrong thing was done for a good one. Brilliant. And now that I think about it, I wonder whether that episode was ever viewed by decision-makers at the former CVS/Caremark, now known as CVS Health.

Nix the nicotine

For readers who haven't heard, the PBM side of the company announced at the end of October that it will form a "tobacco-free" network of pharmacies that will require a patient to cough up an extra co-pay, reported to be as much as $15, to fill a prescription at any pharmacy that sells tobacco products. This comes after the announcement made earlier this year, with much fanfare, that tobacco would no longer be sold at CVS stores.

So CVS Health stops selling tobacco and then develops a plan that would charge people extra for going to a competing pharmacy that does sells tobacco. Evidently the company that pledged to be "agnostic" when the CVS/Caremark merger was under review has now found religion.

It's hard to see this move as anything other than a cynical, albeit brilliant, ploy to use the power that comes with being simultaneously one of the country's largest pharmacy chains and one of its largest pharmacy benefit managers to damage the other "Big Two" of the chain pharmacy world, Walgreen's and Rite Aid, both of which continue to sell tobacco at their thousands of stores.

Can't lose

There's simply no way CVS can lose. Either:

- Their competitors stop selling tobacco, costing them billions in revenue
- Their competitors risk losing prescription business, as customers end up at CVS, Target, or any of the vast majority of independent drugstores that quit selling tobacco long ago, or
- Walgreen's and Rite Aid fight CVS, and maybe even win, while becoming known as the pharmacies that went to the mat to sell poison, losing credibility when making any claims to be concerned about their customer's health.

One could make a very good argument that this type of conduct is exactly why such "vertical integration" should be curtailed in the name of competition. Any business student could easily write a thesis drawing similarities to the bad old days of Standard Oil, railroad robber barons, or Andrew Carnegie's U.S. Steel.

Except for one thing.

Almost looks premeditated

Tobacco really *shouldn't* be sold in pharmacies, and the fact that these sales continue, more than 50 years after the Surgeon General officially linked tobacco to myriad health problems, is ridiculous.

I'll come flat out and say it. Any entity that makes tobacco available to anyone has no right to claim any status as a healthcare provider. People who go into a place that sells cigarettes are not seen as patients; they are customers, there only to provide dollars to the owner in any way possible, whether it be through the purchase of health or the purchase of death.

No amount of money could ever convince me to sell tobacco in my store, and its elimination from our profession would be nothing but a good thing. But ... allowing a huge corporation to take advantage of the synergy of a recent merger to damage its rivals just seems so ... wrong.

A good thing, done for the wrong reasons.

Which brings me to that TV show.

Brilliant. DT

David Stanley *is a pharmacy owner, blogger, and professional writer in northern California. Contact him at drugmonkeyrph@gmail.com.*

Global drug spending to grow 30% by 2018

Total global spending on pharmaceuticals will increase by $305 billion to $335 billion through 2018, compared to $219 billion during the past five years, announced a new study from IMS Institute for Healthcare Informatics..

Global spending for medications will grow up to 30% by 2018, thanks to more specialty drug innovation, greater patient access to medications, and reduced impact from patent expiries, the study found. IMS expects global spending to grow at a 4% to 7% compound annual rate over the next five years. Annual spending will spike this year when absolute growth will be around $70 billion, up from $40 billion in 2013.

"The higher level of spending growth we're projecting over the next five years reflects an unusual combination of higher spending on the surge of innovative medications for patients and lower savings from patent expiries," said Murray Aitken, executive director of the IMS Institute for Healthcare Informatics. "This is particularly evident this year and next in developed countries — and especially in the U.S., which accounts for more than a third of the global market."

Experts forecast the launch of more than 150 new drugs over the next five years, in a wave of innovation similar to levels seen in the mid-2000s, the Institute reported. "More than 2,000 products are currently in late-stage clinical development, of which oncology therapies make up fully one-fourth of the pipeline," said a statement from IMS Institute for Healthcare Informatics. Breakthrough specialty medications will contribute a projected 40% of total global spending growth through 2018. Advances will be particularly notable in the oncology, autoimmune, respiratory, antiviral, and immunosuppressant therapy areas. For example, new treatments for hepatitis C will result in a total of approximately $100 billion spent from 2013 through 2018.

— Christine Blank, Contributing Editor

More than 2,000 products are in the pipeline, and more than 150 new drugs will launch in the next five years.

TRANSITIONS

Burgess, Milenkovich elected to new posts; Plagakis ends a long run

Philip P. Burgess, MBA, DPh, RPh, has been elected to serve a three-year term on the Executive Committee of the National Association of Boards of Pharmacy (NABP), representing District 4, which comprises the boards of pharmacy of Wisconsin, Michigan, Ohio, Indiana, and Illinois. The governing body overseeing all of NABP's operations, the NABP Executive Committee includes representatives of the eight NABP districts across the country.

"Public safety is always the overarching issue" of interest to the committee, Burgess told *Drug Topics*. He added, "High on the list this year has been sterile compounding, drug abuse, illicit websites (implementation of '.pharmacy'), and assisting member boards with inspections."

Burgess, a member of *Drug Topics*' editorial advisory board, has been a member of the Illinois State Board of Pharmacy since 2002 and is currently serving in his fifth term as chair of that board. He is a member of several Illinois State committees and has served several national pharmacy organizations as well.

Now president of Philip Burgess Consulting, LLC, in Chicago, Burgess spent more than 40 years with Walgreen Company, serving in several capacities,and was the chain's national director of pharmacy affairs for 10 years.

Milenkovich assumes new post — again

The law firm of Roetzel & Andress LPA recently announced that Ned Milenkovich, partner and practice group manager of Roetzel's Health, Drug & Pharmacy Law group and featured egal columnist for *Drug Topics*, has been elected by the Illinois State Board of Pharmacy to a one-year term as the board's vice-chair, a position in which he has served twice before.

"I am looking forward to serving the board, as well as the public, in this capacity once again," said Milenkovich. "The board's role in setting standards for the professional conduct, discipline, and qualifications of pharmacist candidates and licensees in Illinois is an important one, and I expect to work with the chair and the rest of the Board's members in maintaining the high standards of pharmacists in the state of Illinois."

End of an era

Drug Topics' gratitude and appreciation go to Jim Plagakis, whose column "JP at Large" has ended its 25-year run. His contributions to the magazine, his fellow pharmacists, and the profession of pharmacy are countless and ongoing. Along with his many fans, *Drug Topics* wishes him all the best, as well as a speedy recovery as he continues to convalesce after his recent surgeries. Loyal fans can continue to read his commentaries on his own blog, at *www.jimplagakis.com*.

— Julianne Stein, Content Channel Manager

TRANSITIONS OF CARE

Shoppers Drug Mart study to test transitional care model

Toronto, Ontario-based Shoppers Drug Mart is conducting a pilot project to help patients avoid medication errors and reduce hospital readmissions after hospital care.

In a partnership with Health Sciences North/Horizon Santé-Nord, pharmacists from five Shoppers Drug Mart locations in Greater Sudbury, Ontario, are consulting with patients after discharge from HSN. Patients are advised to talk to their Shoppers Drug Mart pharmacist about all their current medications, in addition to any new ones prescribed by the care team. Then, HSN will contact each patient's pharmacist to review the patient's medication list, to ensure correct dosages and avoid possible interactions between the medications.

Seamless transition

"We're here to help patients by identifying and resolving issues with their medications as swiftly as possible, to ensure the transition from hospital to home is as seamless as possible," said Matthew King, pharmacist and associate owner of Shoppers Drug Mart's Frood & Elm location. "We're committed to reducing readmission rates of patients to hospital by carefully evaluating all medications a patient is prescribed in hospital and at discharge, and comparing that to existing therapies, in order to minimize the risk of medications errors and adverse events."

If patients are unable to come to the Shoppers Drug Mart location, owing to weakness or mobility problems, the pharmacist will make a home visit.

Better communication

The medication review is sponsored by the Ontario government through a program called MedsCheck, for eligible patients. "We wanted to launch this pilot project because we know that when healthcare providers communicate better with each about the medications being given to patients, we can avoid some of the problems those patients are facing with their prescriptions," said Wilf Steer, HSN's lead pharmacist on the pilot project.

Pharmacists' medication reviews are needed to reduce medication error rates in Canada. A 2012 study by Accreditation Canada, the Canadian Institute of Health Information, the Canadian Patient Safety Institute, and the Institute for Safe Medication Practices Canada found that more than 40% of adults with one chronic health conditions reported not receiving appropriate management of their medications.

In addition, 20% of patients discharged from acute care facilities experienced an adverse event, and of those, 66% were drug-related.

— *Mark Lowery, Content Editor*

COMMUNITY ACTION

CVS Health provides $1 million+ for smoking cessation programs

CVS Health and its foundation are investing more than $1 million in grant support for tobacco cessation and prevention programs nationwide, a company statement announced.

The funds will be distributed to a number of healthcare and community partners working to promote tobacco-free communities, help individuals to quit smoking, and help persuade people not to start smoking.

Grant recipients

Some of the grant monies will go to support quit lines operated by National Jewish Health and the American Lung Association. Other grant recipients include B'More for Healthy Babies, providing support for a smoking cessation partnership with CareFirst BlueCross BlueShield, which helps pregnant women and new mothers to stop smoking.

Another grant will support Live Well San Diego, a metropolitan-wide health and wellness initiative administered by the Department of Health, to provide smoking cessation services to 1,750 residents who are part of the behavioral health system. Sixteen Connecticut Area Boys and Girls Clubs will receive support for their youth tobacco awareness and education program "Be Smart, Don't Start."

Path to better health

"As we mark the Great American Smokeout, CVS Health is proud to make this investment in smoking cessation programs that give people the resources and support they need to quit smoking and lead tobacco-free lives," said Eileen Howard Boone, senior vice president of Corporate Social Responsibility and Philanthropy at CVS Health.

"Our company's purpose is helping people on their path to better health, and by supporting these dedicated community and healthcare partners, we are able to extend that purpose into our local communities."

According to a statement published by CVS, these grants are being made as research from the CVS Health Research Institute, published earlier this year online with *Health Affairs*, illustrates the impact private sector action can have on smoking rates. The statement noted that after Boston and San Francisco banned pharmacy tobacco sales, those communities saw a reduction in tobacco purchasers of up to 13% in those communities. Researchers concluded from this that if retailers with pharmacies across the country stopped selling tobacco products, "there could be as many as 60,000 fewer tobacco-related deaths per year."

For a complete list of grant recipients, go to *www.cvshealth.com/newsroom/press-releases/cvs-health-and-its-foundation-commit-more-1-million-grants-support-tobacco.*

— *Mark Lowery, Content Editor*

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ADVERSE EVENTS

FDA panel favors safer corticosteroid injections

An FDA advisory panel recently voted 15 to 7 in favor of a contraindication for certain injectable corticosteroid formulations for epidural use because of the risk of adverse neurological events, such as spinal cord infarction, paraplegia, quadriplegia, stroke, and death.

Risks vs. benefits

FDA's Anesthetic and Analgesic Drug Products Advisory Committee concluded that the risks associated with corticosteroid injections in the neck outweigh the benefits, saying that certain injectable corticosteroid formulations classified as "particulate" should be contraindicated for epidural administration. These include betamethasone acetate, methylprednisolone acetate, triamcinolone acetonide, triamcinolone hexacetonide, and the combination of betamethasone acetate/betamethasone sodium phosphate.

The panel noted that pain doctors are already using neck injections much less frequently because of the higher risk.

Had the advisory committee ruled that all epidural corticosteroids be contraindicated, it would have meant that the risk of use — such as death — outweighs any possible benefits, according to FDA.

Rare but serious events

"These situations include the use of the drug in a subpopulation of patients that have a substantial risk of being harmed by the drug and for whom no potential benefit makes the risk acceptable," the agency said in its briefing document provided to the committee.

The deaths of five patients who received injections in the artery instead of the epidural space triggered FDA's request for the panel's input on the safety of epidural injections.

In April, FDA issued a drug safety communication announcing that all labeling for injectable corticosteroids must warn about the possibility of rare, serious events occurring after the injection into the spine's epidural space. "Rare but serious adverse events" include loss of vision, stroke, paralysis, and death, according to the safety announcement.

More than one million Americans receive epidural steroid injections annually, the agency estimates. FDA began evaluating the issue of serious neurologic events arising from epidural corticosteroid injections in 2009, but the injections received more national attention in 2012, when a compounding pharmacy in Massachusetts distributed tainted steroid injections, killing dozens and sickening hundreds. The FDA advisory committee did not consider the issue of contamination during its November meeting.

— Christine Blank, Contributing Editor

COMPOUNDING

FDA offers more guidance for "outsourcing facilities"

In mid-November, FDA provided additional assistance to help compounders of sterile human drugs that have registered with the agency as "outsourcing facilities" under the Drug Quality and Security Act (DQSA),which was enacted in November 2013. The DQSA added Section 503B to the Federal Food, Drug, and Cosmetic Act. It is this section that the additional guidance addresses.

Drugs compounded in an outsourcing facility that meet certain conditions may be entitled to exemptions from certain provisions of the FDC Act, including the new drug approval requirements and the requirement to label drug products with adequate directions for use. Outsourcing facilities are subject to increased federal oversight.

The three policy documents produced by the agency outline in greater detail the registration process, the specific fees to be paid for registration, and the requirements for electronics submission of drug product reports.

"As an agency committed to protecting public health, it's important to the FDA that outsourcing facilities fully understand how to comply with the new law," said Janet Woodcock, MD, director of the FDA's Center for Drug Evaluation and Research.

Logistics

The documents that concern registration and fees for registration have been finalized. This final guidance helps acquaint outsourcing facilities with the logistics of the process for registering with FDA and provides specifics on how to re-register and de-register.

Fees

FDA has outlined the specific fees that are required for registration, how the fees can be submitted, penalties for failure to pay the fees, and qualifications a small business entity would need to provide in order to apply for reduced fees.

Reporting

The third document is a revised draft guidance that addresses the electronic submission of drug products compounded by the facility. When the outsourcing facility initially registers with FDA, the registrant must provide a drug product report that identifies all drugs compounded by the facility. The report must be submitted twice each year, with documentation on all drugs that were compounded within the previous six months.

The draft guidance for electronic reporting of drug products is available for public comment for 60 days. For more information, go to *www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm376732.htm*.

— Julia Talsma, Content Channel Director

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EBOLA UPDATE

NIH: First experimental Ebola vaccine produces immune response

Results from a National Institutes of Health (NIH) phase 1 clinical trial indicate that the first experimental Ebola vaccine has been shown to be safe and to prompt an immune response.

NIH's National Institute of Allergy and Infectious Diseases (NIAID) co-developed the candidate vaccine with GlaxoSmithKline (specifically the GSK biotech company, Okairos).

The study

The vaccine produced immune system responses and was well tolerated in the study cohort of 20 healthy adults. Although two volunteers who received larger doses developed a fever within a day of vaccination, there were otherwise no serious side effects.

The 20 volunteers enrolled in the trial ranged in age between 18 and 50 years. Half the cohort were given the vaccine intramuscularly at a lower dose, while the other half received a higher dose. Within four weeks of receiving the vaccine, all the participants developed anti-Ebola antibodies.

These positive interim results mean that other trials of the candidate vaccine will be initiated in West Africa, possibly as soon as in the final weeks of 2014 or in early 2015. NIAID Director Anthony S. Fauci, MD, stated, "We are continuing our accelerated plan for larger trials to determine if the vaccine is efficacious in preventing Ebola infection."

The candidate vaccine contains segments of Ebola virus genetic material from 2 virus species, Sudan and Zaire, which is delivered by a carrier virus that in chimpanzees causes the common cold but does not cause illness in humans. The vaccine does not actually contain Ebola virus and cannot cause the disease.

These study results were made available online in advance of print in the *New England Journal of Medicine*.

Drug development

To this point, yet the research dollars have not kept up with the need to develop effective vaccines and therapies.

A report from GlobalData underscores the relative lack of response by pharmaceutical manufacturers, attributed to Ebola virus disease's (EVD) low incidence to date and its main outbreaks occurring in impoverished countries that cannot pay for expensive drugs. Clinical studies are also difficult to design and carry out due to the rapid onset of severe symptoms in patients with EVD and a mortality rate of about 50%. However, cooperative efforts between the public and private sectors are ongoing, and several drugs are in the pipeline.

— *Gretchen Schwenker*

OPIOID REVERSAL

WHO recommends greater access to naloxone

In new guidelines, the World Health Organization (WHO) is recommending that countries significantly expand access to naloxone to help manage opioid overdoses.

Safe drug, low risk

"Naloxone has been used in the management of opioid overdose for more than 40 years. It is a safe drug with a low risk of serious side effects," stated an article on the new guidelines on WHO's website. "According to the guidelines, any adult capable of learning basic life support can also learn to recognize an opioid overdose, and administer naloxone in time to save lives."

However, naloxone is currently accessible only through hospitals and ambulance crews, who may not be able to treat overdose patients quickly enough. "The guidelines recommend countries expand naloxone access to people likely to witness an overdose in their community, such as friends, family members, partners of people who use drugs, and social workers," the article stated.

According to the guidelines, intranasal naxolone, in the range of 0.4 mg to 2 mg for initial doses, has been used successfully for reversing opioid overdoses in the community.

Study findings

Meta-analysis of two studies examining intravenous vs. intranasal naxolone found no difference in the rate of overdose complications, overdose morbidity, opioid withdrawal reaction to naloxone, or time to opioid reversal. "There were no deaths in either study," the guidelines stated.

WHO also reviewed five observational studies on mortality risk following opioid overdose reversal with naloxone. In one prospective study of 3,245 individuals treated for opioid overdose, rebound opioid toxicity was identified in three of 14 deaths recorded within 48 hours of receiving naloxone. A further three retrospective studies linking emergency medical services (EMS) and forensic examiners' datasets reported no deaths within 12 hours of naloxone reversal.

In addition, a retrospective review of hospital emergency department admissions following transportation after being treated for opioid overdose found that 97% of 444 transported individuals were discharged from care without further intervention.

While the WHO panel found that there is a potential for harm from rebound opioid toxicity following reversal of opioid overdose with naloxone, that can be significantly reversed "if the first responder remains with the person who has overdosed until after the effects of naloxone have worn off" and monitors breathing and level of consciousness.

— *Christine Blank, Contributing Editor*

Up front
In Depth

Julia Talsma, Content Channel Director

Social media presence offers benefits to pharmacies

Responsible use necessary to avoid pitfalls, such as HIPAA violations

Developing a social media presence gives pharmacies an opportunity to interact with patients and consumers, build relationships, participate in the community, and expand their businesses.

More than 70% of U.S. adults are engaged with social media, on platforms such as Facebook, Twitter, Instagram, YouTube, and Pinterest. Adults ages 45 to 54 represent the fastest growing demographic on both Facebook and Google Plus. Even seniors 65 and older are involved with social media, according to Jessica Skelley, PharmD, BCACP, who spoke about social media policies during the National Community Pharmacists Association annual convention in Austin, Texas.

"From a business perspective, you need to know who is using it and who your audience is," said Skelley, assistant professor of pharmacy practice, Samford University, McWhorter School of Pharmacy, Birmingham, Ala.

Use of social media is an excellent way to market your pharmacy to potential customers and patients, Skelley said. "As of 2012, effective use of Facebook and Twitter improved the bottom lines of small businesses by as much as 43% when used in the right way," she continued. "As healthcare professionals, we need to use it safely — within the realms of the law."

A growing presence

More than 25% of U.S. hospitals have established a social media presence, and that continues to grow each year. In Skelley's hometown of Birmingham, Ala., the University of Alabama at Birmingham, a large health system, initiated a social media campaign last year with promotional and informational posts announcing some of its current projects. The use of social media can be quite effective, said Skelley, if appropriately implemented.

What people say on social media can be influential. Statistics reveal that most young adults in the 18- to 34-year-old age group trust medical information that is shared by peers on their social media networks. Also, more than 40% have said that social media could influence their choice of a doctor or hospital.

"So you could be led to believe that it could also influence their choice of a pharmacy as well," Skelley said.

Issues and challenges

Pharmacists active in social media should be aware of the challenges and issues associated with their use. These include patient privacy, fraud and abuse, tax-exempt status, and licensing, Skelley said during her presentation.

Violations on social media vary in severity. The worst are unlawful, such as HIPAA violations. Speech and photos posted on social media, which are legal, may also be problematic for the state licensing board and/or employers. Other postings on social media platforms can reflect poorly on the poster's professional judgment and may damage a pharmacist's professional aspirations.

In connection with patient privacy, pharmacists need to be careful not to reveal information that could identify a specific patient in a posting.

"You can violate HIPAA easily without disclosing actual patient health

Continued on pg. 32

General tips for a business social media account

1. Create a separate business account and keep it separate from your personal account.
2. Provide news from reputable sources, such as FDA and CDC.
3. Promote your pharmacy events and seasonal services using social media.
4. Be organized with your social media accounts; know your audience; know what you are posting.
5. Create a schedule for posting and keep your posts short.
6. Create a social media flow chart to know how to respond to interactions with patients and consumers.
7. Engage consumers and patients by asking questions occasionally.
8. Be consistent with your posts to keep your accounts up to date.
9. Consider posting between 9 am and 5 pm when individuals are most likely to be engaged and share your posts.
10. Create a policy for social media for your business and your employees.

Source: Jessica Skelley, PharmD, BCACP

VIDEO

Jessica Skelley, PharmD, BCACP, Samford University, McWhorter School of Pharmacy, discussed with ***Drug Topics*** the pitfalls pharmacies should avoid while using social media. To view the video, go to **http://drugtopics.com/socialmedia.**

Social media presence offers benefits to pharmacies

Continued from pg. 31

information, such as disclosing a patient's name or a date of birth, because the test is whether someone could reasonably figure who it is you are talking about," Skelley said.

Healthcare professionals and medical students need to be aware that any details of a patient case may reveal someone's identity and that violating HIPAA, even unintentionally, has legal implications, she said.

ASHP guidance

The American Society of Health-System Pharmacists (ASHP) provides guidance for pharmacy professionals who use social media, with specific sections on patient privacy and professionalism. ASHP encourages pharmacists to use social media, Skelley said, but it must be done in a responsible manner. In its statement, ASHP recommends that pharmacy professionals "employ established best practices to ensure compliance with privacy requirements when communicating with patients or about specific patient cases on social media."

When healthcare professionals communicate with each other, they are obligated to protect patient privacy and confidentiality under all circumstances, including when they use social media. ASHP suggests that pharmacists make sure that privacy settings have been selected in social media accounts to protect PHI. These privacy settings should be continuously monitored because social media sites may alter their privacy practices.

