Drug Topics®
October 2014
CE: MOTIVATIONAL INTERVIEWING TECHNIQUES FOR CHRONIC DISEASE MANAGEMENT: FOCUS ON CARDIOVASCULAR DISEASE • OTC: PERSONAL CARE PRODUCTS
VOL. 158 NO. 10

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How retail pharmacies can help health plans 28

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A shot in the arm for anxious patients 46

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Drug Topics®

Voice of the Pharmacist

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2014 RISING

Introducing the new ACCU-CHEK® Aviva Plus system

Dependable Accuracy

ACCU-CHEK Aviva meters and ACCU-CHEK Aviva Plus test strips meet the new tighter ISO standard[1]

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[1] The FDA currently assesses approval based on the previous ISO standard.
[2] Coverage, co-payments, and preferred statuses vary from plan to plan. Lowest co-pay is available for Medicare Part B patients who receive ACCU-CHEK test strips through a Medicare National Mail Order contract supplier or a retail pharmacy that accepts Medicare assignment.

Roche

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2014

RISING STARS

Three women entrepreneurs share their paths to pharmacy success PAGE 30

Staci Hubert, PharmD, co-owner of Ashland Pharmacy, a retail pharmacy, and owner of Silver Street Pharmacy, a closed-door compounding pharmacy, Ashland, Neb.

CPE CREDIT: 2.0 ACPE

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

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COVER STORY

Rising Stars

Professional women can find tremendous career opportunity in pharmacy. Today they're business owners, executives, advocates, and mentors. Here, three successful women show how it's done.

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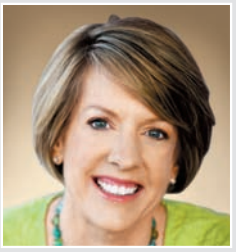

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CPE **CONTINUING EDUCATION**

Motivational interviewing techniques: Focus on CVD

As healthcare providers who are often closest to patients, pharmacists need to know the best way to conduct conversations about healthy lifestyle choices. **PAGE 53**

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DISPENSED AS WRITTEN Oluwole Williams, BS Pharm, 2014 PharmD Candidate

Credit for pharmacy supervisors

Eleven years ago, I began my pharmacy practice experience here in the United States as an intern at a pharmacy in Philadelphia, Penn., after interviewing with the pharmacy manager and his pharmacy district supervisor.

I was green as a pea. I had only very sketchy knowledge of third-party reimbursements, labor overheads, inventory costs, prescription sales and turnover, manpower development, federal statutes and board regulations, business competition, psychology of patient behaviors, and more — all critical indices of pharmacy operations that my supervisor and manager would have been grappling with to ensure an efficient and profitable outcome for the company's business services.

Where the buck stops

The above concerns summarize where the buck stops in most pharmacy stores — at the pharmacy supervisor's desk. And some supervisors may have as many as 12 stores on their watch, for which they are accountable to the corporate home office.

Think of yourself for a moment as the house monitor in a boarding school, watching over four dormitories teeming with teenagers. How do you ensure that everyone participates and that all are present for studies, chores, games, and so on?

The difference between that example and the extreme challenge facing supervisors of pharmacy chain stores nowadays is only a matter of degree. Prescription sales income is in decline; the cost of business operations is eroding net profit; drugs are in short supply; employee output and productivity are down; minimum wages are being raised on a state-by-state basis, hampering business projections; expensive personnel are hired for clinical services, but because of price competition within the industry, return on investment is poor; and erosion of federal Medicare and state Medicaid budgets has overextended an already emaciated financial portfolio.

The hot seat

The case could be made that at this time in U.S. history the role of pharmacy supervision is replete with every imaginable potential disruption of business order.

In my opinion, this is the time to recognize the struggles of pharmacy managers to keep pharmacies open and running smoothly, albeit on a very tight rein.

Most supervisors are our colleagues in pharmacy. We need to share our ideas openly with them, in service to our collective good as healthcare professionals.

What it takes

For a pharmacy supervisor to survive at this time, he/she will need:

1. An honest, dedicated, professional, and creative workforce that knows, understands, and recognizes the current challenges besetting pharmacy businesses in North America.
2. A committed, enthusiastic, and disciplined team of technical/professional staff willing to place company goals/missions above pecuniary gain and personal aggrandizement.
3. Astute regional business managers who negotiate workable agreements at contractor meetings to drive down the expensive costs of operations.
4. Awareness of the need to pay attention to employee recruitment at the level of each individual pharmacy, to prevent the entry of questionable characters whose activities may be lethal to the organization's objectives.
5. The ability to communicate clearly and concisely to all pharmacy employees the company's business ethics, as well as the codes of conduct — including dress code —expected of staff, in the context of the organization's healthcare business image.