Professionalism matters

Pharmacists are among the most trusted healthcare professionals, along with nurses and physicians. Because pharmacists are members of a highly visible profession, it is important that they be aware of the public image they present in various social media platforms.

ASHP recommends that pharmacists use extreme care if they offer medical advice and understand their obligations and liabilities when doing so. For example, if a pharmacy patient asks for medical advice through a social media platform, it would be best to ask the patient to come to the pharmacy to speak directly with the pharmacist.

Any medical advice delivered through social media could be construed as a patient-provider relationship and could cause liability issues in terms of licensing, especially if the patient is located in another state, Skelley said.

The use of social media provides opportunities to educate patients and practitioners, promote the profession and the role of the pharmacist, and debate healthcare issues and policy. Professionalism is required at all times in social media interactions, ASHP noted in its statement.

Skelley summed it up best: "Think before you post. Pause before you post. Protect your own privacy and your patient's privacy." DT

NEW INSTITUTE

Pharmacy school gets $100 million gift for research

Pharmaceutical entrepreneur Fred Eshelman has donated $100 million to the UNC-Chapel Hill pharmacy school named in his honor.

A philanthropic record

The donation, the largest gift from an individual in the school's history and the largest ever to a U.S. pharmacy school, will establish the Eshelman Institute for Innovation, for research and innovation.

"We're setting up this institute where we really hope to supercharge the ability of faculty and graduate students and others to really get a leg up on their research ideas, get some form around them, push them forward with certain milestones," Eshelman told Raleigh's *News & Observer*.

Eshelman, who earned his undergraduate degree from UNC-Chapel Hill in 1972, earlier donated $38 million to the school. He founded Pharmaceutical Product Development, a 13,000-employee company that performs contract research for pharmaceutical companies, and was also founding chairman of Furiex Pharmaceuticals, a drug development company.

"There could be nothing more exciting to a chancellor than to think that we have the resources here to take the talent of these people and really put it to use," said Carol Folt, chancellor of UNC-Chapel Hill. "I think it's fantastic for our state, too, because one of the things we most want to do is see them take this kind of discovery and creativity they have and see it drive all the way out into the community."

High-reward research

The money will fund potentially high-reward research that could spur economic development and jobs throughout the region. "My goal is for North Carolina to become the third vertex of what we call the nation's Innovation Triangle," Gov. Pat McCrory said. "We are poised to compete nationally and internationally."

Many investments, many returns

Eshelman's past donations have supported the school's drug-discovery center, pharmacy education, pharmacy practice, research and training, cancer research, scholarships, fellowships, and faculty development. He has also funded partnerships with community pharmacists, residency programs, and five Eshelman Distinguished Professorships at the school.

The UNC Eshelman School of Pharmacy is second among the nation's pharmacy schools in total federal research funding and specifically in National Institutes of Health funding. The school has generated more than 130 patents and created 15 spin-off companies.

— Mark Lowery, Content Editor

Up front
» In Depth

Joel Claycomb, PharmD

Managing medication shortages: The pharmacist's role

During the recent International Pharmaceutical Federation (FIP) Congress in Bangkok, Thailand, one session I attended delved into the topic of medication shortages. These shortages can result in hefty financial losses for the healthcare sector. It has been estimated that medication shortages led to an increase in labor costs in the United States of more than $200 million in 2011. As this subject has grown in significance over the past few years, I was hoping to gain a greater understanding of the underlying issues by attending this discussion.


Joel Claycomb

The presentation by Sherry Peister, BS Pharm, former president of the Canadian Pharmacists Association, began by acknowledging that while medication shortages are not a new phenomenon, they have increased in frequency over the past four years. With a complex global supply chain and sourcing in India and China for most of the raw material needed to manufacture the active ingredients of medications, any number of disruptions can lead to medication shortages.

The issues

So what are some of the issues that can affect the supply chain or otherwise lead to a shortage of medication?

First and foremost, increased demand around the globe has put stress on production. With the continued emergence of markets in Brazil, China, India, and Russia leading the charge, demand is greater than ever before.

In addition, increased regulation and inspection of manufacturing facilities has led to stoppages in production.

National stockpiling of "disaster" medications can create public shortages, as was the case with Tamiflu in recent years in response to threats of avian influenza.

Natural disasters have wrought havoc on some manufacturing facilities, resulting in delays with production.

And finally, shortages can also result from a lack of communication between nations about the medication supply. Without reliable information, drug shortages can be difficult to predict and challenging to address.

Increasing rates of shortages mean many hospitals are operating in crisis mode with their medication supply chain. In a sense, management of medication shortages is similar to disaster management, as available supplies are used while future demands are determined, and adaptation occurs as needed. Every day, in hospitals and community locations across the country, pharmacists must manage these shortages in an effort to minimize the impact on patients.

Assessment

Douglas Scheckelhoff, MS, vice president of Practice Advancement, ASHP, also presented on the topic, with an overview of the role pharmacists play in managing medication shortages.

He began by detailing some of the problems that result from these shortages. Shortages can result in an increase in medication errors, particularly in connection with chemotherapeutics and opioid agents. Depending on the type of medication, delays or alternative treatments could be life-threatening. Having a plan in place to account for shortages is essential to providing the best patient care.

Scheckelhoff provided an assessment strategy for pharmacies dealing with potential shortages. The initial phase involves determination of which medications are being shorted, identification of current stock counts, and verification of how long the current stock will last.

Next comes a clinical assessment, to determine whether therapeutic alternatives exist and to decide what the impact will be on patients in terms of both outcome and safety.

Action

It is also important to have a communication strategy for the healthcare team, so that all parties know what drug products are affected and why they are being shorted, as well as how long the shortage is expected to last.

Managing these situations requires flexibility and creativity on the part of both the prescriber and the pharmacist. Also, necessary are speed and attention to detail. Lastly, advanced planning and communication are critical to handling medication shortages.

Ultimately the pharmacist's role is to minimize the impact medication shortages will have on patients. By staying up to date, developing management strategies, and recommending evidence-based alternatives, pharmacists can provide patients with safer, more timely treatment. As with most things in life, open communication and having a plan of action in place are essential to optimal outcomes. DT

A frequent contributor to Drug Topics, **Joel Claycomb** *specializes in reports from far-flung locations. Contact him at jcclaycomb@gmail.com.*

Up front
In Depth

Fred Gebhart, Contributing Editor

Critical error in methadone label, guidelines

An error in the methadone package insert and clinical guidelines may contribute to the high rates of patient harm associated with its use.

The package insert approved by the Food and Drug Administration incorrectly identifies CYP3A as the enzyme responsible for the metabolism of methadone in the human body. A different enzyme, CYP2B6, mediates methadone metabolism, clearance, and serum concentrations.

The error could have profound effects on drug utilization review for patients taking methadone, as well as on dosing, clinical activity, morbidity, and mortality, said Evan Kharasch, MD, PhD, professor and director, Clinical and Translational Research in Anesthesiology and professor, Biochemistry and Molecular Biophysics at Washington University, St. Louis. Kharasch delivered his warning during a presentation on translational research at the annual meeting of the American Society of Anesthesiologists.

Increased risk of wrong dosing

"Practitioners who avoid methadone or alter methadone dosing in patients known to be taking drugs which inhibit CYP3A may be doing so needlessly," he told *Drug Topics*. "Drugs known to alter the activity of CYP2B6 may alter methadone metabolism and clearance, and should be evaluated as such."

Both enzymes are members of the cytochrome P450 family, but the two are enhanced and inhibited differently by different drugs in common clinical use.

Ritonavir (Norvir, AbbVie), for example, is often used in antiviral regimens because it is a powerful inhibitor of CYP3A and can potentiate the activity of antiviral agents metabolized by the enzyme.

Inhibition of CYP3A would be expected to decrease metabolism of methadone and increase plasma levels, prompting dose adjustments for methadone or avoidance of the agent altogether.

But ritonavir also induces CYP2B6 in the liver, increasing methadone metabolism and clearance, and leading to decreased plasma concentrations of the drug. So practitioners whose choices result from errors in labeling and clinical guidelines could unknowingly put patients at increased risk of overdosing or underdosing with methadone.

"Methadone is a highly effective drug, but also a drug with significant adverse events when used by an individual who does not fully understand its use," Kharasch said. "Clinical guidelines for the use of methadone need to be rewritten. More accurate clinical guidelines may improve the use of methadone, improve the treatment of pain and substance abuse, and improve patient safety."

The basic science used to support the current labeling and clinical guides was incomplete, he said. *In vitro* data identifying CYP3A as the primary mediator for methadone metabolism was never verified in clinical trials.

Skyrocketing AEs

The gap in translational research became obvious as methadone use increased.

Total prescriptions for methadone rose 1,300% between 1997 and 2006. Adverse events skyrocketed 1,800% between 1997 and 2004. Fatalities increased nearly 400% between 1999 and 2004, the years with the greatest increase in methadone prescribing.

By the late 1990s, it was becoming clear that there is significant interindividual variability in the activity of methadone. The drug is susceptible to drug interactions, elimination can vary up to a hundredfold, and oral dosing is subject to autoinduction of clearance.

Clinical consequences include withdrawal, toxicity, respiratory depression, inadequate analgesia, breakthrough pain, and a substantial risk of overdose during the first two weeks of oral use.

What researchers found

Clinical research using healthy volunteers found that the conventional wisdom on methadone metabolism and clearance mediated by CYP3A is wrong.

Subsequent laboratory work identified CYP2B6 as a predominant enzyme responsible for methadone metabolism *in vitro*, activity that was subsequently confirmed in clinical research. Clinical work confirmed that CYP2B6 inhibitors such as ticlopidine (Ticlid, a branded Roche product no longer available in the United States) decrease methadone metabolism and clearance, increasing plasma concentrations and clinical activity.

Researchers also found that CYP2B6 has more than 20 common alleles. One subtype, CYP2B6.4, markedly increases CYP activity, leading to increased methadone metabolism and lower plasma concentrations. Another subtype, CYP2B6.6, markedly decreases CYP activity, leading to lower methadone metabolism and plasma concentrations five times higher than normal.

"We have already seen editorial calls to revise labeling and clinical recommendations in light of these findings," Kharasch said. "It is in the hands of regulatory agencies to move forward with these new data." DT

Up front
» In Depth

Julia Talsma, Content Channel Director

N.C. program adds missing link to the medical home

Collaborative care in a small town in North Carolina worked well years ago. When L. Allen Dobson Jr., MD, the family practitioner, had a concern about a medication, he would pick up the phone and speak with the local pharmacist. If a patient showed up at the pharmacy with a medication problem or appeared to be ill, the community pharmacist would reach out to Dobson.


L.Allen Dobson, Jr.

"In our town of 1,200, my family practice and the local pharmacist were the healthcare system," said Dobson, who is now president and CEO of Community Care of North Carolina (CCNC), an organization devoted to the patient-centered medical care model. "Even if I was seeing someone after hours, the pharmacist would be available and get the patient the medicine. The next healthcare facility was 20 miles away."

Today's healthcare delivery lacks that level of coordination, because the system isolates healthcare providers into professional silos. "The [community] pharmacist has become just a dispenser, and is a huge missing component of the healthcare system," Dobson said.

To recapture that missing link and connect the pharmacist back to the medical community, Community Care of North Carolina (CCNC) and its affiliates announced in October that they are embarking on an ambitious three-year project to develop and test a community pharmacy network working with its 1,800 primary care practices, which represent 95% of primary care delivery in the state. CCNC serves approximately 1.3 million patients, including Medicaid beneficiaries, Medicaid/Medicare beneficiaries, privately insured employees, and the uninsured.

The purpose of this statewide initiative is to reconnect the clinical pharmacist with the primary care physician, so that the pharmacist can be an integral part of the multidisciplinary team of healthcare professionals. With the help of its partners, GlaxoSmithKline (GSK) and the Eshelman School of Pharmacy of the University of North Carolina (UNC), as well as a CMS Innovation grant, CCNC will test different ways the pharmacist can participate to help improve patient outcomes, quality of care, and cost.

"Our research shows that pharmacists have frequent, face-to-face contact with patients, far more than even physicians do," Dobson said. "This alliance will help show that close patient-pharmacist relationships, coordinated with the patient's physician, are indeed valuable to our healthcare system and can help improve quality and lower costs."

A network of 150 pharmacies

CCNC will be working with a network of 150 pharmacies — independent community pharmacies, chain pharmacies, federally qualified health-center pharmacies, and hospital outpatient pharmacies.


Troy Trygstad

"This is a system for any willing provider who can do the service and is willing to be measured," said Troy Trygstad, PharmD, PhD, CCNC's chief pharmacist and administrator of this project. He is vice president of CCNC's Pharmacy Programs.

"This is not meant to be a narrow network. It is meant to be a high-performing network, which is a big difference. Anybody who can be a high performer is absolutely welcome," Trygstad said.

Throughout the course of this initiative, CCNC plans to build a community pharmacy network and develop processes of care and relationships between the medical home teams, care teams, and community pharmacy. The first goal will be to test the processes and protocols of care in order to develop real interprofessional relationships, Trygstad said.

The second aim is to focus on the technology, so that CCNC can interact with the community pharmacies that will be responsible for a panel of patients, in a fashion similar to that employed in the medical home model. It will be important for the pharmacy and primary care physician to have access to a common pharmacy record, so that everyone is on the same page and the medication records can be saved.

Third, CCNC plans to compensate community pharmacies for their involvement, using a pay-for-performance approach. "With this, they would receive a certain level of payment. They would be paid for comprehensive medication reconciliations and medication reviews, which are additional services," Trygstad said.

The role of the pharmacy school

In this endeavor, the UNC Eshelman School of Pharmacy is a critical partner

Continued on pg. 41 »

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Indications

TREANDA is indicated for the treatment of patients with chronic lymphocytic leukemia (CLL). Efficacy relative to first-line therapies other than chlorambucil has not been established.

TREANDA is indicated for the treatment of patients with indolent B-cell non-Hodgkin lymphoma (NHL) that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen.

Important Safety Information

Contraindication: TREANDA is contraindicated in patients with a known hypersensitivity (e.g., anaphylactic and anaphylactoid reactions) to bendamustine.

Myelosuppression: TREANDA caused severe myelosuppression (Grade 3-4) in 98% of patients in the two NHL studies. Three patients (2%) died from myelosuppression-related adverse reactions. If myelosuppression occurs, monitor leukocytes, platelets, hemoglobin (Hgb), and neutrophils frequently. Myelosuppression may require dose delays and/or subsequent dose reductions if recovery to the recommended values has not occurred by the first day of the next scheduled cycle.

Infections: Infection, including pneumonia, sepsis, septic shock, and death have occurred. Patients with myelosuppression following treatment with TREANDA are more susceptible to infections.

Important Safety Information (continued)

Anaphylaxis and Infusion Reactions: Infusion reactions to TREANDA® have occurred commonly in clinical trials. Symptoms include fever, chills, pruritus, and rash. In rare instances severe anaphylactic and anaphylactoid reactions have occurred, particularly in the second and subsequent cycles of therapy. Monitor clinically and discontinue drug for severe (Grade 3-4) reactions. Ask patients about symptoms suggestive of infusion reactions after their first cycle of therapy. Consider measures to prevent severe reactions, including antihistamines, antipyretics, and corticosteroids in subsequent cycles in patients who have experienced Grade 1 or 2 infusion reactions.

Tumor Lysis Syndrome: Tumor lysis syndrome associated with TREANDA treatment has occurred. The onset tends to be within the first treatment cycle of TREANDA and, without intervention, may lead to acute renal failure and death. Preventive measures include vigorous hydration and close monitoring of blood chemistry, particularly potassium and uric acid levels. There may be an increased risk of severe skin toxicity when TREANDA and allopurinol are administered concomitantly.

Skin Reactions: Skin reactions have been reported with TREANDA treatment and include rash, toxic skin reactions, and bullous exanthema. In a study of TREANDA (90 mg/m^2) in combination with rituximab, one case of toxic epidermal necrolysis (TEN) occurred. TEN has been reported for rituximab. Cases of Stevens-Johnson syndrome (SJS) and TEN, some fatal, have been reported when TREANDA was administered concomitantly with allopurinol and other medications known to cause these syndromes. Where skin reactions occur, they may be progressive and increase in severity with further treatment. Monitor patients with skin reactions closely. If skin reactions are severe or progressive, withhold or discontinue TREANDA.

Other Malignancies: There are reports of pre-malignant and malignant diseases that have developed in patients who have been treated with TREANDA, including myelodysplastic syndrome, myeloproliferative disorders, acute myeloid leukemia, and bronchial carcinoma. The association with TREANDA therapy has not been determined.

Extravasation Injury: TREANDA extravasations have been reported in postmarketing resulting in hospitalizations from erythema, marked swelling, and pain. Ensure good venous access prior to starting TREANDA infusion and monitor the intravenous infusion site for redness, swelling, pain, infection, and necrosis during and after administration of TREANDA.

Embryo-fetal Toxicity: TREANDA can cause fetal harm when administered to a pregnant woman. Women should be advised to avoid becoming pregnant while using TREANDA.

Most Common Adverse Reactions: The most common non-hematologic adverse reactions for CLL (frequency ≥15%) are pyrexia, nausea, and vomiting. The most common non-hematologic adverse reactions for NHL (frequency ≥15%) are nausea, fatigue, vomiting, diarrhea, pyrexia, constipation, anorexia, cough, headache, weight decreased, dyspnea, rash, and stomatitis. The most common hematologic abnormalities for both indications (frequency ≥15%) are lymphopenia, anemia, leukopenia, thrombocytopenia, and neutropenia.

Please see accompanying brief summary of Full Prescribing Information on the following pages.

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TEVA Oncology

LIQUID FORMULATION
TREANDA™
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Injection

TREANDA™
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Brief Summary of Prescribing Information

1 INDICATIONS AND USAGE

1.1 Chronic Lymphocytic Leukemia (CLL)

TREANDA® is indicated for the treatment of patients with chronic lymphocytic leukemia. Efficacy relative to first line therapies other than chlorambucil has not been established.

1.2 Non-Hodgkin Lymphoma (NHL)

TREANDA is indicated for the treatment of patients with indolent B-cell non-Hodgkin lymphoma that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen.

2 DOSAGE AND ADMINISTRATION

2.1 Dosing Instructions for CLL

Recommended Dosage:

The recommended dose is 100 mg/m^2 administered intravenously over 30 minutes on Days 1 and 2 of a 28-day cycle, up to 6 cycles.

Dose Delays, Dose Modifications and Reinitiation of Therapy for CLL:

TREANDA administration should be delayed in the event of Grade 4 hematologic toxicity or clinically significant ≥ Grade 2 non-hematologic toxicity. Once non-hematologic toxicity has recovered to ≤ Grade 1 and/or the blood counts have improved [Absolute Neutrophil Count (ANC) ≥ 1 x 10^9/L, platelets ≥ 75 x 10^9/L], TREANDA can be reinitiated at the discretion of the treating physician. In addition, dose reduction may be warranted. *[See Warnings and Precautions (5.1)]*

Dose modifications for hematologic toxicity: for Grade 3 or greater toxicity, reduce the dose to 50 mg/m^2 on Days 1 and 2 of each cycle; if Grade 3 or greater toxicity recurs, reduce the dose to 25 mg/m^2 on Days 1 and 2 of each cycle.

Dose modifications for non-hematologic toxicity: for clinically significant Grade 3 or greater toxicity, reduce the dose to 50 mg/m^2 on Days 1 and 2 of each cycle.

Dose re-escalation in subsequent cycles may be considered at the discretion of the treating physician.

2.2 Dosing Instructions for NHL

Recommended Dosage:

The recommended dose is 120 mg/m^2 administered intravenously over 60 minutes on Days 1 and 2 of a 21-day cycle, up to 8 cycles.

Dose Delays, Dose Modifications and Reinitiation of Therapy for NHL:

TREANDA administration should be delayed in the event of a Grade 4 hematologic toxicity or clinically significant ≥ Grade 2 non-hematologic toxicity. Once non-hematologic toxicity has recovered to ≤ Grade 1 and/or the blood counts have improved [Absolute Neutrophil Count (ANC) ≥ 1 x 10^9/L, platelets ≥ 75 x 10^9/L], TREANDA can be reinitiated at the discretion of the treating physician. In addition, dose reduction may be warranted. *[See Warnings and Precautions (5.1)]*

Dose modifications for hematologic toxicity: for Grade 4 toxicity, reduce the dose to 90 mg/m^2 on Days 1 and 2 of each cycle; if Grade 4 toxicity recurs, reduce the dose to 60 mg/m^2 on Days 1 and 2 of each cycle.

Dose modifications for non-hematologic toxicity: for Grade 3 or greater toxicity, reduce the dose to 90 mg/m^2 on Days 1 and 2 of each cycle; if Grade 3 or greater toxicity recurs, reduce the dose to 60 mg/m^2 on Days 1 and 2 of each cycle.

2.3 Preparation for Intravenous Administration

Each vial of TREANDA Injection is intended for single use only. Aseptically withdraw the volume needed for the required dose from the 90 mg/mL solution.

Immediately transfer the solution to a 500 mL infusion bag of 0.9% Sodium Chloride Injection, USP (normal saline). As an alternative to 0.9% Sodium Chloride Injection, USP (normal saline), a 500 mL infusion bag of 2.5% Dextrose/0.45% Sodium Chloride Injection, USP, may be considered. The resulting final concentration of bendamustine HCl in the infusion bag should be within 0.2 - 0.7 mg/mL. The admixture should be a clear colorless to yellow solution. Use either 0.9% Sodium Chloride Injection, USP, or 2.5% Dextrose/0.45% Sodium Chloride Injection, USP, for dilution, as outlined above. No other diluents have been shown to be compatible.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. Any unused solution should be discarded according to institutional procedures for antineoplastics.

2.4 Admixture Stability

TREANDA Injection contains no antimicrobial preservative. The admixture should be prepared as close as possible to the time of patient administration. Once diluted with either 0.9% Sodium Chloride Injection, USP, or 2.5% Dextrose/0.45% Sodium Chloride Injection, USP, the final admixture is stable for 24 hours when stored under refrigerated conditions at 2°-8°C (36°-46°F) or for 2 hours when stored at room temperature 15°-30°C (59°-86°F) and room light. Administration of TREANDA must be completed within this period.

3 DOSAGE FORMS AND STRENGTHS

TREANDA Injection is supplied in single-use vials containing either 45 mg/0.5 mL or 180 mg/2 mL of bendamustine HCl.

4 CONTRAINDICATIONS

TREANDA is contraindicated in patients with a known hypersensitivity (e.g., anaphylactic and anaphylactoid reactions) to bendamustine. *[See Warnings and Precautions (5.3)]*

5 WARNINGS AND PRECAUTIONS

5.1 Myelosuppression

TREANDA caused severe myelosuppression (Grade 3-4) in 98% of patients in the two NHL studies (see Table 4). Three patients (2%) died from myelosuppression-related adverse reactions; one each from neutropenic sepsis, diffuse alveolar hemorrhage with Grade 3 thrombocytopenia, and pneumonia from an opportunistic infection (CMV).

In the event of treatment-related myelosuppression, monitor leukocytes, platelets, hemoglobin (Hgb), and neutrophils frequently. In the clinical trials, blood counts were monitored every week initially. Hematologic nadirs were observed predominantly in the third week of therapy. Myelosuppression may require dose delays and/or subsequent dose reductions if recovery to the recommended values has not occurred by the first day of the next scheduled cycle. Prior to the initiation of the next cycle of therapy, the ANC should be ≥ 1 x 10^9/L and the platelet count should be ≥ 75 x 10^9/L. *[See Dosage and Administration (2.1) and (2.2)]*

5.2 Infections

Infection, including pneumonia, sepsis, septic shock, and death have occurred in adult and pediatric patients in clinical trials and in postmarketing reports. Patients with myelosuppression following treatment with TREANDA are more susceptible to infections. Advise patients with myelosuppression following TREANDA treatment to contact a physician if they have symptoms or signs of infection.

5.3 Anaphylaxis and Infusion Reactions

Infusion reactions to TREANDA have occurred commonly in clinical trials. Symptoms include fever, chills, pruritus and rash. In rare instances severe anaphylactic and anaphylactoid reactions have occurred, particularly in the second and subsequent cycles of therapy. Monitor clinically and discontinue drug for severe reactions. Ask patients about symptoms suggestive of infusion reactions after their first cycle of therapy. Patients who experience Grade 3 or worse allergic-type reactions should not be rechallenged. Consider measures to prevent severe reactions, including antihistamines, antipyretics and corticosteroids in subsequent cycles in patients who have experienced Grade 1 or 2 infusion reactions. Discontinue TREANDA for patients with Grade 4 infusion reactions. Consider discontinuation for Grade 3 infusions reactions as clinically appropriate considering individual benefits, risks, and supportive care.

5.4 Tumor Lysis Syndrome

Tumor lysis syndrome associated with TREANDA treatment has occurred in patients in clinical trials and in postmarketing reports. The onset tends to be within the first treatment cycle of TREANDA and, without intervention, may lead to acute renal failure and death. Preventive measures include vigorous hydration and close monitoring of blood chemistry, particularly potassium and uric acid levels. Allopurinol has also been used during the beginning of TREANDA therapy. However, there may be an increased risk of severe skin toxicity when TREANDA and allopurinol are administered concomitantly *[see Warnings and Precautions (5.5)]*.

5.5 Skin Reactions

Skin reactions have been reported with TREANDA treatment in clinical trials and postmarketing safety reports, including rash, toxic skin reactions and bullous exanthema. Some events occurred when TREANDA was given in combination with other anticancer agents.

In a study of TREANDA (90 mg/m^2) in combination with rituximab, one case of toxic epidermal necrolysis (TEN) occurred. TEN has been reported for rituximab (see rituximab package insert). Cases of Stevens-Johnson syndrome (SJS) and TEN, some fatal, have been reported when TREANDA was administered concomitantly with allopurinol and other medications known to cause these syndromes. The relationship to TREANDA cannot be determined.

Where skin reactions occur, they may be progressive and increase in severity with further treatment. Monitor patients with skin reactions closely. If skin reactions are severe or progressive, withhold or discontinue TREANDA.

5.6 Other Malignancies

There are reports of pre-malignant and malignant diseases that have developed in patients who have been treated with TREANDA, including myelodysplastic syndrome, myeloproliferative disorders, acute myeloid leukemia and bronchial carcinoma. The association with TREANDA therapy has not been determined.

5.7 Extravasation Injury

TREANDA extravasations have been reported in post marketing resulting in hospitalizations from erythema, marked swelling, and pain. Assure good venous access prior to starting TREANDA infusion and monitor the intravenous infusion site for redness, swelling, pain, infection, and necrosis during and after administration of TREANDA.

5.8 Embryo-fetal Toxicity

TREANDA can cause fetal harm when administered to a pregnant woman. Single intraperitoneal doses of bendamustine in mice and rats administered during organogenesis caused an increase in resorptions, skeletal and visceral malformations, and decreased fetal body weights.

6 ADVERSE REACTIONS

The following serious adverse reactions have been associated with TREANDA in clinical trials and are discussed in greater detail in other sections of the label *[See Warnings and Precautions]*: Myelosuppression *(5.1)*; Infections *(5.2)*; Anaphylaxis and Infusion Reactions *(5.3)*; Tumor Lysis Syndrome *(5.4)*; Skin Reactions *(5.5)*; Other Malignancies *(5.6)*; Extravasation injury *(5.7)*. The data described below reflect exposure to TREANDA in 329 patients who participated in an actively-controlled trial (N=153) for the treatment of CLL and two single-arm studies (N=176) for the treatment of indolent B-cell NHL. 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.

6.1 Clinical Trials Experience in CLL

The data described below reflect exposure to TREANDA in 153 patients with CLL studied in an active-controlled, randomized trial. The population was 45-77 years of age, 63% male, 100% white, and were treatment naïve. All patients started the study at a dose of 100 mg/m^2 intravenously over 30 minutes on Days 1 and 2 every 28 days.

Adverse reactions were reported according to NCI CTC v.2.0. Non-hematologic adverse reactions (any grade) in the TREANDA group that occurred with a frequency greater than 15% were pyrexia (24%), nausea (20%), and vomiting (16%).

Other adverse reactions seen frequently in one or more studies included asthenia, fatigue, malaise, and weakness; dry mouth; somnolence; cough; constipation; headache; mucosal inflammation and stomatitis.

Worsening hypertension was reported in 4 patients treated with TREANDA in the CLL trial and in none treated with chlorambucil. Three of these 4 adverse reactions were described as a hypertensive crisis and were managed with oral medications and resolved.

The most frequent adverse reactions leading to study withdrawal for patients receiving TREANDA were hypersensitivity (2%) and pyrexia (1%).

Table 1 contains the treatment emergent adverse reactions, regardless of attribution, that were reported in ≥ 5% of patients in either treatment group in the randomized CLL clinical study.

Table 1: Non-Hematologic Adverse Reactions Occurring in Randomized CLL Clinical Study in at Least 5% of Patients

	Number (%) of patients			
	TREANDA (N=153)		Chlorambucil (N=143)	
System organ class Preferred term	**All Grades**	**Grade 3/4**	**All Grades**	**Grade 3/4**
Total number of patients with at least 1 adverse reaction	**121 (79)**	**52 (34)**	**96 (67)**	**25 (17)**
Gastrointestinal disorders				
Nausea	31 (20)	1 (<1)	21 (15)	1 (<1)
Vomiting	24 (16)	1 (<1)	9 (6)	0
Diarrhea	14 (9)	2 (1)	5 (3)	0
General disorders and administration site conditions				
Pyrexia	36 (24)	6 (4)	8 (6)	2 (1)
Fatigue	14 (9)	2 (1)	8 (6)	0
Asthenia	13 (8)	0	6 (4)	0
Chills	9 (6)	0	1 (<1)	0
Immune system disorders				
Hypersensitivity	7 (5)	2 (1)	3 (2)	0
Infections and infestations				
Nasopharyngitis	10 (7)	0	12 (8)	0
Infection	9 (6)	3 (2)	1 (<1)	1 (<1)
Herpes simplex	5 (3)	0	7 (5)	0
Investigations				
Weight decreased	11 (7)	0	5 (3)	0
Metabolism and nutrition disorders				
Hyperuricemia	11 (7)	3 (2)	2 (1)	0
Respiratory, thoracic and mediastinal disorders				
Cough	6 (4)	1 (<1)	7 (5)	1 (<1)
Skin and subcutaneous tissue disorders				
Rash	12 (8)	4 (3)	7 (5)	3 (2)
Pruritus	8 (5)	0	2 (1)	0

The Grade 3 and 4 hematology laboratory test values by treatment group in the randomized CLL clinical study are described in Table 2. These findings confirm the myelosuppressive effects seen in patients treated with TREANDA. Red blood cell transfusions were administered to 20% of patients receiving TREANDA compared with 6% of patients receiving chlorambucil.

TREANDA® (bendamustine hydrochloride) Injection

Table 2: Incidence of Hematology Laboratory Abnormalities in Patients Who Received TREANDA or Chlorambucil in the Randomized CLL Clinical Study

	TREANDA N=150		Chlorambucil N=141	
Laboratory Abnormality	**All Grades n (%)**	**Grade 3/4 n (%)**	**All Grades n (%)**	**Grade 3/4 n (%)**
Hemoglobin Decreased	134 (89)	20 (13)	115 (82)	12 (9)
Platelets Decreased	116 (77)	16 (11)	110 (78)	14 (10)
Leukocytes Decreased	92 (61)	42 (28)	26 (18)	4 (3)
Lymphocytes Decreased	102 (68)	70 (47)	27 (19)	6 (4)
Neutrophils Decreased	113 (75)	65 (43)	86 (61)	30 (21)

In the CLL trial, 34% of patients had bilirubin elevations, some without associated significant elevations in AST and ALT. Grade 3 or 4 increased bilirubin occurred in 3% of patients. Increases in AST and ALT of Grade 3 or 4 were limited to 1% and 3% of patients, respectively. Patients treated with TREANDA may also have changes in their creatinine levels. If abnormalities are detected, monitoring of these parameters should be continued to ensure that further deterioration does not occur.

6.2 Clinical Trials Experience in NHL

The data described below reflect exposure to TREANDA in 176 patients with indolent B-cell NHL treated in two single-arm studies. The population was 31-84 years of age, 60% male, and 40% female. The race distribution was 89% White, 7% Black, 3% Hispanic, 1% other, and <1% Asian. These patients received TREANDA at a dose of 120 mg/m^2 intravenously on Days 1 and 2 for up to eight 21-day cycles.

The adverse reactions occurring in at least 5% of the NHL patients, regardless of severity, are shown in Table 3. The most common non-hematologic adverse reactions (≥ 30%) were nausea (75%), fatigue (57%), vomiting (40%), diarrhea (37%) and pyrexia (34%). The most common non-hematologic Grade 3 or 4 adverse reactions (≥ 5%) were fatigue (11%), febrile neutropenia (6%), and pneumonia, hypokalemia and dehydration, each reported in 5% of patients.

Table 3: Non-Hematologic Adverse Reactions Occurring in at Least 5% of NHL Patients Treated with TREANDA by System Organ Class and Preferred Term (N=176)

	Number (%) of patients*	
System organ class Preferred term	**All Grades**	**Grade 3/4**
Total number of patients with at least 1 adverse reaction	176 (100)	94 (53)
Cardiac disorders		
Tachycardia	13 (7)	0
Gastrointestinal disorders		
Nausea	132 (75)	7 (4)
Vomiting	71 (40)	5 (3)
Diarrhea	65 (37)	6 (3)
Constipation	51 (29)	1 (<1)
Stomatitis	27 (15)	1 (<1)
Abdominal pain	22 (13)	2 (1)
Dyspepsia	20 (11)	0
Gastroesophageal reflux disease	18 (10)	0
Dry mouth	15 (9)	1 (<1)
Abdominal pain upper	8 (5)	0
Abdominal distension	8 (5)	0
General disorders and administration site conditions		
Fatigue	101 (57)	19 (11)
Pyrexia	59 (34)	3 (2)
Chills	24 (14)	0
Edema peripheral	23 (13)	1 (<1)
Asthenia	19 (11)	4 (2)
Chest pain	11 (6)	1 (<1)
Infusion site pain	11 (6)	0
Pain	10 (6)	0
Catheter site pain	8 (5)	0
Infections and infestations		
Herpes zoster	18 (10)	5 (3)
Upper respiratory tract infection	18 (10)	0
Urinary tract infection	17 (10)	4 (2)
Sinusitis	15 (9)	0
Pneumonia	14 (8)	9 (5)
Febrile neutropenia	11 (6)	11 (6)
Oral candidiasis	11 (6)	2 (1)
Nasopharyngitis	11 (6)	0

	Number (%) of patients*	
System organ class Preferred term	**All Grades**	**Grade 3/4**
Investigations		
Weight decreased	31 (18)	3 (2)
Metabolism and nutrition disorders		
Anorexia	40 (23)	3 (2)
Dehydration	24 (14)	8 (5)
Decreased appetite	22 (13)	1 (<1)
Hypokalemia	15 (9)	9 (5)
Musculoskeletal and connective tissue disorders		
Back pain	25 (14)	5 (3)
Arthralgia	11 (6)	0
Pain in extremity	8 (5)	2 (1)
Bone pain	8 (5)	0
Nervous system disorders		
Headache	36 (21)	0
Dizziness	25 (14)	0
Dysgeusia	13 (7)	0
Psychiatric disorders		
Insomnia	23 (13)	0
Anxiety	14 (8)	1 (<1)
Depression	10 (6)	0
Respiratory, thoracic and mediastinal disorders		
Cough	38 (22)	1 (<1)
Dyspnea	28 (16)	3 (2)
Pharyngolaryngeal pain	14 (8)	1 (<1)
Wheezing	8 (5)	0
Nasal congestion	8 (5)	0
Skin and subcutaneous tissue disorders		
Rash	28 (16)	1 (<1)
Pruritus	11 (6)	0
Dry skin	9 (5)	0
Night sweats	9 (5)	0
Hyperhidrosis	8 (5)	0
Vascular disorders		
Hypotension	10 (6)	2 (1)

*Patients may have reported more than 1 adverse reaction.

NOTE: Patients counted only once in each preferred term category and once in each system organ class category.

Hematologic toxicities, based on laboratory values and CTC grade, in NHL patients treated in both single arm studies combined are described in Table 4. Clinically important chemistry laboratory values that were new or worsened from baseline and occurred in >1% of patients at Grade 3 or 4, in NHL patients treated in both single arm studies combined were hyperglycemia (3%), elevated creatinine (2%), hyponatremia (2%), and hypocalcemia (2%).

Table 4: Incidence of Hematology Laboratory Abnormalities in Patients Who Received TREANDA in the NHL Studies

	Percent of patients	
Hematology variable	**All Grades**	**Grades 3/4**
Lymphocytes Decreased	99	94
Leukocytes Decreased	94	56
Hemoglobin Decreased	88	11
Neutrophils Decreased	86	60
Platelets Decreased	86	25

In both studies, serious adverse reactions, regardless of causality, were reported in 37% of patients receiving TREANDA. The most common serious adverse reactions occurring in ≥ 5% of patients were febrile neutropenia and pneumonia. Other important serious adverse reactions reported in clinical trials and/or postmarketing experience were acute renal failure, cardiac failure, hypersensitivity, skin reactions, pulmonary fibrosis, and myelodysplastic syndrome.

TREANDA® (bendamustine hydrochloride) Injection

Serious drug-related adverse reactions reported in clinical trials included myelosuppression, infection, pneumonia, tumor lysis syndrome and infusion reactions *[see Warnings and Precautions (5)]*. Adverse reactions occurring less frequently but possibly related to TREANDA treatment were hemolysis, dysgeusia/taste disorder, atypical pneumonia, sepsis, herpes zoster, erythema, dermatitis, and skin necrosis.

6.3 Postmarketing Experience

The following adverse reactions have been identified during post-approval use of TREANDA. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure: anaphylaxis; and injection or infusion site reactions including phlebitis, pruritus, irritation, pain, and swelling; pneumocystis jiroveci pneumonia and pneumonitis.

Skin reactions including SJS and TEN have occurred when TREANDA was administered concomitantly with allopurinol and other medications known to cause these syndromes. *[See Warnings and Precautions (5.5)]*

10 OVERDOSAGE

The intravenous LD_{50} of bendamustine HCl is 240 mg/m^2 in the mouse and rat. Toxicities included sedation, tremor, ataxia, convulsions and respiratory distress.

Across all clinical experience, the reported maximum single dose received was 280 mg/m^2. Three of four patients treated at this dose showed ECG changes considered dose-limiting at 7 and 21 days post-dosing. These changes included QT prolongation (one patient), sinus tachycardia (one patient), ST and T wave deviations (two patients), and left anterior fascicular block (one patient). Cardiac enzymes and ejection fractions remained normal in all patients.

No specific antidote for TREANDA overdose is known. Management of overdosage should include general supportive measures, including monitoring of hematologic parameters and ECGs.

15 REFERENCES

1. OSHA Hazardous Drugs. OSHA. [Accessed on June 19, 2013, from http://www.osha.gov/SLTC/hazardousdrugs/index.html]

16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 Safe Handling and Disposal

As with other potentially toxic anticancer agents, care should be exercised in the handling and preparation of solutions prepared from TREANDA Injection. The use of gloves and safety glasses is recommended to avoid exposure in case of breakage of the vial or other accidental spillage. If a solution of TREANDA contacts the skin, wash the skin immediately and thoroughly with soap and water. If TREANDA contacts the mucous membranes, flush thoroughly with water.

TREANDA is a cytotoxic drug. Follow special handling and disposal procedures[1].

16.2 How Supplied

TREANDA (bendamustine hydrochloride) Injection is supplied as a 90 mg/mL clear colorless to yellow solution as follows:

NDC 63459-395-02: 45 mg/0.5 mL of solution in an amber single-use vial

NDC 63459-396-02: 180 mg/2 mL of solution in an amber single-use vial

Vials are supplied in individual cartons.

16.3 Storage

TREANDA Injection must be stored refrigerated between 2°-8°C (36°-46°F). Retain in original package until time of use to protect from light.

Distributed By:
Teva Pharmaceuticals USA, Inc.
North Wales, PA 19454

Iss. 09/2013

(Label Code: 00016287.06)

TRE-40202

This brief summary is based on TRE-009 TREANDA full Prescribing Information.

N.C. program adds missing link to the medical home

Continued from pg. 39

with CCNC, working on the creation of new practice models that will enable all healthcare professionals to use the full range of their skills and training in a common cause.

"We want to make sure that patients receive the very best care at the most affordable prices, and do this within a framework that could be scalable across all different kinds of payer systems [public and private]," said Robert A. Blouin, PharmD, dean of the UNC Eshelman School of Pharmacy.


Robert A. Blouin

"There is a clear need to improve the effectiveness and safety of medication use if we are to significantly improve healthcare quality in the United States. This collaboration will allow the school's faculty and researchers to play an integral role in helping to define and evaluate best practices and train pharmacists to effectively implement new models of care," Blouin continued.

GSK's role

GSK will continue to work with CCNC, using analytics on small pharmacy data sets to help predict outcomes for this project and determine which patients will need intervention. In 2012, GSK employees in North Carolina had the option of joining a primary care medical home that was similar to the one that CCNC pioneered in the public sector. This year, the medical home program for GSK employees included a comprehensive medication management initiative provided through the collaborative efforts of CCNC, GSK, and the school of pharmacy.

"We are excited to begin testing new ways to improve patient engagement and hands-on care management that could keep disease under control and patients out of the emergency room," said Jack Bailey, senior vice president of Policy, Payers and Vaccines at GSK, in a prepared statement.

Care Triage: A powerful tool

The first phase of the new statewide initiative will involve the education of pharmacists within the network and the standardization of the best practices for pharmacies. "We want to take what is known that has a high probability of working, but has a high value for patients," Blouin said.

Through the use of Care Triage, a health information technology tool, CCNC, GSK, and the school of pharmacy will use patient data from the pharmacies to identify patients at risk of hospitalization and drug therapy problems and to provide pharmacies with the resources to deliver comprehensive medication management services appropriately.

With Care Triage, CCNC can use this "logistics engine" to decide, on the basis of medication use, whether the patient can be managed by the pharmacist or needs to go to a care manager, a social worker, or a doctor.

"Pharmacists [using Care Triage] can identify in real time which patients have the highest probability of needing the most attention, and provide in a laserlike fashion the kind of pharmacy care that the patient needs to achieve the most desired outcome or to prevent certain events from occurring," Blouin said.

Care Triage is a powerful tool when appropriately used by the pharmacist seeking to engage patients proactively. Through this software tool, pharmacists will receive a notification on a specific patient; for example, a patient who is about to be discharged from the hospital. The pharmacy will be expected to reach out to the patient within 72 hours to respond to the request for help from the medical home.

Key performance indicators

Some of the key performance indicators for the pharmacies include total cost of care, hospitalization rate, emergency department rate, adherence rate, and waste management rate — a problem with autorefills. In addition, the 72-hour response rate to care alerts will be another measure of pharmacy performance.

Patients will be encouraged to work through a consistent pharmacy provider, an approach similar to that of the medical home, whereby patients connect with their primary care physician. If patients don't return to the pharmacy, it will be noted by their refill pattern.

"The network is tightly wound. It creates an even more robust type of relationship between the pharmacist and the primary care physician, where they truly are working as a team," Blouin said.

Program kickoff

The three-year project is expected to be up and running January 2015. CCNC plans to report on the progress of the initiative on a quarterly basis and will share its insights at *www.pharmacyhomeproject.com*.

Although there are technical and pragmatic challenges, as with any endeavor, Trygstad is confident that a high-performing network of pharmacists will be able to deliver services and be measured for their performance. "If you can align incentives [for pharmacists], it is amazing what you can remove as far as barriers," Trygstad said. "If you do that, there is a subset of pharmacies that will respond very well."

Participating pharmacies that follow best practices will be able to use their current resources — staff — and meet the needs of CCNC. During a typical day, Trygstad said, about 15 to 20 patients need a level of reinforcement that takes up to 90 seconds. Another five to 10 patients will need about 90 seconds to 10 minutes of a pharmacist's time. Approximately two to four patients per day will require a substantial amount of time.

"If the pharmacist can do it correctly, this initiative can be accomplished," Trygstad said. DT

Neil DiBernardo, PharmD

Efficient resource management in health-system pharmacy operations

Shrinking and inconsistent reimbursements, coupled with the need for best use of pharmacy resources, now require hospitals and health systems to reassess their pharmacy operations, which can represent up to 10% of operating expense. The goal is to deliver the highest levels of patient safety at the lowest possible cost.