The right priorities

Most pharmacy managers and supervisors know only too well that spending expensive dollars on corporate advertising is a poor morale booster if employees are not issued bonuses or raises periodically.

Indeed, whenever they occur, such practices are a potential source of employee disillusionment and are always injurious to the motivational efforts that many supervisors work so hard to sustain.

Similarly, acquisition of high-tech computer software programs at the expense of methodical, timely manpower training or development is a costly retardation of productivity that often leads to major shrinkages in gross profit and business losses.

At this time, the pharmacy supervisor's job of managing a group of pharmacies is no longer an enviable vocation. Customer complaints, shareholder demands for higher dividends, competition from overseas internet pharmacies, declining national economic productivity, and unemployment have compounded the already difficult task of doing business.

Pharmacy district managers and supervisors deserve our collective understanding and support as we all seek to survive in a rapidly flowing river of uncertainties. DT

Oluwole Williams *practices pharmacy in the Philadelphia area. Contact him at pharmwille@yahoo.co.uk.*

A NOVEL TREATMENT WITH AN ALTERNATIVE TO A PROGESTIN

FOR YOUR POSTMENOPAUSAL PATIENTS WITH A UTERUS[1]

Help her put moderate to severe hot flashes as well as bone loss in their place[2]

The first and only treatment of its kind[1]

DUAVEE combines conjugated estrogens (CEs) with the SERM* bazedoxifene (BZA):

- CEs provide significant relief of **moderate to severe hot flashes due to menopause** and prevent postmenopausal osteoporosis[2]
- BZA helps protect the uterine lining from endometrial hyperplasia associated with estrogen-alone treatment[2]

Purposeful pairing of
CONJUGATED ESTROGENS

with the SERM
BAZEDOXIFENE
instead of a progestin

IMPORTANT SAFETY INFORMATION

Women taking DUAVEE should not take progestins, additional estrogens, or additional estrogen agonists/antagonists.

There is an increased risk of endometrial cancer in a woman with a uterus who uses unopposed estrogens. DUAVEE contains bazedoxifene, an estrogen agonist/antagonist that reduces the risk of endometrial hyperplasia that can occur with estrogens and which may be a precursor to endometrial cancer. Adequate diagnostic measures, including directed or random endometrial sampling when indicated, should be undertaken to rule out malignancy in postmenopausal women with undiagnosed persistent or recurring abnormal genital bleeding.

Estrogen therapy should not be used for the prevention of cardiovascular disease or dementia.

The Women's Health Initiative (WHI) estrogen-alone substudy reported increased risks of stroke and deep vein thrombosis (DVT). Should either of these occur or be suspected, DUAVEE should be discontinued immediately.

The WHI Memory Study (WHIMS) estrogen-alone ancillary study of WHI reported an increased risk of probable dementia in postmenopausal women 65 years of age and older.

Estrogen agonists/antagonists, including bazedoxifene, and estrogens individually are known to increase the risk of venous thromboembolism (VTE).

DUAVEE™

CONJUGATED ESTROGENS/
BAZEDOXIFENE 0.45 MG/20 MG TABLETS

DUAVEE is indicated in women with a uterus for the treatment of moderate to severe vasomotor symptoms associated with menopause and the prevention of postmenopausal osteoporosis.

Use DUAVEE for the shortest duration consistent with treatment goals and risks for the individual woman. Postmenopausal women should be re-evaluated periodically, as clinically appropriate, to determine if treatment is still necessary.

When prescribing solely for the prevention of postmenopausal osteoporosis, therapy should only be considered for women at significant risk of osteoporosis, and non-estrogen medication should be carefully considered.

DUAVEE should not be used in women with undiagnosed abnormal uterine bleeding; known, suspected, or past history of breast cancer or estrogen-dependent neoplasia; active or past history of venous or arterial thromboembolism; hypersensitivity to estrogens, bazedoxifene, or any ingredients; known hepatic impairment or disease; known thrombophilic disorders. Women who are or may become pregnant and nursing mothers should not use DUAVEE.

The use of estrogen alone has been reported to result in an increase in abnormal mammograms requiring further evaluation. The effect of treatment with DUAVEE on the risk of breast and ovarian cancer is unknown.