Pharmacy departments have long made use of pharmacy automation to maximize patient safety, ensure accurate charge capture, and achieve high service levels for nursing and patients. However, they have not yet focused on optimization of pharmacy's medication logistics and enterprise-wide processes.

This broader focus requires management of the movement of medications from "dockside to bedside" in the most efficient way possible, to improve the bottom line of the pharmacy — one of the highest non-labor cost centers in a health system.

The five rights — and more

To date, the primary focus of medication management strategies and pharmacy automation technologies has been to ensure the achievement of the "five rights" of medication administration: the right patient, the right drug, the right dose, the right route, and the right time.

In the uncertain world of the Affordable Care Act, this driver is no longer enough.

Cost. Pharmacies also need to deliver medications at the "right cost" to the organization. By expanding their focus to an enterprise-wide view, pharmacists can gain control of the medication supply chain to achieve more efficient and effective processes for procurement, receiving, storage, and inventory management.

Storage. Consider how traditional storage models within individual pharmacies in a health system house medications on static open shelves, arranged alphabetically or by drug type.

Since many doses have to be filled from multiple areas of the pharmacy, this traditional approach requires staff to move from location to location to find the needed medications. More efficient storage methods, such as those offered through automated storage and dispensing systems, consolidate inventory and arrange drugs by velocity, enabling more efficient and safe acquisition.

Inventories. Another barrier to efficient pharmacy operations is the lack of visibility into medication inventories across a health system's entire network of pharmacies. Manual, time-consuming processes for tracking stock levels limit the efficacy of strategies used to manage inventory turns and minimize waste.

Drug shortages compound this challenge, as pharmacies will often err on the side of overpurchasing, in terms of both quantity and cost, to ensure they have enough of the particular drug needed.

Visibility. Several health systems are leveraging single, centralized views of medication inventory across an enterprise to enable more informed decision-making in their pharmacies.

Access to real-time views of existing medication inventory, as well as usage trends over time, will take process improvement strategies for medication logistics to the next level in terms of efficiency and effectiveness in any size health system.

Health systems of all sizes and configurations (from two-hospital systems to university medical centers to larger integrated delivery networks, or IDNs) can truly realize the financial benefits from an enterprise-wide approach to medication inventory management.

Health systems of all sizes and configurations, from two-hospital systems to delivery networks, can truly realize the financial benefits from any enterprise-wide approach to medication inventory management.

Perpetual inventory control

Knowledge is power. That's why pharmacists are increasingly seeing perpetual inventory models as a best practice for creating more efficient and effective medication supply chains. By arming hospital and health-system pharmacies with an expanded infrastructure of automation and decision support, medication inventory can have real-time visibility.

Understanding exactly what is in stock and how often it is used supports better decisions concerning inventory storage and ordering, such as limiting the amount of a medication that is infrequently dispensed — storing only what is needed for a reasonable amount of time. This type of strategic decision-making reduces "money sitting on the shelves" and frees up funds for other

Continued on pg. 49

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*Per recommended dosing interval.

Reference: 1. Brzeczko AW, Leech R, Stark JG. The advent of a new pseudoephedrine product to combat methamphetamine abuse. *Am J Drug Alcohol Abuse*. 2013;39(5):284-290.

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2015 BUSINESS OUTLOOK SURVEY

Fred Gebhart, Contributing Editor

Pharmacy in flux

Despite concerns over reimbursements, networks, and drug shortages, most pharmacists look forward to 2015

Pharmacists in both the community and hospital settings are looking forward to an improved business climate next year. Although retail pharmacists continue to struggle with lower reimbursements, mail-order competition, and now preferred pharmacy networks, the majority — 62% — still expects a good-to-excellent year ahead.

Expectations are slighter better on the hospital side, with 67% of pharmacists seeing a bright future in 2015, despite the continuing challenges of expanding drug budgets and drug shortages, along with concerns about generic drug price hikes and hospital readmission penalties.

These were some of the top-line findings from *Drug Topics*' 2015 Business Outlook Survey, an annual mail survey of community and hospital pharmacists nationwide. The survey examines both the current business climate in 2014 and prospects for the coming year.

Community pharmacy results

A majority of community pharmacists (53.6%) expect net profits for 2014 to increase over those for 2013 (25.2%) or to remain the same as they were last year (28.4%). Just over one-third (35.7%) expect net profits to decrease this year from last year's level, and 10.7% aren't sure.

Community pharmacists ranked the top five positive factors affecting their business this year as follows (Figure 3):

1. Immunizations (46.6%)
2. Medication therapy management (35.7%)
3. Increase in electronic prescriptions (33%)
4. Patient-care services (e.g., counseling, adherence, medication synchronization/reconciliation) (27.9%)
5. Medicare Part D (24%)

Immunizations, growth in e-prescribing, and Medicare Part D made the top five lists for both 2014 and 2015. MTM and patient-care services replaced health insurance exchanges and expansion of state Medicaid programs on the list for 2015.

The major challenges for 2015, outlined in Figure 4, are little changed from 2014:

1. Lower reimbursement from third-party payers (71.8%)
2. Competition from mail-order pharmacies (56.6%)
3. Preferred pharmacy networks for Medicare Part D (51.9%)
4. Preferred pharmacy networks for commercial programs (47.1%)
5. Decrease in state Medicaid rates and MAC and FUL (36.9%)

GETTY IMAGES/ PAPER BOAT CREATIVE

Figure 1: Overall business view for community pharmacists, 2014-2015

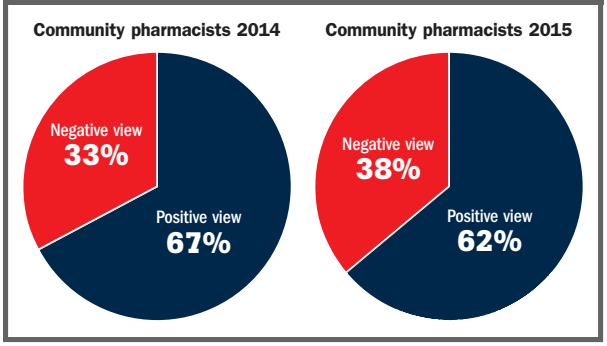
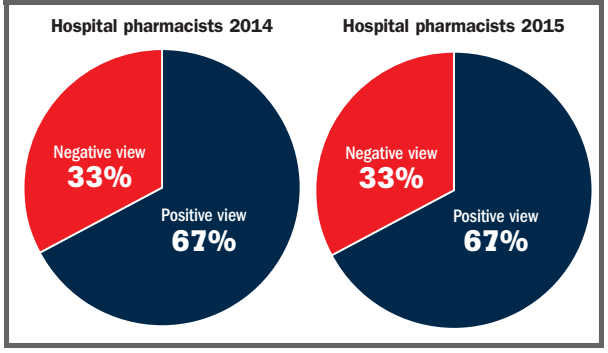


Figure 2: Overall business view for hospital pharmacists, 2014-2015



Impact of Medicare Part D

Medicare Part D has been a question mark for community pharmacy since the program was rolled out in 2006. Initially it was seen as a positive move by both patients and pharmacists. Patients with Part D coverage believed they could stop worrying about the cost of medications, especially generics. Community pharmacists expected an increase in business. Nine years later, reaction is mixed.

Patients have been vocal in their distaste for the Part D "doughnut hole," which can leave them without price protection after they spend a relatively modest amount on drugs. One of the major elements in the Affordable Care Act is a gradual closing of that coverage gap between now and 2020.

Pharmacists are divided. A third (33%) said that Part D has had a positive impact; slightly less than one-third (31.6%) have seen a negative impact; and slightly more than one-third (35.7%) are undecided.

Most Medicare beneficiaries appear to have opted for Part D coverage. Seen from the perspective of community pharmacy, the problem is that patients have enrolled in plans with preferred pharmacy networks and/or mail-order coverage. Both options can have negative effects on retail sales and net profits. And delays in price updates mean that reimbursement increases lag behind the increases in acquisition costs.

"Companies fail to keep up with the cost of medications. Reimbursement is slowly eroding. Contracts resulted in lower reimbursement in order to be a preferred provider. Decreased profits and delayed payments as well as new fees associated with contracts are problematic. There are too many plans, each with their own formulary," are typical survey responses.

"Medicare was a positive . . . when it first started, but with the terrible reimbursement and being locked out of plans, I now say it is a negative," wrote a community pharmacist.

Good for patients, problematic for pharmacies

Several respondents noted that Medicare Part D pricing has helped recipients fill prescriptions on a more regular basis. Beneficiaries with Part D coverage have greater access to pharmacies, more opportunities to consult with pharmacists, and increased availability of medication therapy management.

Those same respondents point out that the patient benefits of Part D come with significant strings attached. Part D pricing is more affordable, but only until the patient hits the doughnut hole. Too many recipients on fixed incomes go back to skipping medications.

Furthermore, patients who can't afford doughnut-hole prices never reach the spending level needed to regain Part D coverage. Their health suffers from poor adherence and pharmacy suffers from missed sales.

Other respondents noted that while prescription and sales volumes have increased under Part D, net profits are falling.

"Reimbursements have continued to fall, many below acquisition cost, forcing us to sell below cost of the medication itself (never mind other overhead) or to turn away customers regularly," a respondent noted.

"Lower reimbursement and higher cost from wholesalers and manufacturers have decreased net profit. We are now

Drug Topics' 2015 Business Outlook Survey

412 community pharmacy respondents
122 hospital pharmacy respondents

This annual e-mail survey of community and hospital pharmacists nationwide was fielded the last week of October and the first week of November, 2014.

Figure 3: Top positive factors affecting community pharmacy

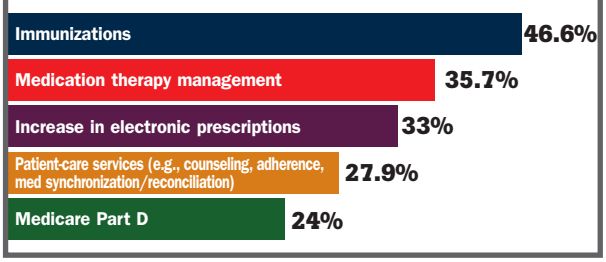
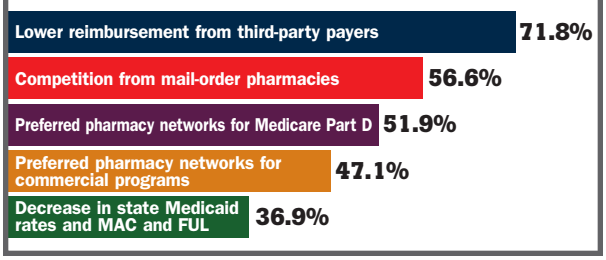


Figure 4: Key challenges for community pharmacy in 2015



refusing to fill money-loser Rxs and send them to other pharmacies," said another pharmacist.

MTM services on the rise

The 2015 survey found that more than half of community respondents, 53.2%, provide medication therapy management (MTM) services under Part D. That is a significant increase from last year, when 43% of pharmacies reported providing MTM.

The not-so-good news is that barely more than one-third of MTM providers are being paid to provide that MTM. Close to half (44.7%) reported receiving less than $250 in MTM payments this year. One-third (33.3%) received $250 to $999, another 17.7% got $1,000 to $4,999, and only 2.8% received $5,000 or more for the year. MTM has not become a significant revenue stream for more than a handful of pharmacists.

Associations under fire

Pharmacy associations say that their primary mission is to represent the best interests of pharmacists. But when *Drug Topics* asked pharmacists whether they were satisfied with the way their association worked for them, only one-third of respondents (33.3%) said yes.

The "yes" response was down slightly from last year, when 34% said they were happy with the way their association represented their interest. The "no" side surged from 35% in 2013 to 43.7% in 2014. The jump in dissatisfaction was fueled by a drop in the "don't know" responses from 31% to 23.1%.

"All they want are my dues!" said one respondent. "Community pharmacy problems (for employed pharmacists) are pretty much ignored," said another. "Don't focus on the relevant and important topics (work conditions, job market, pharmacist surplus, etc.)," added a third. "APhA is about helping the idea of pharmacy rather than pharmacists or pharmacies," noted another.

But even as pharmacists expressed disappointment with pharmacy associations in general, several state and local societies received vocal support for their efforts.

The California Pharmacists Association was praised for its successful campaign to achieve provider status for pharmacists. The Georgia Pharmacy Association was singled out for its active efforts to improve pharmacy conditions. The Oklahoma Pharmacists Association was praised for its efforts to pass the state's PBM transparency legislation. State associations in Louisiana, Michigan, New York, Pennsylvania, South Carolina, Wisconsin, and elsewhere came in for both compliments and complaints.

The overwhelming response, however, concerned areas in which respondents said associations should be doing more.

"[The associations] seem to continue to focus on issues like CEs and provider status, and not on bread-and-butter issues of reimbursement and access," was a typical comment. Several respondents mentioned the growing oversupply of pharmacists and the increasing number of pharmacy schools. Nearly two-thirds of respondents, 62.4%, said there is an oversupply of pharmacists in their state. Most, 44%, said the oversupply was "somewhat severe," 21% called it "very severe," and 18.3% rated it as "extremely severe."

The recent change in the status of hydrocodone from Schedule III to Schedule II also came in for comment.

"I never saw anything on how our profession is standing on the schedule change of hydrocodone. This causes more work for pharmacists. Also, in Texas they continue to open pharmacy schools without realizing what they are doing to our pay scales."

Hospital pharmacy results

Hospital pharmacists' business expectations are generally positive and nearly unchanged from 2014. Most hospital pharmacists, 59%, expect to see their 2015 drug budgets increase compared to what they had to work with in 2014.

Continued on pg. 48

A clear recommendation from you can help your patients decide to get vaccinated

Consider these 4 steps as part of a vaccine recommendation:

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2. Explain the CDC recommendations for each vaccine you recommend.
3. Discuss the benefits and risks of each vaccine.
4. Let your patients know why you believe they should be vaccinated.

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Pharmacy in flux

Continued from pg. 46

Figure 5: Key challenges for hospital pharmacy in 2014

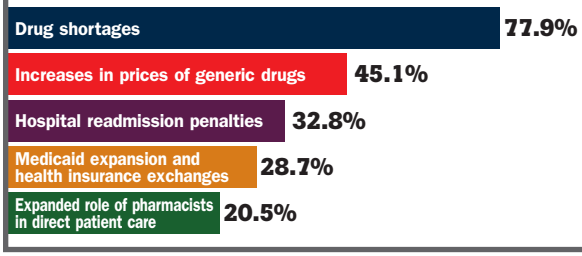
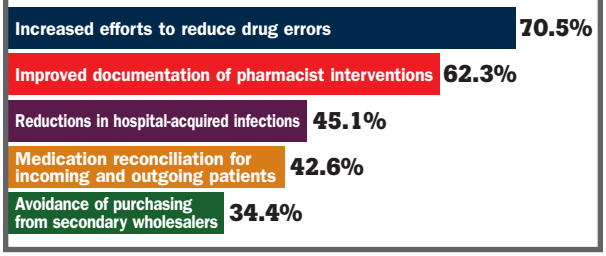


Figure 6: Top five actions to improve hospital patient care in 2014



That number is up from the 41% who expected an increase last year.

There was also an improvement in negative budget expectations, with 11.5% expecting a decrease in the 2015 drug budget, compared with almost 15% who expected to see a drop last year.

The need to increase drug budgets may be explained by the main concerns affecting hospital pharmacists — continuing drug shortages and recent generic drug price hikes (Figure 5). Almost 78% of the survey respondents noted that drug shortages are continuing to affect their health systems this year. Forty-five percent of them said that increases in generic drug prices were a concern, as were hospital readmission penalties (nearly 33%). Other concerns include Medicaid expansion and health insurance exchanges (28.7%), and the expanded role of pharmacists in direct patient care (20.5%).

Compensation and employment

Most pharmacists expect next year's hospital pharmacy staff salaries to remain about the same as they are this year. More than half, 55.7%, expect pharmacist salaries to remain the same, 29.5% expect an increase, and 9.8% expect a decrease. Slightly more, 56.6%, expect technician salaries to remain the same, 36.9% expect an increase, and only 1.6% expect a decrease.

Overall pharmacy employment in hospitals is also expected to remain stable. Some 58.2% expect pharmacist staff levels to remain the same, 23% expect to see more pharmacists, and 16.4% expect fewer pharmacists. Expectations are similar for technicians; 59.6% of respondents expect to see the same number of technicians, 27.1% expect more techs, and 9.6% expect fewer.

Improved patient care

Improvement of patient care is always a priority. The top five actions hospitals took in 2014 to improve patient care (Figure 6) include:

1. Increased efforts to reduce drug errors (70.5%)
2. Improved documentation of pharmacist interventions (62.3%)
3. Reductions in hospital-acquired infections (45.1%)
4. Medication reconciliation for incoming and outgoing patients (42.6%)
5. Avoidance of purchasing from secondary wholesalers (34.4%)

The top five list is virtually identical to last year's responses. The biggest change concerned action to avoid secondary wholesalers, which replaced encouragement of technicians to seek certification. The 2014 top five list continues unchanged into 2015, although the percentages differ slightly.

Association ratings

Hospital pharmacists are ambivalent about their pharmacy associations. Fewer than half, 43.4%, said they are satisfied with the way pharmacy associations represent them, up slightly from 40% in 2013. But nearly one-third of pharmacists, 32%, are not satisfied, and one-quarter, 24.6%, haven't decided.

"ASHP does a great job with education and representation" is followed by "Associations do not reflect reality" and "I have not seen representation, positive or negative."

Multiple respondents voiced concern over the growing number of pharmacy schools and their impact on both employment and patient care.

"We need to correct the overproduction of pharmacists. More pharmacists do not help with the objective of expanded service as most are just trying to keep or maintain their jobs," one respondent wrote.

An older respondent was more direct. "Allowing too many pharmacy schools to open is actually a good thing. I can hire pharmacists at a reduced rate, and I am toward the end of my career. But kids graduating are not able to find full-time positions and are settling for a reduction in pay and benefits. This could be detrimental to the profession in the long run." DT

Efficient resource management in health-system pharmacy

Continued from pg. 42

uses in the pharmacy or organization.

Safety. With knowledge also comes additional safety. Full inventory visibility across multiple locations and campuses can facilitate access to critical medications that may be needed on an emergent basis to support optimal patient care.

Management. With enterprise-wide inventory views, hospital and health-system pharmacies can also increase and better manage inventory turns. Regardless of whether a hospital is using a centralized distribution model or relying mainly on decentralized dispensing cabinets, a single view of inventory must exist before changes in supply volumes can be accurately anticipated and inventory controls streamlined.

Service center. As consolidation within the healthcare industry continues, more health systems will be taking centralized medication inventory management to the next level by creating a centralized service center to aggregate demand for medications across numerous locations.

When individual pharmacies work in silos, each location must buy the full packages from the wholesaler or manufacturer, often creating waste. Centralized service centers allow these medications to be distributed in the right unit of measure. Efficiencies of scale allow slow-moving, expensive medications to be purchased once and shared among multiple hospitals and clinics.

Medication delivery at the right cost

Today's lean, quality-driven healthcare climate demands that medications be delivered at the right cost. Pharmacies don't have to choose: they can gain control of costs through more proactive management of pharmacy operations, medication logistics, and medication inventory while still fully achieving the five rights. Healthcare organizations that capitalize on the advantages of enterprise-wide visibility and perpetual inventory can realize streamlined medication inventory management and, ultimately, a more sustainable cost structure. DT

Neil DiBernardo *is the executive director of professional services at Aesynt.*

Pharmacist's story is the saga of an era

Continued from pg. 20

population with the oral polio vaccine. Our county participated. Each pharmacist was in charge of a district in the county. My district was a small town south of Cairo, where I administered the vaccine to community residents. One of the families I attended had 18 living children. It was the largest family I had ever seen. Overall, this program was very successful in eradicating polio in the United States.

In the store

We had a large assortment of trusses that we fitted for people with hernias. With a good fit, a person could continue working without having to undergo the surgical procedures that were very invasive at the time. We sold pessaries and even rectal dilators that were sometimes prescribed.

One day an 86-year-old lady came in with a prescription for some pain pills. She sat on our little sofa while I filled her prescription. I noticed that she was crying, so I sat down beside her and asked if I could help her in any way.

She said her doctor had just told her that she had terminal cancer and should go home and put her affairs in order. The cancer was too far gone to treat, he said, and she had only six to 12 weeks to live. She looked at me and said, "Mr. Truman, old folks want to live too. Why won't they try to help me?" I told her that most of the treatments for cancer were very debilitating and quite often at her age would cause more misery than the cancer would.

I told her that in my opinion, cancer cells were bullies in the system that took away the nutrients the good cells needed. I said that if she would like me to, I would design a diet for her that would ensure the proper amount of calories her body needed to remain strong. She said she would like that, so I wrote down a diet for her. I told her to write down everything she ingested and to come to the store once a week so I could weigh her and monitor her diet. I told her that in my opinion, she would not experience the pain most people did and would possibly live longer than the doctor said.

This lady was very diligent and came every week. She maintained her weight and remained pain-free. She lived a little over two years after her doctor told her she had up to 12 weeks to live, and she died peacefully in her sleep at home.

Her 56-year-old son came by the store a little later and told me that his mother had asked him to come in and apologize for her crying in the store that day. DT

Truman Lastinger *is the author of "Farming to Pharmacy," released this month and available from* Amazon.com *and* booklogix.com. *Contact him at truros@att.net.*

By the editors of *Medical Economics*

ONC's plan to solve the interoperability puzzle

Healthcare is a decade away from an interoperable national health information technology platform. And while infrastructure expansion and improvements will advance at a blistering pace over the next three years, more work is clearly needed, said Karen B. DeSalvo, MD, MPH, MSc, former national coordinator for Health Information Technology of the U.S. Department of Health and Human Services (HHS), in an exclusive interview with *Medical Economics*.

In fact, despite the dismal numbers of physicians and institutions that reflect the state of progress of the government's meaningful use stage 2 of the electronic health record (EHR) incentive program so far in 2014, DeSalvo said, the slow start isn't indicative of a stalled program, but rather of one that is in a fluid state of development and policymaking.

In doling out more than $24.6 billion in EHR incentives from 2011 to June 2014 to about 408,000 healthcare providers, the government is in this for the long haul.

The payoff, DeSalvo said, will be an interconnected digital healthcare platform built for participants to share and use to learn to improve healthcare delivery and, ultimately, better protect public health.


Karen B. DeSalvo

An interoperable technological infrastructure will cut duplication of testing and streamline the gathering and dissemination of medical information, all factors that contribute to the inefficiencies of a U.S. healthcare system fragmented by size and specialty.

"It is very important for our country to digitize one-fifth of this economy," DeSalvo said, "and have a much better way to address the [needs of the] population and public health at the same time."

The vision

The government's push to digitize health records is about public health. Digital medical records will help in gathering data for comparative effectiveness research; they will help public health officials better respond to outbreaks or other health emergencies, and they will give healthcare professionals analytical and clinical tools to better assess their patient populations to prevent disease, intervene before a major health event, or prevent unnecessary hospitalizations.

The initiative's success and failure relies on IT systems that have the ability to securely exchange healthcare data. That's why the concept of interoperability is so crucial and so heavily tied to the government's meaningful use 2 EHR incentive program and meaningful use 3.

Ultimately, a fully functioning interoperable healthcare system would make "the right data available to the right people at the right time, across products and organizations, in a way that can be relied upon and meaningfully used by recipients," ONC said in a white paper detailing "A 10-Year Vision to Achieve an Interoperable Health IT infrastructure."

So, what is interoperability? The Healthcare Information and Management Systems Society (HIMSS) describes it this way:

> **"My goal is that we set a path together and a road map so that everyone can be brought along."**
>
> *—Karen B. DeSalvo, MD, MPH, MSc, former national coordinator for Health Information Technology, U.S. Department of Health and Human Services*

"In healthcare, interoperability is the ability of different information technology systems and software applications to communicate, exchange data, and use the information that has been exchanged."

Data could be shared by clinicians, labs, hospitals, pharmacies, and patients regardless of the application or vendor.

"Interoperability means the ability of health information systems to work together within and across organizational boundaries in order to advance the health status of, and the effective delivery of healthcare for, individuals and communities."

In practice, an interoperable system would allow healthcare professionals to easily transfer or view patient health

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†Acid control (pH >4) does not imply symptom relief. The correlation of pH data to clinical outcome has not been directly established.

Reference: 1. Lind T, Rydberg L, Kylebäck A, et al. Esomeprazole provides improved acid control vs. omeprazole in patients with symptoms of gastro-oesophageal reflux disease. *Aliment Pharmacol Ther.* 2000;14:861-867.

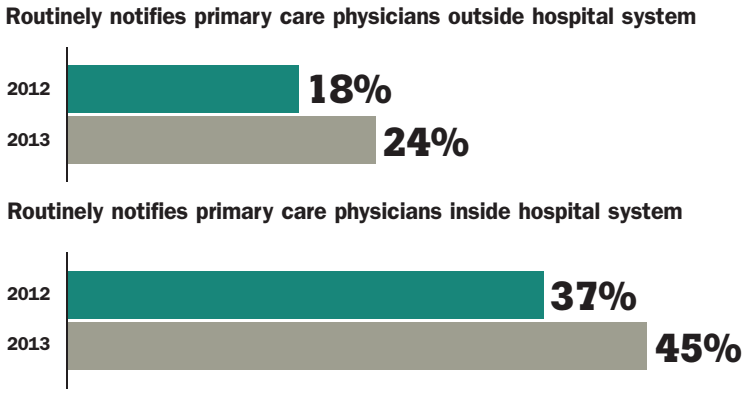
Pfizer Consumer Healthcare

ONC's plan to solve the interoperability puzzle

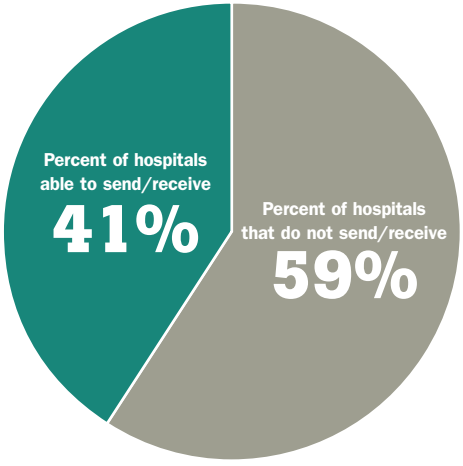
Continued from pg. 50

THE E-COMMUNICATIONS DIVIDE

Percentage of hospitals that notify primary care physicians electronically of an emergency room entry



The majority of hospitals do not send and receive electronic messages containing patient health information to and from external sources



Source: Office of the National Coordinator for Healthcare Information

information from others or from healthcare organizations involved in the care of their patients, receive hospital notifications regarding their patients, or review recommendations from a healthcare provider in a retail clinic if treatment were initiated, and much more.

"Health is more than getting people to a doctor," DeSalvo said. "It's about where they live, learn, work, and play. It's about the choices our patients make when they leave our offices."

Technology has the ability, for the first time, to free providers from the confines of the examination room and help guide health decisions in ways they would think unimaginable just a decade ago.

Remote monitoring and telehealth are just two examples that offer promising and novel approaches to care delivery, DeSalvo said, and it's the technological innovation that will make it a reality.

British writer Arthur C. Clarke was credited with three laws of prediction. In this case, the third law applies, DeSalvo said: Any sufficiently advanced technology is indistinguishable from magic.

The reality

In 2014, HIT hasn't been able to wave its wand to make interoperability appear for most office-based practices.

While there have been successes related to tasks such as e-prescribing, development of healthcare information exchanges, and adoption and use by larger healthcare systems, DeSalvo said, office-based practices are feeling the growing pains associated with time to input data, workflows, costs, or patient engagement, or simply do not yet see the benefits to patient care.

Many primary care physicians are frustrated, according to recent *Medical Economics* surveys about the current state of EHR technology. Physicians are pressed for time and money, and this new technology seems to be placing even more demands on both.

While health information technology is in its adolescence, DeSalvo said, the history of advances in cell phone technology offers a glimpse of the future.

In the early days, cell phones were cumbersome, the batteries died far too quickly, and in most cases the coverage was limited, DeSalvo said. The introduction and adoption of smart phones not only happened quickly, it was transformative, and represents the kind of magic technology can deliver.

"My expectation and hope for the e-health environment is that we let

Medicare EHR incentive payment schedule for eligible professionals (EP)

	Medicare EP qualifies to receive first payment in 2011	Medicare EP qualifies to receive first payment in 2012	Medicare EP qualifies to receive first payment in 2013	Medicare EP qualifies to receive first payment in 2014	Medicare EP qualifies to receive first payment in 2015
2011	$18,000	–	–	–	–
2012	$12,000	$18,000	–	–	–
2013	$8,000	$12,000	$15,000	–	–
2014	$4,000	$8,000	$12,000	$12,000	–
2015	$2,000	$4,000	$8,000	$8,000	–
2016	–	$2,000	$4,000	$4,000	–
Total	**$44,000**	**$44,000**	**$39,000**	**$24,000**	–

Medicaid EHR incentive payment schedule for eligible professionals

	Medicaid EP qualifies to receive first payment in 2011	Medicaid EP qualifies to receive first payment in 2012	Medicaid EP qualifies to receive first payment in 2013	Medicaid EP qualifies to receive first payment in 2014	Medicaid EP qualifies to receive first payment in 2015	Medicaid EP qualifies to receive first payment in 2016
2011	$21,250	–	–	–	–	–
2012	$8,500	$21,250	–	–	–	–
2013	$8,500	$8,500	$21,250	–	–	–
2014	$8,500	$8,500	$8,500	$21,250	–	–
2015	$8,500	$8,500	$8,500	$8,500	$21,250	–
2016	$8,500	$8,500	$8,500	$8,500	$8,500	$21,250
2017	–	$8,500	$8,500	$8,500	$8,500	$8,500
2018	–	–	$8,500	$8,500	$8,500	$8,500
2019	–	–	–	$8,500	$8,500	$8,500
2020	–	–	–	–	$8,500	$8,500
2021	–	–	–	–	–	$8,500
Total	**$63,750**	**$63,750**	**$63,750**	**$63,750**	**$63,750**	**$63,750**

Source: ONC

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ONC's plan to solve the interoperability puzzle

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ONC's technology goals

THREE-YEAR VISION

Improve interoperability so providers can send, receive, find, and use essential health information.

Examples of some tasks include:

- Look up immunization histories
- Share basic patient information between primary care physicians and specialists
- Receive hospital care summaries by automated electronic notification after discharge.

SIX-YEAR VISION

Technology's evolution will better enable patients to be "active participants in managing their care, especially as it relates to patient experience, self-rated health, and self-generated data." Individuals, care providers, and public health departments will send, receive, find, and use an expanded set of health information across the care continuum to support team-based care.

Examples of some tasks include:

- Patients routinely contribute information to their health records
- Patients integrate data from their health records into apps and other health tools
- Primary care providers and researchers access and take action on metrics about glucose levels of their diabetic patient population. Standardized information from multiple sources enables them to see how often those patients have been hospitalized.
- Clinical settings and public health are connected through bi-directional interfaces that enable seamless reporting to public health departments.

TEN-YEAR VISION

"Advanced, more functional technical tools will enable innovation and broader uses of health information to further support health research and public health." Data collection will be more standardized, and health information technology systems will enable analysis of aggregated data and use of local data at the point of care through targeted clinical decision support. Clinical trial recruitment, data collection, and analysis will be accelerated and automated.

- Patients manage information from their own devices and share the information seamlessly across multiple platforms.
- Prescribers choose medications based on genetic profiles and comparative effectiveness research.
- "Individuals, care providers, public health, and researchers contribute information shared across the health IT ecosystem, with rapid advancement in methods for deriving meaning from data without sharing PHI."

Source: Connecting Health and Care for the Nation: A Ten Year Vision to Achieve Interoperable Health IT Infrastructure

innovation happen in such a way that we are making the care experience as magical as it should be, so the joy of medicine comes out and electronic health records are part of a larger portfolio of support for electronic health information, [and so] that doctors and other providers really focus on patients and health, as opposed to technology," she said.

"My goal is that we set a path together and a road map so that everyone can be brought along," she said. "At the end of 10 years, this country will have built an interconnected data and communications system. In the next three years, we have to get the basic infrastructure, the fundamentals, in place."

With interoperability, data could be shared by clinicians, labs, hospitals, pharmacies, and patients regardless of the application or vendor.

According to DeSalvo, while that work is happening, technological advances are posing many other questions related to portability, contracting, care coordination, provider payments, and patient-generated health data. Ultimately, "technology is pushing us to consider that this is also coming faster than we thought."

Technology's great evolution will be used to help build tools to enhance the relationship between patients and healthcare providers, and to improve access to care and their knowledge about care decisions, DeSalvo said.

But it will take time. DT

This article was first published in Medical Economics.

Valerie DeBenedette

Use of insulin therapy to treat diabetes will continue to grow

As the number of U.S. patients with diabetes continues to grow, so will the number of people who use insulin to manage their blood glucose. It is likely that the range of insulin products, administration methods, and ways to determine the best dosage regimen for a given patient will continue to evolve as well.

The basics about diabetes will not change. Treating both type 1 and type 2 diabetes depends on achieving blood glucose levels that are as close to normal as possible. In type 1 diabetes, this can be accomplished only with insulin. In type 2 diabetes, the pharmacotherapeutic options include oral medications, a combination of oral medications and insulin, or insulin alone.

Because type 2 diabetes is a progressive condition, treatment will continue to change, with most patients eventually needing to use insulin to control diabetes, said Jennifer D. Smith, PharmD, BC-ADM, CDE, associate professor at Campbell University College of Pharmacy & Health Sciences and clinical pharmacist practitioner at Wilson Community Health Center in Wilson, N.C. Doses of insulin for patients with type 2 diabetes must be regularly evaluated and increased as needed, she said.


Jennifer D. Smith

When to start

The point at which a patient with type 2 diabetes should begin insulin therapy is a subject of debate and occasional confusion. In 2012, the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD) jointly issued a statement addressing the question.

While emphasizing that treatment must be tailored to the individual patient, the statement called for use of insulin as the initial therapy when the patient's glycated hemoglobin (A1c) level reaches 10% or higher. Patients whose A1c level is 9% or higher can begin using either insulin or a combination therapy with two noninsulin drugs.

For patients who were started on one noninsulin drug and who did not meet glycemic goals, basal insulin can be added to the initial drug after approximately three months.

Insulin should be added as a third medication if therapy with two noninsulin medications does not achieve glycemic control, especially if A1c is 9% or higher.[1]

Insulin types

Once treatment with insulin is determined for a given patient, there comes the choice of which ones and in what combinations. Several types of insulin or insulin mixes are available, which means that patients with diabetes and their physicians and pharmacists need to stay abreast of current practices and of the new types of insulin to come onto the market.

The most common insulin therapy for both type 1 and type 2 diabetes uses the basal-bolus strategy. The intermediate-acting and long-acting insulins are used as basal insulins, the style of insulin injection that most closely mimics the way the pancreas secretes insulin between meals. Basal insulins are usually administered in one dose a day.


Lindsay Sheehan

Rapid-acting and short-acting insulins are used as boluses, the injections that should be administered at the start of meals.

Rapid-acting insulins (such as Humalog or NovoLog) have an onset within 15 minutes and a duration of action of between three and five hours. Short-acting insulins (Humulin or Novolin) have an onset of action of 30 to 60 minutes and a duration of action of between five and eight hours. Intermediate-acting insulins (Humulin N or Novolin N) increase the onset of action to two to four hours and the duration to between 10 and 16 hours. Long-acting insulins (Lantus or Levemir) increase onset further, to an onset of two to three hours and to a duration of 20 to 24 hours.

Then there are the premixes, which combine a long-acting insulin and a short-acting insulin in a single injection. The ratios between the two types are usually 75% longer-acting and 25% shorter-acting or 70% and 30%. The advantage with premixes is that the patient requires fewer injections per day compared to a basal-bolus regimen.

Know the differences

Pharmacists must know the differences between these insulin products, along with when they are appropriate to use and for whom, said Lindsay Sheehan, PharmD, CDE, a clinical pharmacy practitioner and ambulatory care clinic leader with Carolinas

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HealthCare System in Kannapolis, N.C.

"The majority of pharmacists have an understanding that maybe this is a mealtime insulin and that one is long-acting," Sheehan said. "I would say the majority of pharmacists would know that. But there are going to be some who don't."

She noted that, when she worked in a community pharmacy several years ago, some of her pharmacist colleagues did not know the difference between a long-acting and a short-acting insulin.

Now she trains pharmacy students from Wingate University School of Pharmacy in North Carolina.

"My students? I want them to leave here knowing about the different insulins."

Concentration and duration

Insulin concentrations add another wrinkle to the process of choosing the appropriate insulin therapy.

Patients need to understand that the concentration of the insulin they use — such as U100 or U500 — matters, Sheehan said. Patients need to be taught to look at vial labeling to ensure they are getting the right insulin and administering the right amount in each injection.

A patient who is supposed to administer a U100 insulin but who has been given a U500 insulin will be injecting a dose five times as high, she warned.


Marissa Salvo

Many types of insulin concentrations are being studied now, including U200 and U300 concentrations that will come to market within a few years, Sheehan said.

"It will be really confusing then," she said. "Pharmacists are going to have to come up to speed."

Longer-lasting insulins are in the development pipeline. One is degludec, an ultra-long-acting basal insulin, said Marissa C. Salvo, PharmD, BCACP, assistant clinical professor, Department of Pharmacy Practice, University of Connecticut School of Pharmacy, Storrs, Conn. Degludec has a duration of action of up to 40 hours and is approved for use in the European Union.

Administration

Methods of insulin administration also are expanding.

Syringes, preloaded pens, and insulin pumps have been around long enough for most pharmacists to be familiar with them.

However, Sheehan has been working with a disposable insulin delivery device (V-Go; Valeritas), and has found that many community pharmacists are not familiar with it and confuse it with an insulin pump. *[See "Insulin delivery: Disposable device ends need for repeated injections," in this issue.]*

The choice of when to administer long-acting insulins each day is also seeing some changes. Patients are often instructed to take a long-acting insulin at 10 pm, noted Smith. But she has found that many older patients do not want to take it just before bedtime because they are afraid their blood sugar will drop too low while they sleep, she said.

"Now they have found that it can be given any time of the day, as long as you are consistent," she said.

Titration algorithms

Just as there are several types of insulin available, so there are several ways to initiate insulin therapy and titrate doses.

Patients are started on low doses of a long-acting basal insulin (Lantus or Levemir) and are then titrated to achieve the target fasting blood glucose level. Various algorithms are used to titrate doses of basal insulin.

"I don't think there is one right or wrong way to dose insulin. There are myriad ways to dose insulin," said Jennifer Smith. "Insulin dosing is more of an art than a science right now."

"I think pharmacists know the basics about insulin dosing," said Smith. But as the number of people with diabetes rises, the basics about insulin dosing are changing, she added.

The Treat-to-Target Study evaluated a titration algorithm for a long-acting insulin (glargine) in type 2 diabetes patients.[2] The study found that, when glargine was added to oral therapy, good A1c levels were achieved in most type 2 patients through systematic titration of the bedtime dose of basal insulin.

The Adjust-to-Target Study compared two titration algorithms for adjusting mealtime doses of rapid-acting insulin.[3] The study found that basing weekly adjustments of mealtime insulin doses on blood glucose levels from the week before was as safe and effective as adjusting insulin doses to the amounts of carbohydrates consumed.

Adjusting doses to carbohydrate intake can be complex and confusing for some patients, Salvo noted. "For a patient with low health literacy, it is a complex task and may not work as well as something else."

A third method of determining the best insulin dose is "basal plus one."[4] This involves administering an injection of a rapid-acting insulin once or twice per day at meals and has been found to work as well for most patients as three before-meal injections.

"If you can take two injections rather than more each day, why not do that?" Smith said.

Insulin education

Pharmacists have a responsibility to address any concerns and confusion their patients with diabetes may have, whether they pertain to insulin or to other issues related to diabetes management, said Salvo. "We want to be and should be making sure that the patient is using insulin correctly."

The best way to do this is to educate patients each time they pick up their insulin, Salvo said. Pharmacists may have more points of contact with patients than physicians do.

"It is not just sharing information, but getting the patient to participate in his or her care and work toward making changes," she said.

Physicians too might need advice, as they determine which insulin regimen will suit a patient best, Salvo noted. "Pharmacists are abreast of the current drugs on the market; the kinetics of the drugs, the indications, and the appropriate individuals who might be candidates," she said.

Smith agreed. "Pharmacists have to do some doctor education. Some doctors are onboard and understand. But in general, it is education across the board for everyone."

Patient demonstration

If patients are using insulin pens, pharmacists should occasionally ask to see how they are dialing their dosage, Smith noted. Some pens are marked only in even numbers, not odd, and patients might not be dialing odd-numbered doses correctly, she said.

In some instances, the pharmacist might learn that a patient is deliberately using less than the prescribed dose in an effort to manage cost by stretching the prescription.

Patients also might need additional time with a diabetes educator if they seem unsure about how to dial the right amount on an insulin pen, fill the syringe correctly, or rotate their injection spots.

"You have to make sure that all communication is patient-centered," Salvo said.

A patient recently told Smith that he was taking 20 units rather than the 24 that his doctor had prescribed. When she asked him to show her the dosage, he showed her that he was actually dialing the pen to 10 units.

"He was trying to stretch his insulin and he was also afraid of low blood sugar," she said.

There are occasions when patients tell their pharmacists what they think the pharmacists want to hear, just as they might do with their physicians, Smith said. It could be helpful for pharmacists to conduct some motivational interviewing to learn each patient's concerns. DT

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Valerie DeBenedette *is a medical news writer in Putnam County, N.Y.*

Lindsay Sheehan, PharmD, CDE, CPP and Danielle Smith, PharmD Candidate 2015

Insulin delivery: Disposable device ends need for repeated injections

As rates of type 2 diabetes increase each year, novel approaches to management are necessary. Type 2 diabetes is a progressive disease requiring a variety of treatment regimens specific to each patient. Often patients require treatment intensification beyond oral diabetic medications, with subcutaneous basal insulin and eventually prandial insulin to obtain HbA1c goals.

One treatment shown to be effective for insulin-dependent patients with type 2 diabetes is continuous subcutaneous insulin infusion (CSII).[1] In 2012 Valeritas launched V-Go, a disposable insulin delivery device (DIDD) that attaches with an adhesive patch.[2] Approved for adults with type 2 diabetes, the V-Go may turn out to be a valuable treatment option for patients requiring mealtime insulin.[3]

How it works

Through CSII, the V-Go controls basal and bolus mealtime insulin coverage without need for multiple daily injections. It delivers insulin through a 30-gauge, 4.6-mm floating hypodermic needle. The lightweight device is mechanical, not electronic, and does not require batteries or software.[4,5] It supplies CSII for 24 hours and bolus doses of rapid-acting insulin on demand.

Both insulin aspart and insulin lispro have been tested in the V-Go. The bolus doses can be administered with two separate clicks. Clicking the bolus-ready button enables the activation of the bolus-delivery button. Pressing the bolus-delivery button releases two units of subcutaneous insulin, which should be administered 0-15 minutes before a meal.

The V-Go is available in three preset basal rates of 20, 30, and 40 units daily. Bolus dosing is in two-unit increments, with a total daily maximum of 36 units.[4]

Proof of concept

The proof-of-concept study to evaluate blood glucose control with a DIDD in type 2 diabetic patients was conducted over seven days. The device enabled patients to maintain blood glucose control, with a mean reduction in basal insulin of 19 units per day. Continuous glucose monitoring changes from 173 mg/dL to 157 mg/dL (P=0.063) demonstrated overall glycemic improvement. Although the study sample size (N=6) was too small to prove safety and efficacy, the device was well tolerated, with 100% compliance.[5]

A retrospective analysis of glycemic control in a cohort of 23 patients over 12 weeks found a statistically significant reduction in mean HbA1c by 1.2% (P=0.005), achieved through use of DIDD. Twelve weeks after discontinuation, the HbA1c increased to 8.2% (P=0.011).[6]

Patient adherence

Patient adherence is an ongoing challenge in diabetes management. DIDD permits combined control of basal insulin with bolus insulin for mealtime coverage in a once-daily injection. The mealtime insulin is readily available; it is delivered when the appropriate buttons are pressed through the patient's clothing.[2,3]

The V-Go is replaced every 24 hours. It can be prefilled with insulin lispro up to 24 hours before use and, if refrigerated, as long as five days before use with insulin aspart. At room temperature it can be filled three days before use. Billing is done through patients' prescription drug coverage at the pharmacy.[3]

Limitations

The preset basal rates limit the V-Go as an option for patients with type 1 diabetes, since their insulin sensitivity requires individualized incremental amounts of insulin. Use is also limited in patients with type 2 diabetes who are highly insulin-resistant and who require more insulin than the V-Go can deliver. Some prescription benefits do not cover the V-Go, despite prior authorizations and appeals. It is possible for patients to have injection-site reactions or irritation/sticky residue from the adhesive. Valeritas recommends use of a tape barrier and an adhesive remover wipe.[3]

CSII delivered by means of a disposable patch device allows a convenient once-daily injection to provide insulin for 24 hours, as well as before meals. This is novel technology that may increase compliance and reduce HbA1c. While it has its limitations, it offers an innovative option for adult patients with type 2 diabetes requiring basal and bolus insulin. DT

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Lindsay Sheehan *is ambulatory care clinic leader with Carolinas Medical Center NE.* **Danielle Smith** *is a 2015 PharmD Candidate at Wingate University School of Pharmacy.*

Tracey Walker, Contributing Editor

FDA warns of rare brain infection with multiple sclerosis drug

FDA is warning that a patient with multiple sclerosis (MS), who was being treated with dimethyl fumarate (Tecfidera; Biogen Idec), developed progressive multifocal leukoencephalopathy (PML), a rare and serious brain infection, and later died. As a result, a description of this case of PML is being added to the Tecfidera drug label.