Estrogens increase the risk of gallbladder disease. Discontinue estrogen if loss of vision, severe hypertriglyceridemia, or cholestatic jaundice occurs. Monitor thyroid function in women on thyroid replacement therapy, because estrogen increases thyroid binding globulin (TBG) levels.

Adverse reactions more common in the DUAVEE treatment group in four placebo-controlled studies were muscle spasms, nausea, diarrhea, dyspepsia, abdominal pain upper, oropharyngeal pain, dizziness, and neck pain.

Please see brief summary of Full Prescribing Information, including Boxed Warning, on the following pages.

*Selective estrogen receptor modulator, also known as an estrogen agonist/antagonist. †Based on eligibility. ‡Terms and conditions apply.

References: 1. Kharode Y, Bodine PVN, Miller CP, Lyttle CR, Komm BS. The pairing of a selective estrogen receptor modulator, bazedoxifene, with conjugated estrogens as a new paradigm for the treatment of menopausal symptoms and osteoporosis prevention. *Endocrinology.* 2008;149(12):6084-6091. **2.** DUAVEE [package insert]. New York, NY: Pfizer Inc; 2013.

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Pfizer U.S. Pharmaceuticals

DUAVEE™

CONJUGATED ESTROGENS/
BAZEDOXIFENE 0.45 MG/20 MG TABLETS

BRIEF SUMMARY: This is only a brief summary of prescribing information. For current Full Prescribing Information, please visit www.duaveehcp.com.

WARNING: ENDOMETRIAL CANCER, CARDIOVASCULAR DISORDERS, AND PROBABLE DEMENTIA

Women taking DUAVEE should not take additional estrogens *[see Warnings and Precautions]*.

There is an increased risk of endometrial cancer in a woman with a uterus who uses unopposed estrogens. DUAVEE has been shown to reduce the risk of endometrial hyperplasia, which may be a precursor to endometrial cancer. Adequate diagnostic measures, including directed or random endometrial sampling when indicated, should be undertaken to rule out malignancy in postmenopausal women with undiagnosed persistent or recurring abnormal genital bleeding *[see Warnings and Precautions]*.

Estrogen therapy should not be used for the prevention of cardiovascular disease or dementia *[see Warnings and Precautions]*.

The Women's Health Initiative (WHI) estrogen-alone substudy reported increased risks of stroke and deep vein thrombosis (DVT) in postmenopausal women (50 to 79 years of age) during 7.1 years of treatment with daily oral conjugated estrogens (CE) (0.625 mg)-alone, relative to placebo *[see Warnings and Precautions]*.

The WHI Memory Study (WHIMS) estrogen-alone ancillary study of WHI reported an increased risk of probable dementia in postmenopausal women 65 years of age and older during 5.2 years of treatment with daily CE (0.625 mg)-alone, relative to placebo. It is unknown whether this finding applies to younger postmenopausal women *[see Warnings and Precautions]*.

In the absence of comparable data, these risks should be assumed to be similar for other doses of CE and other dosage forms of estrogens.

Estrogens should be prescribed at the lowest effective doses and for the shortest duration consistent with treatment goals and risks for the individual woman.

INDICATIONS AND USAGE

DUAVEE is indicated in women with a uterus for the treatment of moderate to severe vasomotor symptoms associated with menopause and the prevention of postmenopausal osteoporosis.

Important Limitations of Use

Use DUAVEE for the shortest duration consistent with treatment goals and risks for the individual woman. Postmenopausal women should be re-evaluated periodically as clinically appropriate to determine if treatment is still necessary. When prescribing solely for the prevention of postmenopausal osteoporosis, therapy should only be considered for women at significant risk of osteoporosis and non-estrogen medication should be carefully considered.

CONTRAINDICATIONS

DUAVEE is contraindicated in women with any of the following conditions:

- Undiagnosed abnormal uterine bleeding
- Known, suspected, or past history of breast cancer
- Known or suspected estrogen-dependent neoplasia
- Active DVT, pulmonary embolism (PE), or history of these conditions
- Active arterial thromboembolic disease (for example, stroke, myocardial infarction) or history of these conditions
- Hypersensitivity (for example, anaphylaxis, angioedema) to estrogens, bazedoxifene, or any ingredients
- Known hepatic impairment or disease
- Known protein C, protein S, or antithrombin deficiency or other known thrombophilic disorders
- Pregnancy, women who may become pregnant, and nursing mothers. DUAVEE may cause fetal harm when administered to a pregnant woman. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus

WARNINGS AND PRECAUTIONS

Drugs Containing Progestins, Estrogens or Estrogen Agonist/Antagonists

DUAVEE contains CE and bazedoxifene, an estrogen agonist/antagonist. Women taking DUAVEE should not take progestins, additional estrogens or additional estrogen agonist/antagonists.