Patients taking dimethyl fumarate should immediately contact their healthcare professional if they experience symptoms of concern, such as new or worsening weakness; trouble using their arms or legs; or changes to thinking, eyesight, strength, or balance. Healthcare professionals should stop dimethyl fumarate if PML is suspected.

New oral therapies

Biogen Idec's dimethyl fumarate is one of the new market entrants driving the shift to oral therapy growth in MS treatment, according to John Santilli of Access Market Intelligence, which provides business information to the pharmaceutical and healthcare industries.

"Although this is Tecfidera's first incident tied to PML use in more than 100,000 patients treated, it is a cause for concern for Biogen Idec, as the market for MS treatment continues to become more competitive," Santilli said.

"Biogen Idec will need to monitor the activities of Novartis' Gilenya [fingolimod] oral treatment, Sanofi's Aubagio [teriflunomide], and Teva's Copaxone [glatiramer acetate injection] going generic," he said.

Rare and serious

Dimethyl fumarate has been shown to benefit patients with remitting/relapsing forms of MS. This type of MS causes attacks or relapses.

The patient who died had been treated with dimethyl fumarate in a clinical trial. Before the clinical trial, the 54-year-old patient had received glatiramer acetate for three years. She then received placebo for two years followed by dimethyl fumarate for four-and-a-half years before the brain infection developed. The patient was not taking any other drugs that affect the immune system or drugs that are thought to be associated with PML, FDA reported in a drug safety communication.

This is the only confirmed case of this rare and serious brain infection reported in patients taking dimethyl fumarate.

PML is caused by the John Cunningham (JC) virus, which is a common virus that is harmless in most people but can cause the brain infection in some patients who have weakened immune systems.

Symptoms of PML are diverse and may include progressive weakness on one side of the body, clumsiness, vision problems, confusion, and changes in thinking, personality, memory, and orientation. The progression of deficits can lead to severe disability or death.

Before developing PML, the patient had a very low number of lymphocytes in her blood. Reduced lymphocyte counts can weaken the immune system, increasing the risk of PML. It is unknown whether the low lymphocyte count contributed to the development of PML in this patient, or whether low lymphocyte counts are a risk factor for PML development in dimethyl fumarate-treated patients.

Healthcare professionals and patients should report side effects involving dimethyl fumarate to FDA's MedWatch program.

This article was first published online November 26 in FormularyWatch. DT

Final rule changes Rx labeling for pregnancy, lactation

FDA issued a final rule Dec. 3 that changes the labeling of prescription drugs and biological products in connection with the risks and benefits of their use by womenwho are pregnant or breastfeeding.

The current product letter categories of A, B, C, D, and X, used to classify the risks of using prescription drugs during pregnancy, will be replaced with three detailed subsections, including a summary of the risk of using a drug during pregnancy and breastfeeding, a discussion about data supporting the summary, and relevant information for healthcare providers who prescribe and counsel pregnant and lactating patients.

Three new subsections

The three subsections in the labeling are "Pregnancy," "Lactation," and "Females and Males of Reproductive Potential."

"Prescribing decisions during pregnancy and lactation are individualized and involve complex maternal, fetal, and infant risk-benefit considerations," said Sandra Kweder, MD, deputy director of the Office of New Drugs in the FDA's Center for Drug Evaluation and Research. "The new labeling rule provides for explanations, based on available information, about the potential benefits and risk for the mother, fetus, and the breastfeeding child."

FDA's final rule will be in effect as of June 30, 2015. DT

NEW DRUG REVIEW Kevin W. Chamberlin

FDA approves extended-release oxycodone combo to deter abuse

An opioid analgesic with an abuse deterrent, the product exhibits properties that can deter, but not entirely prevent, abuse through snorting or injection.

Development of opioids with abuse-deterrent properties is one goal of FDA's campaign against the national epidemic of opioid misuse and abuse. The combination tablet oxycodone hydrochloride and naloxone hydrochloride extended-release (ON-ER) (Targiniq ER; Purdue Pharma) is an opioid agonist and antagonist (2:1 ratio, respectively) approved by FDA on July 23, 2014, for treatment of severe pain. ON-ER is not approved for as-needed pain relief.

As an opioid analgesic with an abuse deterrent, ON-ER exhibits properties that can deter, but not entirely prevent, abuse through snorting or injection.

Efficacy

When crushed or snorted, the naloxone contained in ON-ER blocks the euphoric effects of oxycodone, making it less attractive to abusers than oxycodone alone. Naloxone has low bioavailability due to extensive first-pass metabolism. This low oral availability reduces any risk of antagonism to the opioid.

ON-ER was administered to 2,396 patients in controlled or open-label clinical studies. One-third (n=794) of the subjects were treated for approximately six months, and 26% (n=621) were treated for approximately one year.

A prospective study of two age groups (19-44 vs. 65-77) assessed age effects of the pharmacokinetics of ON-ER. Compared to younger subjects, elderly subjects showed a higher steady-state oxycodone AUC (18% increase) and higher steady-state naloxone AUC (82% increase). Elderly patients should therefore be monitored more frequently until stable drug effects are achieved.

Safety

Several black-box warning accompany ON-ER, including risk of addiction, abuse, and misuse; serious, life-threatening, or fatal respiratory depression; accidental ingestion by children, resulting in a fatal overdose; neonatal opioid withdrawal syndrome; and fatal overdose concentrations of oxycodone resulting from initiation or discontinuation of CYP3A4 inhibitors.

As with other opioids, the most common adverse reactions with ON-ER were nausea and vomiting. ON-ER, like all opioids, can cause severe hypotension, and concern should be given to patients with reduced blood volume or concurrent administration of certain CNS depressant drugs.

ON-ER is a pregnancy category C. Oxycodone is likely to be present in breast milk; the presence of naloxone is unknown. Nursing mothers should not use or initiate ON-ER. Neither should patients with a history of significant respiratory depression, acute or severe bronchial asthma, known or suspected paralytic ileus and gastrointestinal obstruction, known hypersensitivity to either drug, or moderate-to-severe hepatic impairment.

FDA is requiring post-marketing studies to assess the deterrent features of ON-ER on the risk of abuse, as well as the serious risks of misuse, abuse, increased sensitivity to pain, addiction, overdose, and death associated with use beyond 12 weeks. ON-ER is part of the ER/LA Opioid Analgesics Risk Evaluation and Mitigation Stategy (REMS).

Dosing

ON-ER is supplied as 10 mg/5 mg, 20 mg/10 mg, and 40 mg/20 mg of oxycodone/naloxone, respectively, in 100-count bottles. Opioid-naïve and opioid intolerant patients should be initiated on 10 mg/5 mg tablets orally every 12 hours. There are no well-controlled clinical studies evaluating the safety and efficacy of dosing more often than every 12 hours.

Standard opioid equivalencies are appropriate for ON-ER, just as for plain oxycodone ER. The ON-ER package insert contains initial ON-ER dose targets based on total daily morphine equivalency doses, and also specific guidelines for methadone, transdermal fentanyl, and transdermal buprenorphine conversions.

ON-ER can be up-titrated from the current dose by increasing the dose 10 mg/5 mg every 12 hours every one to two days; however, doses above 80 mg/40 mg have not been studied sufficiently for safety and thus should not be exceeded.

ON-ER is contraindicated in patients with moderate and severe hepatic impairment, and the starting dose should be reduced by one-third to one-half the usual starting dose in patients with mild hepatic impairment. When patients with renal impairment use ON-ER, the initial dose should be reduced to one-half the usual starting dose and followed by close titration. When opioid therapy is no longer warranted, the dose should be reduced gradually to prevent signs and symptoms of withdrawal.

ON-ER tablets should be swallowed intact, and not crushed, dissolved, or chewed, due to the risk of rapid release and absorption of a potentially fatal dose of oxycodone. DT

Kevin W. Chamberlin, PharmD, *is associate clinical professor and assistant department head, pharmacy practice, University of Connecticut School of Pharmacy, Storrs, Conn.*

ANTICOAGULATION THERAPIES Anna D. Garrett, PharmD, BCPS

Pre-op sepsis increases risk of thrombosis

Arterial and venous thromboses are common serious postoperative complications. More than 4% of surgical procedures are followed by an arterial thrombosis and at least another 4% by venous thrombosis.

Studies have identified risk factors such as existing coronary atherosclerosis, older age, male sex, previous venous thromboembolism (VTE), and malignancy, but limited data are available regarding infection as a risk factor.

A recent study evaluated the impact of preoperative sepsis on risk of postoperative arterial and venous thromboses. The study included 2.3 million patients who underwent surgical procedures over a seven-year period.

The main outcome measures were arterial thrombosis (myocardial infarction or stroke) and venous thrombosis (deep venous thrombosis or pulmonary embolism) in the 30 days after surgery.

Patients with preoperative systemic inflammatory response syndrome or any sepsis had three times the odds of having an arterial or venous postoperative thrombosis compared with patients without any systemic inflammation. In patients with preoperative sepsis, both emergency and elective surgical procedures had increased the odds of thrombosis twofold.

The authors concluded that preoperative sepsis represents an important independent risk factor for both arterial and venous thrombosis and that suspicion of thrombosis should be higher in patients with sepsis who undergo surgery.

Source: Donze JD, Ridker PM, Finlayson SRG, et al. Preoperative sepsis is associated with risk for arterial and venous thrombosis. BMJ. *2014;349:g5334.*

Predicting thrombosis in relatives of patients with VTE

Family history is an important consideration in determining risk of VTE for close relatives of patients with VTE.

Researchers assessed the risk of VTE in 915 first-degree relatives of patients with provoked VTE and compared this to the risk in 1,752 first-degree relatives of patients with unprovoked VTE. The data was then combined to identify predictors of thrombosis.

The risk of VTE in first-degree relatives was higher if the index cases had an unprovoked VTE compared with a provoked VTE (odds ratio [OR] 2.38), if the index case was younger (OR 0.97 per year older), and if an additional family member had VTE (OR 2.71).

Among first-degree relatives of an index case with factor V Leiden or the prothrombin 20210A gene variant, the presence of these abnormalities also predicted thrombosis (OR 4.42). The authors concluded that unprovoked VTE at a young age predicts VTE in first-degree relatives and that the influence of these two factors is additive.

Source: Couturaud F, Leroyer C, Tromeur C, et al. Factors that predict thrombosis in relatives of patients with venous thromboembolism. Blood. *2014 Sep 25;124(13):2124-30. Prepublished online July 21, 2014: doi:10.1182/blood-2014-03-559757.*

Another novel anticoagulant nears FDA approval

A U.S. Food and Drug Administration (FDA) advisory panel has voted overwhelmingly in favor of another novel anticoagulant for the treatment of patients with atrial fibrillation (AF).

The Cardiovascular and Renal Drugs Advisory Committee voted 9 to 1 in favor of approving edoxaban (Savaysa; Daiichi Sankyo), a factor Xa inhibitor, for the prevention of stroke and non-central-nervous-system (CNS) systemic embolism in patients with nonvalvular AF.

The decision was based on the results of the ENGAGE AF-TIMI 48 trial, a large, event-driven study of 21,105 patients with nonvalvular AF. The trial compared once-daily therapy with edoxaban at either 30 mg or 60 mg with warfarin. Doses were reduced by 50% in patients with renal dysfunction, low body weight, or concomitant treatment with P-glycoprotein-inhibiting drugs such as verapamil or quinidine.

Overall, edoxaban was shown to be non-inferior and to be associated with significantly less major bleeding than the vitamin-K antagonist in the trial.

The risk of hemorrhagic stroke went down 46% for high-dose edoxaban and 53% for low-dose edoxaban compared with warfarin ($P<0.001$ for both differences). But for ischemic stroke, high-dose edoxaban was comparable to warfarin ($P=0.97$), and the risk of this event went up 41% with low-dose edoxaban vs. warfarin ($P<0.001$).

Source: FDA Advisory Panel Votes 9 to 1 in Favor of Edoxaban for Stroke Prevention in AF Patients. Medscape. Oct 30, 2014. http://www.medscape.com/viewarticle/834164 DT

Anna D. Garrett *is a clinical pharmacist and president of Dr. Anna Garrett (www.drannagarrett.com). Her mission is to help women in midlife maximize their mojo! Contact her at info@drannagarrett.com.*

Nexium 24HR uses the same formulation as Rx Nexium's to treat frequent heartburn.

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OTC

Tummy tips: Digestive precautions for the holidays

JULIANNE STEIN, CONTENT CHANNEL MANAGER

The end of the year brings rounds of holiday celebrations that can sorely tax partygoers' good intentions — and digestions. For those who have a tendency to overindulge, it's a good time to consider some products to keep on hand for the night before or the morning after.

Heartburn, gastric reflux

Symptom relief is a good place to start. For frequent heartburn sufferers who haven't heard, Nexium went OTC this year and is now available under the name **Nexium 24HR**. The extremely popular proton pump inhibitor — its active ingredient is esomeprazole 20 mg — from AstraZeneca is being marketed by Pfizer, which has exclusive global rights. Here is some intriguing Nexium math, found at the Nexium website: "Nexium 24HR may take 1-4 days for full effect, which is 24 hours of complete relief from frequent heartburn." Don't try to decode this. The website also states that "Nexium 24HR has been shown to treat frequent heartburn for up to 24 hours when taken once each morning before eating for 14 consecutive days." Incidentally, patients should not take this product for more than 14 days, or more often than every four months, unless a doctor tells them to. For patients who ask the difference between Rx Nexium and OTC Nexium24, according to the manufacturer it is a matter of indications and directions for use; in the case of esomeprazole 20 mg, the drug and the dosage are identical. Other dosages and formulations remain available by prescription only. **(www.nexium24hr.com/us)**

Flatulence

As our theoretical case of unbridled gourmandise moves from excess to distress, one symptom of crabby tummy might turn out to be flatulence. Relief is at hand, in the form of **Phazyme Anti-Gas soft gels**, a product of C.B. Fleet Co., available in strengths of 180 mg and 250 mg. Calling the latter formulation "the first increased-strength anti-gas product in over 15 years," the company states that **Maximum Strength Phazyme**'s 250 mg of simethicone qualify it as "the strongest dose available without a prescription to relieve the bloating, discomfort, and pressure from gas." The single-dose soft gels are easy to swallow and go to work in minutes. **(www.phazyme.com)**

For simethicone fans who want to play the field, Boehringer Ingelheim offers **DulcoGas Maximum Strength Chewable Tablets** (125 mg), available in three flavors: Wild Berry, Tangy Citrus, and Sabor Tropical. The product starts working in minutes to provide "dependable relief from discomfort, bloating and pressure ... from gas that may accompany constipation or result from eating certain foods." **(www.dulcolax.com)**

Constipation

This brings us to another unfortunate consequence of holiday excess: consumption of so much — or so much of the wrong

IMAGES COURTESY OF PFIZER / C.B. FLEET CO.

sort of thing — that the hardworking digestive enterprise simply lays down its tools in protest and grinds to a halt. As all post-surgical patients know, constipation is notable for knocking thoughts of anything nonconstipatory entirely out of one's head.

No visit to the Dulcolax armamentarium is complete without a look at the other weapons it offers to those seeking to fight the good fight, including **DulcoLax** and (for women) **DulcoLax Pink Laxative Tablets** (active ingredient bisacodyl USP 5 mg), **Dulcolax Stool Softener** and (for women) **DulcoEase Pink liquid gels** (active ingredient, docusate sodium 100 mg), and **Dulcolax Laxative Suppositories** (active ingredient, bisacodyl USP 10 mg), with or without **DulcoGlide Applicators**. **(www.dulcolax.com)**

But wait — there's more. Constipation sufferers who prefer to place their trust in a less overtly pharmaceutical alternative can avail themselves of the Prunelax products from Garden House, which are made from dried plum extract and an assortment of herbs. The **Prunelax Tablet** is described as an "effective yet gentle laxative that relieves occasional constipation within 8 to 12 hours." Dried-plum aficionados can go for **Prunelax Jam**, while the whole family can down **Prunelax Liquid**, made with fruit juice and herb extracts, and designed for users two years of age and up. The tablets do not contain sugar and are safe for diabetics; the other two products do contain sugar and are not recommended. It should be added that the Prunelax website presents a page of health tips that is notable for its common sense and clear information. **(www.ciruelax.com/usa/prunelax/)**

Immune support

Once the misery of overindulgence and its attendant ills has been remedied, the thoughts of the newly penitent may turn to prevention.

It is becoming more widely known by consumers that the immune system can be considered to reside in the gut, powered by troops of friendly bacteria (probiotics are new recruits), and that it is a good thing to nourish them and keep them strong (enter digestive enzymes and prebiotics), so that they will stay on the job of keeping us strong. To that end, probiotics, prebiotics, and digestive enzymes are high on many people's daily go-to list. Below are some possibilities.

The **Digestive Health** line of Core Health Products offers several items. The company states that its **Digestive Enzyme Blend** includes high levels of proteases designed for maximal protein use and a lipase blend that maximizes digestion and use of fat for energy. Its **Probiotic Blend** provides "more than 2.5 billion CFU of live, active probiotics from 13 different species," chosen for their known health benefits. The **Prebiotic and Herbal Support Blend** combines inulin, a dietary fiber, with glutamine and the digestive aids ginger, peppermint, beet root, and chamomile, and according to the manufacturer addresses all aspects of intestinal health. The **Maximum Enzyme Delivery System** is said to offer numerous benefits, including digestive and eliminative aid, calming properties for stomach and digestion, immune support, enhanced use of muscle-building nutrients, and increased nutritional absorption. **(www.corehealthproducts.com)**

While we're on the subject, worth noting, although not new, is the **Digestive Health Probiotic** from Nature Made. Each capsule has 10 billion live cells of Lactobacillus plantarum 299v, a probiotic occurring naturally in human beings that helps foster the growth of friendly bacteria and supports balanced digestive health. **(www.naturemade.com/supplements/probiotics/digestive-health-probiotic)**.

Also from Nature Made is **Lactobacillus Acidophilus**, said to "improve intestinal motility to help maintain regularity" in addition to promoting digestive balance and supporting intestinal health. Each tablet contains 500 million live cells; recommended dosage is two tablets daily. **(www.naturemade.com/supplements/acidophilus)**

Those with a tendency to celebrate not wisely but too well might consider stocking up on some of these digestive aids. And hey, whether you go for an ounce of prevention or a pound of cure, be careful out there! DT

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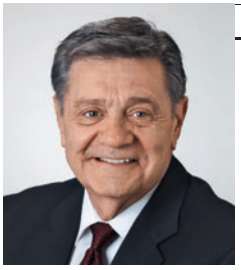

ETHICAL DECISION-MAKING IN PHARMACY Kenneth R. Baker, BS Pharm, JD

Apology laws and the ethics of saying "I'm sorry"

A pharmacist I will call Sam made a mistake, a prescription error. As are most claims against pharmacists, Sam's mistake was a mechanical error; he had filled a prescription with the wrong drug.[1]

Sam called me because, at that time, I was the General Counsel at Pharmacists Mutual Insurance Company and the head of the company's professional liability claims department. He said, "It was stupid. I filled the prescription myself and I am the one who made the mistake. I don't know how I could have done that."

Sam then told me one other thing. Before he called me, he had called his patient. He told her what he had done and told her to quit taking the wrong medicine immediately. Sam said to his patient, "I am sorry, I made a mistake." He then filled the prescription correctly; refunded the money previously paid; and did not charge her for the corrected prescription. He also called the patient's physician and confessed again so their records would be complete. As it eventually turned out, the patient was not injured and no claim was made against Sam or the pharmacy.

Sam said to me, "I probably should have called you first, before I admitted liability." In every insurance policy there is a clause stipulating that the policyholder must not admit liability.

I told Sam that a year earlier, the insurance company had send a letter to every professional liability policyholder, saying that the admission of an obvious error with a statement of apology is not considered a violation of our "no admission of liability clause."

Not every insurance company or every pharmacy chain will take the same position, but today many do. Check to see what your company says on the subject.

Professional and ethical

After handling pharmacy claims for almost 20 years, I have found that, in the case of an obvious error, saying "I am sorry, I made a mistake," is usually a good thing.

Often a patient isn't looking for revenge or money beyond what it takes to treat any injuries suffered. However, patients do expect a professional pharmacist to be willing to admit a mistake and to apologize. Remaining silent when an apology is appropriate often exacerbates the problem and complicates the claim.

No money was ever paid in Sam's case, perhaps because he took the actions he did. I have often thought not only that what Sam did professional; it could even be considered an ethical duty.

Today, 36 states have apology laws that cover most healthcare professionals. These laws prohibit many or most statements of sympathy or empathy — including, in many cases, statements such as the one Sam made to his patient — from being used by attorneys in a lawsuit.[2]

These laws are important. They give healthcare professionals the freedom to take care of their patients and to do so without concern that something they say that sounds like an apology will be used against them. These laws allow the pharmacist, physician, nurse, or other covered healthcare provider to act professionally and ethically without fear that the words chosen will come back to haunt them.

Find out the law

But there is a problem. Only 36 states have apology laws, and while all cover physicians, some do not include protection for pharmacists.

Find out the circumstances in your state. Get in touch with your fellow pharmacists, your state board, and your state pharmacy association. Apology laws covering all healthcare professionals, including pharmacists, should be the law in every state.

If this protection is not available in your state, work to change the law. This is worth lobbying for, not just for pharmacists, but for their patients, as well. DT

References

1. See Pharmacists Mutual Claims Study: http://www.phmic.com/RM/Pages/pharmliab.aspx Accessed 11/4/2014.
2. See www.sorryworks.net for list of states with apology law. The site explains: "Thirty-six states have 'apology laws' which prohibit certain statements, expressions, or other evidence related to disclosure from being admissible in a lawsuit. Most states simply cover expressions of empathy or sympathy, while a few states go further and protect admissions of fault." Accessed 11/3/2014.

These articles are not intended as legal advice and should not be used as such. When a legal question arises, the pharmacist should consult with an attorney familiar with pharmacy law in his or her state.

Ken Baker *is a pharmacist and an attorney. He teaches ethics at the Glendale, Arizona, campus of Midwestern University, and risk management for the University of Florida. He consults in the areas of pharmacy error reduction, communication, and risk management. Mr. Baker is an attorney of counsel with the Arizona law firm of Renaud Cook Drury Mesaros, PA. E-mail him at* ken@kenbakerconsulting.com.

LEGAL COMPLIANCE Ned Milenkovich, PharmD, JD

Controlled substances: Bipartisan team introduces new legislation

Senators Brown and Cornyn spearhead changes to CSA

Senators Sherrod Brown (D-Oh) and John Cornyn (R-Tx) recently introduced S. 2825, the Ensuring Safe Access to Prescription Medication Act. The bill would amend the Controlled Substances Act (CSA) to permit constructive transfers of controlled substances from pharmacies to prescribing practitioners, including physicians and veterinarians, on behalf of the ultimate user. Under the CSA, an ultimate user may be a patient, an animal's owner, or a member of the patient's or owner's household.

Define the terms

For years, pharmacies have raised concerns with the way the Drug Enforcement Administration (DEA) has interpreted the CSA's definitions of "dispense," "distribute," and "deliver" or "delivery" in the context of constructive transfers.

According to the DEA argument:

- The transfer of a controlled substance from a pharmacy to anyone (including a prescribing practitioner) is distribution, not dispensing to the ultimate user
- Compounding for distribution is manufacturing

From a pharmacy's perspective, this interpretation is problematic, because distribution is outside the scope of a pharmacy's DEA registration status as a practitioner, and registration as a manufacturer is also required.

In addition, to dispense a controlled substance to a patient instead of to the doctor may increase the risk of diversion and create safety concerns for handling of sterile drugs prior to their injection or administration by the prescriber.

Changes sought

Recent efforts to change the DEA's position can be traced to a 2007 federal appellate court decision.

In *Wedgewood Village Pharmacy v. DEA*, the U.S. Court of Appeals for the D.C. Circuit sharply criticized the DEA's restrictive interpretation of constructive transfers. The court found the DEA's interpretation to be in conflict with dictionary and statutory definitions, as well as with the DEA's own regulations.

After the court decision, which stated that the DEA should address the issue of constructive transfers, the DEA and the pharmacy reached a settlement agreement. The settlement allowed the DEA to maintain its legal position on constructive transfers to the present day.

Members of Congress have introduced legislative fixes and requested that the DEA solicit input through a rulemaking on the topic of constructive transfers.

Bills introduced in earlier Congresses would have permitted the delivery from pharmacies to prescribing practitioners of controlled substances administered through the use of intrathecal pumps. Unlike those bills, S. 2825 does not limit the types of controlled substances that could be delivered from a pharmacy to a prescribing practitioner.

What would change

If S. 2825 becomes law, it will force the DEA to change its determination that transfers of controlled substances to prescribing practitioners, as opposed to the ultimate users, are distributions of controlled substances. The bill would amend the CSA definition of "dispense" to include the delivery of a controlled substance by a pharmacy to a prescribing practitioner.

The proposed legislation would permit pharmacies to provide the necessary packaging, labeling, and compounding required for delivery of the controlled substance to a prescribing practitioner.

The bill also would require DEA to review its position that compounding of controlled substances by pharmacies for delivery to prescribing practitioners is manufacturing under the CSA.

S. 2825 mandates that delivery be conducted pursuant to the practitioner's issuance of a patient-specific prescription. In addition, the prescribing practitioner must deem it medically necessary, in the usual course of professional practice, for the controlled substance to be administered by the practitioner to the patient. Finally, the bill would remove the current requirement that controlled substances be dispensed only to the ultimate user or research subject.

Unless S. 2825 sees floor action in the next few weeks, it must be reintroduced at the start of the 114th Congress in January 2015. DT

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 partner and head of the healthcare, drug, and pharmacy legal practice at Roetzel and Andress LPA. He is also vice chair of the Illinois State Board of Pharmacy. Contact Ned at 312-582-1676 or at nmilenkovich@ralaw.com.*

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Grant Funding: None

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MTM essentials for smoking cessation

Stefanie C. Nigro, PharmD, BCACP, BC-ADM
ASSISTANT PROFESSOR OF PHARMACY PRACTICE, MCPHS UNIVERSITY, BOSTON, MASS.

Elizabeth Travis
2015 PHARMD CANDIDATE, MCPHS UNIVERSITY, BOSTON, MASS.

Abstract

Tobacco abuse remains the leading cause of preventable death in the United States and contributes to many serious health complications including chronic obstructive pulmonary disease, lung cancer, and cardiovascular disease. Continued efforts are needed to promote both abstinence of smoking and maintenance over time. As part of providing comprehensive medication therapy management, pharmacists can assist interested quitters by designing smoking cessation care plans that include both nonpharmacologic and pharmacologic support. First-line treatment options include nicotine replacement therapy, bupropion, and varenicline. By providing behavioral counseling along with pharmacotherapy support, pharmacists may greatly affect a patient's ability to successfully quit smoking.

Faculty: Stefanie C. Nigro, PharmD, BCACP, BC-ADM and Elizabeth Travis
Dr. Nigro is an assistant professor of pharmacy practice, MCPHS University, Boston, Mass. Ms. Travis is a 2015 PharmD candidate at MCPHS University, Boston, Mass.

Faculty Disclosure: Dr. Nigro and Ms. Travis have no actual or potential conflict of interest associated with this article.

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IMAGE: GETTY IMAGES / ANTON ZHELTOV

CPE SERIES: MTM CONSIDERATIONS FOR ADULT PATIENTS WITH CARDIOVASCULAR DISEASE

Welcome to the CPE series, Medication Therapy Management Considerations for Adults with Cardiovascular Disease, which was designed for pharmacists who take care of patients with CVD. Beginning in February 2014 and continuing through January 2015, pharmacists can earn up to 24 hours of CPE credit with 12 monthly knowledge-based activities from the University of Connecticut School of Pharmacy and *Drug Topics*.

This month, pharmacists will learn about medication therapy management for smoking cessation. The knowledge-based part of the series ends in January 2015 with an activity about medication therapy management opportunities in caring for the patient with CVD.

The series also offers an application-based activity in April 2015. The case studies in the activity will apply CVD management concepts to practice-relevant cases. Pharmacists will answer questions throughout the activity in an interactive web-based format and receive immediate feedback to their answers.

Introduction

Tobacco use remains the leading cause of preventable death and illness in the United States, killing 480,000 Americans and totaling $289 billion in healthcare costs annually, so continued efforts to help patients quit smoking are needed.[1] In 2012, 18.2% or 42 million U.S. adults reported current tobacco use, with most of these adults aged 25 to 44 years.[2] Vulnerable populations include, but are not limited to, those with a diagnosed psychiatric illness, those with less education, and those of a lower socioeconomic status.[2] Smoking has serious health implications, including a 25 times increased risk of lung cancer and a 12 to 13 times increased risk of dying from chronic obstructive pulmonary disease.[1] Most notably, smokers more than double their risk for stroke and cardiovascular disease, which are the leading causes of death in the United States.

Fortunately, quitting smoking has immediate health benefits, including a lowering of heart rate, blood pressure, and carbon monoxide levels and an improvement in breathing over time.[3] The excess risk of cardiovascular disease is decreased by half after one year of abstinence. Fifteen years after smoking cessation, the risk of cardiovascular disease and stroke is comparable to the risk in those who have never smoked.[4]

Curbing tobacco use is part of the national Healthy People 2020 initiative, which aims for a goal of ≤12% smoking Americans.[5] To this end, the establishment of the 2009 Tobacco Control Act placed the U.S. Food and Drug Administration (FDA) in charge of regulating tobacco sales and marketing, with a focus on preventing youths from starting smoking.[6] Additionally, the establishment of the 2010 Affordable Care Act expanded coverage for those seeking evidence-based smoking cessation treatments.[7]

Successful cessation efforts need to begin with identifying smokers. All healthcare providers are encouraged to use the "5A's" model to screen for tobacco abuse (**Table 1**).[8] This brief intervention, which is intended to raise awareness and provide basic education regarding smoking, can be used at one visit or repeated over subsequent contacts. Regardless of willingness to quit, all patients should be *asked* about smoking status, *advised* to quit, and *assessed* for their willingness to quit.[8] For those interested in quitting, *assistance* with a quit plan and *arrangement* of follow-up can be provided. For those unwilling to quit, motivational interviewing techniques should be used.[9] Such strategies include expressing empathy, developing discrepancy between continued smoking and the importance of quitting, accepting the patient's resistance to quit, and supporting a patient's self-efficacy as it relates to quitting.[10]

Pharmacists as smoking cessation advisors

Pharmacists, widely accessible in the community and knowledgeable about pharmacotherapy, are ideally positioned resources for patients seeking assistance with smoking cessation.[11] Pharmacist-led smoking cessation programs have shown demonstrable success in tobacco abstinence and maintenance over time. Community-based pharmacists in New Mexico implemented a tobacco cessation program that resulted in quitting success rates similar to those of other healthcare professionals.[12] Further, at the VA San Diego Healthcare System, patients counseled by a pharmacist about quitting (in addition to receiving medication) showed significant improvements in quit rates at six months compared to patients who did not receive pharmacist counseling.[13]

Behavioral counseling and pharmacotherapy are independently effective for treating tobacco abuse; however, the combination is more effective than either alone.

Many smoking cessation therapies are available over-the-counter (OTC) direct from the pharmacist. These nicotine-based OTC aids have demonstrated comparable effectiveness to prescription alternatives and are considered first-line options for treating tobacco abuse.[8] As part of providing comprehensive medication therapy management

(MTM), pharmacists can assist smokers interested in quitting by designing a smoking cessation care plan that includes both nonpharmacologic and pharmacologic support. Behavioral counseling and pharmacotherapy are independently effective for treating tobacco abuse; however, the combination is more effective than either alone.[8]

Before designing a care plan, pharmacists should gather pertinent patient information to aid with drug selection and behavioral counseling. A thorough intake interview is advised. Pharmacists should obtain information about pack-year history, number of cigarettes smoked, previous quit attempts, reasons for quitting, patient-reported triggers for smoking, pharmacotherapy preference, and anticipated quit date. The Fagerstrom Test for Nicotine Dependence is a validated, patient-reported tool that can be used to determine a patient's level of nicotine dependence; higher scores indicate higher dependence.[14] Gathering relevant information about medications and past medical history is also advised. Finally, pharmacists must consider both medication- and patient-specific factors that may influence care planning (**Table 2**).

Nonpharmacologic interventions for smoking cessation

Nonpharmacologic strategies should be considered and implemented when appropriate. Use of the STAR acronym can be a useful first step when developing any care plan. Patients are encouraged to *set* a quit date ideally within one to two weeks, *tell* family and friends about quitting, *anticipate* challenges to abstinence especially during the first few weeks, and *remove* tobacco products from the surrounding environment.[8] This strategy is easy to remember and gets the patient to start thinking about preparing for their quit attempt.

TABLE **1**

THE 5 A'S MODEL OF TREATING TOBACCO USE AND DEPENDENCE

Ask	Ask patient about smoking status at every visit
Advise	Advise patient to quit in a clear, strong, and personalized manner
Assess	Assess patient's commitment to quitting
Assist	Assist patient by providing help setting quit date; personalized advice regarding previous attempts, upcoming challenges, and surrounding environment; pharmacologic therapy as necessary; information regarding support groups; referral to specialist
Arrange	Arrange follow-up with patient to reassess progress and needs

Source: Ref 8

Behavioral counseling or cognitive behavioral therapy (CBT) is an evidence-based approach aimed at identifying and modifying maladaptive behaviors related to smoking. CBT is useful in the group or individual setting and has been shown to result in higher abstinence rates.[8] The primary goal of CBT is to boost one's motivation to quit.[10] Through the use of CBT, healthcare providers warn about any obstacles that may impede patients' ability to be successful in their attempt to quit. Patients are encouraged to explore their triggers and challenges and to plan solutions or coping strategies.[10] Commonly used solutions include avoiding, altering, or substituting the trigger. For example, if a patient reports stress as a trigger for smoking, education on alternative stress-reducing techniques such as deep breathing can be considered. There is no "one size fits all" approach; care planning must be individualized and led by the patient. To help patients identify triggers, self-monitoring of tobacco intake can be encouraged.

Another technique to consider is nicotine fading (tapering). Nicotine fading is a form of gradual cessation that advises patients to either (a) change their cigarette brands to those containing progressively less nicotine and tar over the course of time or (b) progressively decrease the amount of cigarettes smoked each day or week.[15,16] This strategy acknowledges the addictive aspect of smoking and may lessen the intensity of withdrawal symptoms. Gradual cessation has been shown to be as effective as abrupt cessation.[15] Patients should be counseled not to compensate by smoking deeper or with longer puffs.

Pharmacotherapy for smoking cessation

Pharmacotherapy should be offered to all smokers who are attempting to quit unless medication is contraindicated or the patient belongs to a specific population in which the safety and efficacy of such medication is yet to be established (ie, pregnant women, adolescents, light smokers, smokeless tobacco users).[8] Drug therapy is intended to ease the physical discomfort from nicotine withdrawal symptoms (eg, restlessness, irritability, depressed mood, insomnia, constipation) and minimize cravings.[17] Seven first-line therapies are recommended and FDA approved for smoking cessation: five types of nicotine replacement therapy (NRT) (patch, gum, lozenge, nasal spray, and inhaler), bupropion, and varenicline (**Table 3**).[8,18,19] When compared to placebo or no treatment, use of any recommended first-line agent doubles a patient's odds of achieving abstinence at six months.[8] Varenicline and combination NRT (eg, patch plus gum) are associated with the highest abstinence rates (33% and 37%, respectively) when compared to placebo. Both are also more effective than the NRT patch alone.[8] Given the comparable efficacy among agents, selection should be highly individualized. Choosing a therapy that is

Pause&Ponder

What barriers exist in your current practice that hinders your ability to providing smoking cessation services/counseling to patients?

consistent with a patient's preference may enhance adherence and confidence.[8]

Combination therapy can be appropriate for highly dependent smokers or for those in whom monotherapy is not helping to achieve abstinence.[8] Using products with complementary mechanisms is advised, except in the case of combining the NRT patch plus gum, lozenge, spray, or inhaler.[17] Combining the patch with a short-acting NRT product is more effective than monotherapy.[20] Currently, the only combination approved by the FDA is bupropion plus NRT. Other combinations, including bupropion plus varenicline and varenicline plus NRT, appear to be well tolerated but are not approved at this time.[21,22]

Most smoking cessation therapies are recommended to be used for less than three to six months. In the case of bupropion and varenicline, if a smoker remains abstinent at the end of three months, treatment can be extended to six months. Pharmacists should encourage frequent and timely follow-up to evaluate tolerability, effectiveness of treatment, and any safety concerns.

NRT

Nicotine-based therapy is intended to provide low levels of "clean nicotine" and is best suited for patients who experience significant symptoms of withdrawal. All five nicotine-based options have demonstrated higher abstinence rates compared to placebo at six months.[8] The NRT patch provides a steady nicotine level and may be the easiest nicotine-based product to use. However, its slow-acting, long duration of action may not help with breakthrough cravings. Because of its transdermal preparation, skin irritation may occur; patients with skin disorders such as eczema and psoriasis should use the patch with caution. The fast-acting gum, lozenge, spray, or inhaler can assist with breakthrough cravings because the patient is able to control the dose provided.[17] These methods are often used as a substitute for cigarettes and can help with hand-to-mouth coordination. Fast-acting NRT therapies require more frequent administration and should be dosed around-the-clock to enhance efficacy. This dosing schedule coupled with avoidance of food or beverage 15 minutes before and after administration may present adherence problems for patients. The gum may be problematic for patients with dentures or recent dental work. The spray offers the most rapid delivery of nicotine but may have a higher potential for dependence than the other NRT products. Both the spray and inhaler can cause mouth and/or throat irritation, predisposing patients with reactive airway disease to possible bronchospasm.

Nicotine-based therapy has long been labeled as contraindicated for patients with cardiovascular disease. However, some studies have indicated mixed hemodynamic effects on both blood pressure and heart rate.[23,24] A large meta-analysis comparing the adverse events of NRT patch versus placebo found no increased risk of myocardial infarction, hypertension, stroke, angina, or arrhythmia with the NRT patch.[25] Similar findings were observed in studies of patients with acute or chronic coronary disease: no significant increases in cardiovascular morbidity or mortality were observed.[26,27] These findings may suggest that NRT is generally safe in patients with cardiovascular disease. Prudent monitoring of high-risk patients is advised when recommending NRT for smoking cessation. Pharmacists are encouraged to check for and assess blood pressure and heart rate during follow-up encounters.

In 2013, the FDA announced its consideration to change the labeling on the three OTC therapies for nicotene replacement. [28] After reviewing safety data, the FDA has concluded the use of NRT has low potential for abuse and/or dependence. Labeling changes will include removing the warning that patients should not use an NRT product if they are still smoking, chewing tobacco, or using any other product that contains nicotine; this includes other forms of NRT. This revised labeling is intended to promote greater use of NRT among interested quitters.

Bupropion

Bupropion was the first non-nicotine-based therapy to be approved for smoking cessation. Although its mechanism of action is poorly understood, bupropion is believed to interfere with the dopamine-mediated reward pathway.[18] Its effects on smoking cessation appear to be independent of its antidepressant effects. Patients with comorbid depression or those with concerns about weight gain may benefit the most from bupropion use. This agent should be avoided in patients with a history of seizure disorders, those with anorexia and/or bulimia, and those who have used a monoamine oxidase inhibitor within the past 14 days.[18]

Because bupropion also inhibits the reuptake of norepinephrine, an increase in blood pressure is a potential risk. Various doses of sustained-release preparations of bupropion (150–400 mg/d) have been evaluated to assess this risk.[29] In 300 out-

TABLE 2

MEDICATION AND PATIENT FACTORS AFFECTING CHOICE OF PHARMACOTHERAPY

Medication factors	Patient factors
■ Efficacy	■ Level of nicotine dependence
■ Safety	■ Prior experiences with medication
■ Ease of use • Frequency of administration • Route of administration	■ Comorbid medical conditions ■ Insurance coverage/access to medications ■ Adherence
■ Cost	■ Preference

Source: Ref 8

Pause&Ponder

What additional training/information do you feel you need to provide effective smoking cessation support?

TABLE 3

FDA-APPROVED AGENTS FOR SMOKING CESSATION

Agent	Dosing	Instructions for use	Adverse reactions
Dopamine and norepinephrine reuptake inhibitor			
Bupropion sustained release (Prescription)	Days 1-3: 150 mg by mouth in the morning Days 4+: 150 mg by mouth twice daily	Start treatment, then set quit date 1-2 weeks after initiation date. Avoid taking at bedtime to minimize insomnia. Treat for 8-12 weeks, with maintenance of up to 6 months.	Insomnia Dry mouth Nervousness Agitation WARNING[a]
Partial agonist/antagonist of neuronal nicotinic receptors			
Varenicline (Prescription)	Days 1-3: 0.5 mg by mouth once daily Days 4-7: 0.5 mg by mouth twice daily Days 8+: 1 mg by mouth twice daily	Set a quit date, then start treatment 1 week before quit date. Take after a meal with a full glass of water. Treat for 12 weeks; an additional 12-week cycle is also recommended.	Nausea Insomnia Abnormal dreams Headache WARNING[b]
Agonist of neuronal nicotinic receptors			
Nicotine nasal spray (Prescription)	One dose: 2 sprays; each spray delivers 0.5 mg nicotine 1-2 doses/hr Minimum of 8 doses/d initially; gradually decrease use Maximum of 5 doses/hr, 40 doses/d	Do not sniff, swallow, or inhale through the nose while dose is administered. Treat for a maximum of 3 months.	Moderate to severe nasal irritation in first 2 days of use; mild to moderate nasal irritation in first 3 weeks Temporary changes in sense of smell or taste
Nicotine inhaler (Prescription)	6-16 cartridges/d; dosing and tapering should be individualized One 10-mg cartridge delivers 4 mg nicotine Minimum of 6 cartridges/d for first 3-6 weeks	Inhale deeply into back of throat or puff in short breaths continuously for 20 min. Do not eat or drink 15 min before, during, or after use. Treat for 3 months, then taper for 3 months	Mouth and throat irritation Unpleasant taste Cough Rhinitis Dyspepsia
Transdermal nicotine patch (OTC)	≤10 cigarettes/d: Weeks 1-6: 14 mg/d Weeks 7-8: 7 mg/d >10 cigarettes/d: Weeks 1-6: 21 mg/d Weeks 7-8: 14 mg/d Weeks 9-10: 7 mg/d	Patch may be worn for full 24 hours. Use a new patch every day. Rotate the location of patch application. May remove patch before bedtime if sleep disturbances occur.	Nausea Hiccups Heartburn Headache Cough Insomnia
Nicotine lozenge (OTC)	1st cigarette ≤30 min after waking: 4-mg dose 1st cigarette >30 min after waking: 2-mg dose Weeks 1-6: 1 lozenge every 1-2 hr Weeks 7-9: 1 lozenge every 2-4 hr Weeks 10-12: 1 lozenge every 4-8 hr Maximum of 5 lozenges every 6 hr; 20 lozenges/d	Allow lozenge to fully dissolve for about 20-30 min. Do not chew or swallow lozenge. Rotate the location of the lozenge in the mouth. Do not eat or drink 15 min before or during use.	
Nicotine gum (OTC)	1st cigarette ≤30 min after waking: 4-mg dose 1st cigarette >30 min after waking: 2-mg dose Weeks 1-6: 1 piece every 1-2 hr Weeks 7-9: 1 piece every 2-4 hr Weeks 10-12: 1 piece every 4-8 hr Maximum of 24 pieces/d	Chew each piece until peppery flavor or tingling sensation begins, then park between cheek and gum until tingling fades. Repeat for about 30 min or until taste or tingle does not reappear. Rotate the location of where gum is parked. Do not eat or drink for 15 min before or during use.	Mouth soreness Dyspepsia Hiccups Jaw ache

Abbreviation: OTC, over-the-counter.