Cardiovascular Disorders

Estrogen agonist/antagonists (including bazedoxifene, a component of DUAVEE) and estrogens individually are known to increase the risk of venous thromboembolism (VTE).

An increased risk of stroke and DVT has been reported with estrogen-alone therapy. Should any of these occur or be suspected, DUAVEE should be discontinued immediately.

Risk factors for arterial vascular disease (for example, hypertension, diabetes mellitus, tobacco use, hypercholesterolemia, and obesity) and/or VTE (for example, personal history or family history of VTE, obesity, and systemic lupus erythematosus) should be managed appropriately.

Stroke

In the WHI estrogen-alone substudy, a statistically significant increased risk of stroke was reported in women 50 to 79 years of age receiving daily CE (0.625 mg)-alone compared to women in the same age group receiving placebo (45 versus 33 per 10,000 women-years). The increase in risk was demonstrated in year 1 and persisted.

Subgroup analyses of women 50 to 59 years of age suggest no increased risk of stroke for those women receiving CE (0.625 mg)-alone versus those receiving placebo (18 versus 21 per 10,000 women-years).

Should a stroke occur or be suspected, DUAVEE should be discontinued immediately *[see Contraindications]*.

Coronary Heart Disease

In the WHI estrogen-alone substudy, no overall effect on coronary heart disease (CHD) events (defined as nonfatal myocardial infarction, silent myocardial infarction, or CHD death) was reported in women receiving estrogen-alone compared to placebo.

Subgroup analyses of women 50 to 59 years of age suggest a statistically non-significant reduction in CHD events (CE [0.625 mg]-alone compared to placebo) in women with less than 10 years since menopause (8 versus 16 per 10,000 women-years).

Venous Thromboembolism (VTE)

In the WHI estrogen-alone substudy, the risk of VTE [DVT and PE] was increased for women receiving daily CE (0.625 mg)-alone compared to placebo (30 versus 22 per 10,000 women-years), although only the increased risk of DVT reached statistical significance (23 versus 15 per 10,000 women-years). The increase in VTE risk was demonstrated during the first 2 years.

If feasible, DUAVEE should be discontinued at least 4 to 6 weeks before surgery of the type associated with an increased risk of thromboembolism, or during periods of prolonged immobilization. Because immobilization increases the risk for venous thromboembolic events independent of therapy, DUAVEE should be discontinued prior to and during prolonged immobilization (e.g., post-surgical recovery, prolonged bed rest) and DUAVEE therapy should be resumed only after the patient is fully ambulatory. In addition, women taking DUAVEE should be advised to move about periodically during travel involving prolonged immobilization.

Malignant Neoplasms

Endometrial Cancer

An increased risk of endometrial cancer has been reported with the use of unopposed estrogen therapy in women with a uterus. The reported endometrial cancer risk among unopposed estrogen users is about 2 to 12 times greater than in non-users, and appears dependent on duration of treatment and on estrogen dose. Most studies show no significant increased risk associated with use of estrogens for less than 1 year. The greatest risk appears associated with prolonged use, with increased risks of 15- to 24-fold for 5 to 10 years or more of treatment. This risk has been shown to persist for at least 8 to 15 years after estrogen therapy is discontinued.

DUAVEE contains an estrogen agonist/antagonist. This component reduces the risk of endometrial hyperplasia that can occur with the CE component. Endometrial hyperplasia may be a precursor to endometrial cancer. Women taking DUAVEE should not take additional estrogens as this may increase the risk of endometrial hyperplasia.

Clinical surveillance of all women taking DUAVEE is important. Adequate diagnostic measures, including directed or random endometrial sampling when indicated, should be undertaken to rule out malignancy in postmenopausal women with undiagnosed persistent or recurring abnormal genital bleeding.

Breast Cancer

The most important randomized clinical study providing information about breast cancer in estrogen-alone users is the WHI substudy of daily CE (0.625 mg)-alone. In the WHI estrogen-alone substudy, after an average follow-up of 7.1 years, daily CE (0.625 mg)-alone was not associated with an increased risk of invasive breast cancer (relative risk [RR] 0.80).

The use of estrogen-alone has been reported to result in an increase in abnormal mammograms requiring further evaluation. The effect of treatment with DUAVEE on the risk of breast cancer is unknown.

All women should receive yearly breast examinations by a healthcare provider and perform monthly breast self-examinations. In addition, mammography examinations should be scheduled based on patient age, risk factors, and prior mammogram results.

Ovarian Cancer

In some epidemiological studies, the use of estrogen-only products, in particular for 5 or more years, has been associated with an increased risk of ovarian cancer. However, the duration of exposure associated with increased risk is not consistent across all epidemiologic studies, and some report no association. The effect of treatment with DUAVEE on the risk of ovarian cancer is unknown.

Probable Dementia

In the WHIMS estrogen-alone ancillary study of WHI, a population of 2,947 hysterectomized women 65 to 79 years of age was randomized to daily CE (0.625 mg)-alone or placebo.

After an average follow-up of 5.2 years, 28 women in the estrogen-alone group and 19 women in the placebo group were diagnosed with probable dementia. The relative risk of probable dementia for CE-alone versus placebo was 1.49 (95 percent CI, 0.83-2.66). The absolute risk of probable dementia for CE-alone versus placebo was 37 versus 25 cases per 10,000 women-years *[see Use in Specific Populations]*.

Gallbladder Disease

A 2- to 4-fold increase in the risk of gallbladder disease requiring surgery in postmenopausal women receiving estrogens has been reported.

Visual Abnormalities

Retinal vascular thrombosis has been reported in patients receiving estrogens. Discontinue medication pending examination if there is sudden partial or complete loss of vision, or a sudden onset of proptosis, diplopia, or migraine. If examination reveals papilledema or retinal vascular lesions, DUAVEE should be permanently discontinued.

Elevated Blood Pressure

In a small number of case reports in women receiving estrogens, substantial increases in blood pressure have been attributed to idiosyncratic reactions to estrogens. In a large, randomized, placebo-controlled clinical study, a generalized effect of estrogens on blood pressure was not seen.

Hypertriglyceridemia

In women with pre-existing hypertriglyceridemia, treatment with estrogens may be associated with elevations of plasma triglycerides leading to pancreatitis. Consider discontinuation of DUAVEE if pancreatitis occurs.

Hepatic Impairment and Past History of Cholestatic Jaundice

DUAVEE has not been studied in women with impaired liver function or past history of cholestatic jaundice.

Estrogens may be poorly metabolized in women with impaired liver function.

On average, women with hepatic impairment treated with bazedoxifene alone showed a 4.3-fold increase in overall exposures compared with controls *[see Use in Specific Populations]*.

For women with a history of cholestatic jaundice associated with past estrogen use or with pregnancy, caution should be exercised; and in the case of recurrence, DUAVEE should be discontinued. Use of DUAVEE in patients with hepatic impairment is contraindicated *[see Contraindications]*.

Hypothyroidism

Estrogen administration leads to increased thyroid-binding globulin (TBG) levels. Women with normal thyroid function can compensate for the increased TBG by making more thyroid hormone, thus maintaining free T4 and T3 serum concentrations in the normal range. Women dependent on thyroid hormone replacement therapy who are also receiving estrogens may require increased doses of their thyroid replacement therapy. These women should have their thyroid function monitored in order to maintain their free thyroid hormone levels in an acceptable range.

Fluid Retention

Estrogens may cause some degree of fluid retention. Because of this, patients who have conditions that might be influenced by this factor, such as cardiac dysfunction or renal impairment, warrant careful observation when estrogens are prescribed. Use of DUAVEE in patients with renal impairment is not recommended *[see Use in Specific Populations]*.

Hypocalcemia

Estrogen therapy should be used with caution in women with hypoparathyroidism as estrogen-induced hypocalcemia may occur.

Hereditary Angioedema

Exogenous estrogens may exacerbate symptoms of angioedema in women with hereditary angioedema.

Exacerbation of Other Conditions

Estrogens may cause an exacerbation of asthma, diabetes mellitus, epilepsy, migraine or porphyria, systemic lupus erythematosus, and hepatic hemangiomas and should be used with caution in women with these conditions.

Premenopausal Women

There is no indication for premenopausal use of DUAVEE. The efficacy and safety of DUAVEE in premenopausal women have not been established, and its use is not recommended.

Laboratory Tests

Serum follicle stimulating hormone (FSH) and estradiol levels have not been shown to be useful in the management of moderate to severe vasomotor symptoms.