[a]May increase risk of suicidal thinking or behavior; monitor closely

[b]May cause agitation, hostility, suicidal thinking or behavior, or depressed mood; monitor closely

Source: Ref 8,18,19

patient smokers with mild untreated hypertension, no increase in the risk of myocardial infarction, stroke, angina, arrhythmia, hypertension, or palpitations was observed with any bupropion treatment dose.[28] As with NRT, the use of bupropion does not appear to increase harm in patients with cardiovascular disease.

Varenicline

The approval of varenicline added to the non-nicotine-based oral armamentarium for smoking cessation. Given its dual action at nicotinic receptors, varenicline helps minimize nicotine withdrawal symptoms and blocks the reward center that is normally activated by smoking.[19] Total daily doses of 1 or 2 mg appear to be effective for smoking cessation.[8]

Similar to NRT, varenicline therapy is most appropriate for patients who experience symptoms of nicotine withdrawal upon quitting. Slow dose titration of this medication is recommended to minimize symptoms of nausea. Varenicline should be avoided in long-distance drivers and pilots because of a reported increase in blackouts and unintended accidents in these populations.[19] Additionally, varenicline should be used with caution in patients with a history of serious or unstable psychiatric illness and/or renal dysfunction. A black box warning highlights the potential for neuropsychiatric events in select patients taking varenicline.[19] However, its risks in patients with psychiatric history may be understated. Armed with new evidence, the manufacturer is petitioning FDA to remove its black box warning. A recent randomized controlled trial conducted in smokers with depression treated with varenicline showed doubled quit rates and no increase in depressive symptoms of suicidality. [30] Moreover, an industry-sponsored retrospective analysis of 17 placebo-controlled trials of varenicline showed that in patients with past or present psychiatric diagnoses, the risk of neuropsychiatric events was equal among placebo and varenicline-treated groups. [31]

On June 16, 2011, the FDA issued a safety warning notifying the public that use of varenicline may be associated with a slightly increased risk of certain cardiovascular adverse events in patients with preexisting cardiovascular disease.[32] A randomized, double-blind, placebo-controlled trial of 700 smokers (assigned to either varenicline 2 mg daily or placebo) had demonstrated that cardiovascular adverse events were infrequent overall; however, nonfatal myocardial infarction, angina pectoris, and the need for coronary revascularization were reported more frequently in patients treated with varenicline than in patients treated with placebo.[33] As a result, the labeling of varenicline was updated to reflect this warning. In subsequent years, two meta-analyses examining cardiovascular risk with varenicline were published; the findings were mixed.[34,35] The first analysis of 14 double-blind, randomized, controlled trials found that varenicline was associated with a significantly increased risk of any ischemic or arrhythmic adverse events.[34] Of note, most of the trials included in this analysis excluded patients with preexisting cardiovascular disease. Conversely, a later review evaluated 22 double-blind, placebo-controlled trials, more than half of which included patients with a history of or concurrent cardiovascular disease.[35] No significant increase in serious cardiovascular adverse events was observed in patients treated with varenicline. The safety of varenicline in patients with cardiovascular disease is therefore still unclear. Pharmacists should recommend the use of this agent with extreme caution in this patient population.

Electronic cigarettes for smoking cessation

Electronic cigarettes, also known as e-cigarettes, e-cigs, or vapes, are designed to resemble cigarettes in both form and function. They contain cartridges that upon inhalation produce a smoke-free, often flavored vapor that may or may not contain nicotine.[36] Since being introduced to the market in 2004, e-cigarettes have gained popularity among smokers looking to quit. An estimated 40.2% of Americans are aware of e-cigarettes, and 11.4% of smokers use them.[37] Many marketing campaigns promote e-cigarettes as a safer alternative to smoking through social media platforms such as Twitter.[38] This has serious public health implications. Provided the manufacturers make no claims regarding therapeutic benefit such as smoking cessation, the FDA currently allows e-cigarettes to be marketed as tobacco products rather than as drugs or devices.[39] Because of this, the contents of these products remain highly variable and unregulated.[36]

Much of the literature available regarding e-cigarettes is centered on patient awareness and acceptability.[36] Although limited evidence does suggest a modest smoking cessation benefit with these products,[40,41] adequately powered randomized controlled trials are needed. Currently, there is a paucity of long-term safety and efficacy information. Data are also lacking regarding the effects, if any, of second-hand vaping. Until further safety and efficacy tests are conducted, e-cigarette use should be recommended with caution. When counseling patients regarding use, pharmacists should warn of potential local side effects including mouth and throat irritation and xerostomia.

Conclusion

Smoking continues to have significant health implications despite ongoing efforts to curb its abuse. Twenty percent of all smokers are ready to quit at any given time, yet smoking cessation services are not consistently offered.[10] Cessation efforts need to begin with identifying smokers. This can be accomplished through the use of the 5A's or can be obtained as a vital sign in clinical settings.[42] All smokers should be advised to quit and asked about their willingness to do so during each point of contact. Providing smoking cessation services is a role well suited for pharmacists, especially those based in the community where access to care is abundant. Pharmacists can provide behavioral counseling and design pharmacotherapy care plans. With continued efforts to standardize tobacco products and provide smoking cessation services, it is possible that the Healthy People 2020 goals can be achieved. •

The references are available online at *www.drugtopics.com/cpe*.

TEST QUESTIONS

1. What dose of the NRT patch is recommended for a patient who reports smoking 15 cigarettes per day?
a. 42 mg
b. 21 mg
c. 14 mg
d. 7 mg

2. Which of the following tobacco treatment methods is associated with the greatest efficacy in helping patients to quit smoking?
a. Behavioral therapy and pharmacotherapy
b. Pharmacotherapy and patient education
c. Behavioral therapy only
d. Pharmacotherapy only

3. Which of the following side effects is NOT commonly associated with varenicline use?
a. Insomnia
b. Nausea
c. Vivid dreams
d. Dry mouth

4. Which of the following nicotine-based products is dosed based on time to first cigarette?
a. Gum only
b. Lozenge only
c. Both gum and lozenge
d. Neither gum nor lozenge

5. The prevalence of smoking in the United States today is approximately:
a. <10%
b. 20%
c. 40%
d. >50%

6. Smokers who quit can expect to see which of the following immediate health benefits?
a. Decreased heart rate
b. Improvement in breathing
c. Decreased risk of cardiovascular disease
d. Improvement in symptoms of depression

7. Which of the following is the next best action to take for a smoker who is not interested in quitting at this time?
a. Do nothing since they are unwilling to quit at this time.
b. Provide counseling for a minimum of 10 minutes regarding how quitting will help improve their health.
c. Set a quit date with the patient and recommend a medication for smoking cessation.
d. Use motivational interviewing to explore their barriers to quitting.

8. For a smoker attempting to quit in whom monotherapy has failed, which of the following is an FDA-approved combination option?
a. Bupropion plus varenicline
b. Nicotine patch plus nicotine lozenge
c. Varenicline plus NRT
d. Bupropion plus NRT

9. Which of the following has the possible adverse effect of temporary changes in smell or taste?
a. Nicotine gum
b. Varenicline
c. Nicotine nasal spray
d. Bupropion

10. Which of the following is NOT part of the 5 A's brief intervention?
a. Acknowledge
b. Arrange
c. Advise
d. Assess

11. Bupropion is thought to exert its mechanism of action by increasing levels of which neurotransmitter?
a. Epinephrine
b. Dopamine
c. Serotonin
d. Glutamate

12. Which of the following smoking cessation aids can be initiated one week before a patient's quit date?
a. Bupropion only
b. Varenicline only
c. Bupropion and varenicline
d. Neither bupropion nor varenicline. Both need to be started on the target quit date

13. Which of the following is LEAST likely to cause insomnia?
a. Bupropion
b. Varenicline
c. Nicotine patch
d. Nicotine lozenge

14. Which of the following is NOT a common symptom of nicotine withdrawal?
a. Irritability
b. Insomnia
c. Restlessness
d. Diarrhea

15. Which of the following statements is most consistent with "assisting" the patient to quit smoking?
a. "I am worried that smoking will worsen your blood pressure and asthma."
b. "There are many effective treatments to help you quit. Which are you interested in trying?"
c. "Do you smoke? If so, how many cigarettes do you currently smoke?"
d. "I hear that you are worried about weight gain and not being successful in your quit attempt."

16. Which of the following is NOT considered a recommended first-line agent for smoking cessation?
a. Nicotine inhaler
b. Bupropion
c. Nortriptyline
d. Nicotine gum

17. Which of the following statements is TRUE regarding the use of varenicline and cardiovascular safety?
a. The maximum daily dose recommended for patients with preexisting cardiovascular disease is 1 mg daily.
b. Varenicline use may increase the risk of heart failure in patients with preexisting hypertension.
c. The safety of varenicline in patients with cardiovascular disease has yet to be determined.
d. Varenicline use increases systolic blood pressure but not diastolic blood pressure.

18. Which of the following nicotine-based products is available by prescription only?
a. Patch
b. Spray
c. Gum
d. Lozenge

19. Which of the following pieces of patient-related information is LEAST likely to influence care planning?
a. Level of nicotine dependence
b. Comorbid conditions
c. Pack-year history
d. Age

20. Which of the following statements is TRUE?
a. Having higher socioeconomic status is a risk factor for smoking.
b. The Fagerstrom Test for Nicotine Dependence calculates how many cigarettes a patient smokes.
c. Most smoking cessation therapies should be used for a minimum of one year.
d. The dose of varenicline is titrated slowly to minimize symptoms of nausea.

RX & OTC

New products

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RX CARE

New drugs

Boehringer Ingelheim has announced that **nintedanib** (Ofev) **[1]**, approved in October to treat idiopathic pulmonary fibrosis (IPF), is now available in 100-mg and 150-mg dosage strengths in certain U.S. pharmacies. The only kinase inhibitor approved to treat IPF, nintedanib is one of only two medications in the country specifically designed to treat this disease. **(www.ofev.com)**

FDA has approved **hydrocodone bitartrate [2]** (Hysingla ER; Purdue Pharma), an extended-release opioid analgesic with abuse-deterrent properties, to treat pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. FDA has called for a boxed warning, post-marketing studies, a Risk Evaluation and Mitigation Strategy (REMS), and a Medication Guide. **(www.purduepharma.com/hysinglaerpi)**

Reversing its decision made last December, FDA has approved **alemtuzumab** (Lemtrada; Genzyme/Sanofi) to treat patients with relapsing forms of multiple sclerosis (MS). The product is accompanied by a boxed warning and is available under a REMS program. Its use is appropriate for patients who have shown an inadequate response to two or more MS drug therapies. **(www.lemtrada.com)**

FDA also recently approved AstraZeneca's combination therapy **dapagliflozin and metformin hydrochloride extended-release** (Xigduo) for treatment of type 2 diabetes in adults, making it the first and only once-daily combination tablet composed of an SGLT2 inhibitor and metformin HCl extended-release to be approved in the United States. Several dosage strengths are available, including 5 mg/500 mg, 5 mg/1,000 mg, 10 mg/500 mg, and 10 mg/1,000 mg. **(www.xigduoxr.com)**

Salix and Pharming Group NV have announced the launch of their **C1 esterase inhibitor [recombinant]** (Ruconest) 50 IU/kg for treatment of acute attacks in adult and adolescent patients with hereditary angioedema, characterized by rapid swelling in various parts of the body, including the hands, feet, face, and abdomen. The product is not a plasma derivative. Comprehensive patient support services are available through the website or by calling 855-613-4HAE. **(www.ruconest.com)**

Arbor Pharmaceuticals has announced FDA approval of its **sotalol hydrochloride oral solution** (Sotylize), indicated to treat life-threatening ventricular arrhythmias and to maintain normal sinus rhythm in patients with a history of highly symptomatic atrial fibrillation/flutter. This product is the first and only sotalol oral solution for treatment of this condition; it was previously available only in tablet form. It is accompanied by a boxed warning describing the risk of life-threatening ventricular tachycardia associated with QT prolongation. **(www.arborpharma.com)**

FDA has granted accelerated approval to Wyeth's **Trumenba**, the first vaccine licensed in the United States to prevent invasive meningococcal disease caused by *Neisseria meningitidis* serogroup B in individuals 10 through 25 years of age, basing its approval upon patients' immune response to four group B strains. Trumenba was also granted breakthrough

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New Products

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therapy status, designed to expedite the development and review of therapies addressing a serious or life-threatening condition. Wyeth, a subsidiary of Pfizer, will conduct additional studies to verify Trumenba's effectiveness against additional strains of serogroup B. According to FDA, vaccination is the most effective way to prevent meningococcal disease. **(www.trumenba.com)**

New indications

Protein Sciences' **recombinant influenza vaccine** (Flublok) is now approved to treat all adults 18 years of age and older. Flublok is the only 100% egg-free flu vaccine available. **(www.flublok.com)**

FDA has approved the combined use of Janssen's **simprevir** (Olysio) with Gilead's **sofosbuvir** (Sovaldi) to treat hepatitis C genotype 1, making the pair the second all-oral treatment for this condition. FDA approved the combination for a standard 12 weeks of therapy if patients don't have cirrhosis and 24 weeks if they do. A full course (12 weeks) of sofosbuvir costs $84,000. A full course of simeprevir costs $66,000. **(www.olysio.com)**

FDA has approved Roche's **bevacizumab** (Avastin) to be used in combination with chemotherapy (paclitaxel, pegylated liposomal doxorubicin, or topotecan chemotherapy) for the treatment of women with platinum-resistant, recurrent, epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received no more than two prior chemotherapy regimens. Bevacizumab has already been approved to treat cancers of the lungs, colon, cervix, kidneys, and brain (glioblastoma). Avastin carries boxed warnings for GI perforation, complications connected with surgery and wound healing, and hemorrhage. **(www.avastin.com)**

Janssen announced FDA approval, under priority review, of its supplemental new drug applications for use of **paliperidone palmitate** (Invega Sustenna), a once-monthly atypical long-acting antipsychotic, as an adjunctive or monotherapy to treat schizoaffective disorder. A boxed warning notes risk of increased mortality in elderly patients with dementia-related psychosis. **(www.invegasustenna.com)**

Eli Lilly announced that **ramucirumab** (Cyramza) has been approved for use in combination with **paclitaxel** for second-line advanced gastric cancer after previous chemotherapy containing fluoropyrimidine or platinum has been tried. A boxed warning notes increased risk of hemorrhage. **(www.cyramzahcp.com)**

FDA has approved Regeneron's **aflibercept injection [3]** (Eylea) to treat macular edema following retinal vein occlusion (RVO). Aflibercept is already approved to treat wet age-related macular degeneration, diabetic macular edema, and macular edema following CRVO. **(www.eylea.com).**

New generics

Heritage Pharmaceuticals has launched **felodipine extended-release tablets [4]** in strengths of 2.5 mg, 5 mg, and 10 mg. Indicated to treat hypertension, felodipine is the AB-rated generic equivalent to Plendil, AstraZeneca's calcium channel blocker. **(www.heritagepharma.com)**

Also available from Heritage is sterile **rifampin for injection USP [5]**, 600 mg/vial,

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New Products

Continued from pg. 78

the AP-rated generic equivalent to Rifadin IV, the Sanofi Aventis antibiotic drug, indicated to treat all forms of tuberculosis. **(www.heritagepharma.com)**

Amneal has announced the launch of **estradiol/norethindrone acetate tablets [6]** (Lopreeza) in strengths of 0.5 mg/0.1 mg and 1 mg/0.5 mg, the first authorized generic equivalent to Novo Nordisk's Activella, indicated to treat postmenopausal symptoms. Both strengths are now shipping. **(www.amneal.com/productpage/lopreeza/)**

Dr. Reddy's recently launched **docetaxel injection USP**, 20 mg/1 mL and 80 mg/4 mL, a therapeutically equivalent generic version of Taxotere (Sanofi Aventis), used to treat locally advanced or metastatic breast cancer after failure of previous chemotherapy. A boxed warning cites risk of toxic deaths, hepatotoxicity, neutropenia, hypersensitivity reactions, and fluid retention. **(www.drreddys.com)**

Dr. Reddy's has also launched **sirolimus tablets [7]** in 1-mg and 2-mg strengths, a therapeutically equivalent generic version of Wyeth's Rapamune. It is indicated to prevent kidney rejection in renal transplant patients 13 years of age and older. A boxed warning states that its use is not recommended for liver or lung transplant patients. **(www.drreddys.com)**

FDA has granted approval to both Dr. Reddy's and Endo International for their generic versions of Genentech's antiviral **valganciclovir tablets USP**, (Valcyte), 450 mg. Ranbaxy lost the opportunity to launch the first generic version of Valcyte after quality control issues at its Indian production facilities led to a ban on Ranbaxy exports to the United States. **(www.drreddys.com) (www.endo.com)**

Perrigo recently announced that it has agreed to market **tacrolimus ointment**, the authorized generic version of Protopic ointment 0.1% and 0.03% from Astellas U.S., indicated to treat moderate-to-severe eczema. **(www.perrigo.com)**

Teva has launched **dexmethylphenidate hydrochloride extended-release capsules,** CII, 5 mg, the AB-rated bioequivalent to Novartis' Focalin XR extended-release capsules, CII, used to treat attention deficit hyperactivity disorder in patients six years of age and older. Teva also offers this product in strengths of 15 mg, 30 mg, and 40 mg. **(www.teva.com)**

Mylan has launched **lamivudine and zidovudine tablets USP**, 150 mg/300 mg, its generic version of Combivir from Viiv Healthcare, indicated for the treatment of HIV-1 infection in combination with other antiretroviral agents. A boxed warning cites a range of possible reactions. **(www.mylan.com)**

OTC

Dr. Reddy's has announced the U.S. launch of **fexofenadine hydrochloride 60 mg/pseudoephedrine hydrochloride 120 mg extended-release tablets**, a bioequivalent generic version of Allegra-D 12 Hour Allergy and Congestion (Chattem/Sanofi Aventis), indicated for relief of symptoms of indoor and outdoor allergies, such as congestion, sinus pressure, runny nose, sneezing, and itchy eyes and nose. **(www.drreddys.com)**

Seasonal travelers seeking relief from symptoms of jet lag such as fatigue, insomnia, and anxiety can now opt for **JetRyte Effervescent Tablets**, formulated with sodium, potassium, vitamins B6, B12, and C, magnesium, and melatonin to replenish key nutrients lost through dehydration. The citrus-flavored tablets dissolve in any water bottle within two minutes. **(www.jetryte.com)**

Dermend Alpha+Beta Hydroxy Therapy [8], is a thick, rich moisturizer available as both a lotion and a cream from Dermend Moisturizing Bruise Formula. It is formulated with glycolic and salicylic acids to exfoliate and soothe severely dry, flaky skin. Products should be used with sunscreen and sun exposure should be limited. (**www.lovelyskin.com**)

Zicam has launched two new homeopathic products for the winter season: **Zicam Cold Remedy Nasal Spray** for adults and **Zicam Kids**, a zinc-based grape-flavored soft chew for children from six to 11 years of age. **(www.zicam.com)** DT

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IN MY VIEW James "Goose" Rawlings, RPh

In the pharmacy, integrity is Job One

I've been around the healthcare business a few years, and one thing that sticks out is how wrong we can be about a fellow professional. I have been surprised more than once by the misdeeds of pharmacists, nurses, and physicians I have worked with. When you deal with powerful and addictive medications, it is easy to get into trouble — a lot easier than you think.

Careers and reputations can be destroyed by a single lapse in judgment, and I don't mean filling somebody's Xanax prescription three days early.

I'm talking about when you have done something wrong, something that is illegal, and you know it and continue to do it. Everybody keeps records pretty well now, and I think that while you can fool people for a while, eventually somebody with a badge is going to figure things out.

Case in point

A good example is a former doctor of mine, just busted for writing controlled scripts to friends and others — scripts for which his office kept no medical records.

There are some other shenanigans involved that I won't get into, but let's just say the allegations sound really bad.

The DEA, the state police, and even the town policeman have just raided his office, his home, and his car. He was placed under arrest and his office is closed. I figure his office staff will have trouble getting employment, even if they don't get charged. As for him, he's done.

Imagine being led out of your place of employment in handcuffs. Imagine explaining that to your family, your fellow workers, or your patients.

What do you tell your spouse and children? How does this sound? "Honey, you know that trip we took to Cancun last year? Well, I had to sell some stuff out of the back door to pay for that. Also Joey's sport camps and the equipment and coaching he needed. We really needed the break, and I want the kids to succeed."

Yeah, your spouse will really buy that.

Pharmacists too

Usually with a pharmacist, things are not so dramatic. However, we had a recent case locally where the FBI shut down an independent for overbilling Medicaid and Medicare. The owner went to jail after they seized his six cars and his quarter-million-dollar baseball-card collection.

This person will never work as a pharmacist again. This individual is banned for life from working for anyone who bills a government agency. This pharmacist went to jail for six years, for stealing from the government to buy baseball cards that had to be sold to pay the government back.

Baseball cards.

You are vulnerable

The thing that concerns me is that many readers of this column have big loans to pay back. You may be one. You may feel pressure to put your morals on hold in exchange for some quick and easy money.

You need to know that there are unscrupulous people in this world who will uncover your vulnerability, aided perhaps by some loose talk from you or an casual post on Facebook.

Maybe they will get hold of information from someone who is servicing your student loan. They might learn that you are a little behind on payments, that you could be desperate, maybe willing to turn to them — it's worth a try.

If you do it once, you're hooked. You are then blackmail material. Or they might threaten you or your family. You now work for them, and it will never end.

It will come back

Maybe you work for an employer who bends the rules frequently. If you are the pharmacist of record or the pharmacist in charge, that will come back to bite you.

If you work for or with dishonest people, they will eventually make you dishonest too. It could start out with small things like gaming customer satisfaction scores, but it won't end there. You will eventually be filling questionable scripts to keep your counts up. Or refilling scripts you don't have permission to fill.

If your employer gets fined on a regular basis, that should indicate something is wrong.

I tell my students to ask themselves constantly: "Is this ethical? Is it in the best interest of the patient?" If the answer to either question is no, the obvious question is "Why am I doing it?"

Be careful. You have people depending on you. Do things the right way. Be honest, and insist on honesty in those you work with.

Your career depends on it.

If something sounds too good to be true … It is. DT

Jim "Goose" Rawlings *is a senior pharmacist in central Indiana. E-mail him at redgoose54@gmail.com.*

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