Drug-Laboratory Test Interactions

Accelerated prothrombin time, partial thromboplastin time, and platelet aggregation time; increased platelet count; increased factors II, VII antigen, VIII antigen, VIII coagulant activity, IX, X, XII, VII-X complex, II-VII-X complex, and beta-thromboglobulin; decreased levels of antifactor Xa and antithrombin III, decreased antithrombin III activity; increased levels of fibrinogen and fibrinogen activity; increased plasminogen antigen and activity.

Increased thyroid-binding globulin (TBG) leading to increased circulating total thyroid hormone, as measured by protein-bound iodine (PBI), T4 levels (by column or by radioimmunoassay), or T3 levels by radioimmunoassay. T3 resin uptake is decreased, reflecting the elevated TBG. Free T4 and free T3 concentrations are unaltered. Women on thyroid replacement therapy may require higher doses of thyroid hormone.

Other binding proteins may be elevated in serum, for example, corticosteroid binding globulin (CBG), sex hormone-binding globulin (SHBG), leading to increased total circulating corticosteroids and sex steroids, respectively. Free hormone concentrations, such as testosterone and estradiol, may be decreased. Other plasma proteins may be increased (angiotensinogen/renin substrate, alpha-1-antitrypsin, ceruloplasmin).

Increased plasma high-density lipoprotein (HDL) and HDL2 cholesterol subfraction concentrations, reduced low-density lipoprotein (LDL) cholesterol concentrations, increased triglyceride levels.

Impaired glucose tolerance.

ADVERSE REACTIONS
The following adverse reactions are discussed in greater detail in other sections of the label:
- Cardiovascular Disorders *[see Warnings and Precautions]*
- Malignant Neoplasms *[see Warnings and Precautions]*
- Gallbladder Disease *[see Warnings and Precautions]*
- Hypertriglyceridemia *[see Warnings and Precautions]*

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

The safety of CE/bazedoxifene was evaluated in four Phase 3 clinical trials ranging from 12 weeks to 24 months in duration and enrolling 6,210 postmenopausal women age 40 to 75 years (mean age 55 years). A total of 1,224 patients were treated with DUAVEE and 1,069 patients received placebo. Women enrolled in Studies 1 and 2 received calcium (600-1200 mg) and vitamin D (200-400 IU) daily, while women in Studies 3 and 4 received no calcium and vitamin D supplementation as part of the protocol.

The incidence of all-cause mortality was 0.0% in the DUAVEE group and 0.2% in the placebo group. The incidence of serious adverse reactions was 3.5% in the DUAVEE group and 4.8% in the placebo group. The percentage of patients who withdrew from treatment due to adverse reactions was 7.5% in the DUAVEE group and 10.0% in the placebo group. The most common adverse reactions leading to discontinuation were hot flush, abdominal pain upper, and nausea.

The most commonly observed adverse reactions (incidence ≥ 5%) more frequently reported in women treated with DUAVEE than placebo are summarized in the following table.

ADVERSE REACTIONS (INCIDENCE ≥ 5%) MORE COMMON IN THE DUAVEE TREATMENT GROUP IN PLACEBO-CONTROLLED TRIALS

	DUAVEE (N=1224) n (%)	Placebo (N=1069) n (%)
Gastrointestinal disorders		
Nausea	100 (8)	58 (5)
Diarrhea	96 (8)	57 (5)
Dyspepsia	84 (7)	59 (6)
Abdominal pain upper	81 (7)	58 (5)
Musculoskeletal and connective tissue disorders		
Muscle spasms	110 (9)	63 (6)
Neck pain	62 (5)	46 (4)
Nervous system disorders		
Dizziness	65 (5)	37 (3)
Respiratory, thoracic, and mediastinal disorders		
Oropharyngeal pain	80 (7)	61 (6)

Venous thromboembolism: In the clinical studies with DUAVEE, the reporting rates for venous thromboembolism (deep venous thrombosis, pulmonary embolism, and retinal vein thrombosis) were low in all treatment groups. Adverse reactions of venous thromboembolism were reported in 0.0% of patients treated with DUAVEE and 0.1% of patients treated with placebo. Due to the low rate of events in both groups, it is not possible to conclude that the risk of venous thromboembolism with DUAVEE is different from that seen with other estrogen therapies *[see Warnings and Precautions]*.

DRUG INTERACTIONS
No drug interaction studies were conducted with DUAVEE. Results from *in vitro* and *in vivo* studies and clinical studies conducted with the CE or bazedoxifene components of DUAVEE are noted below:

Cytochrome P450 (CYP)
In vitro and *in vivo* studies have shown that estrogens are metabolized partially by cytochrome P450 3A4 (CYP3A4). Therefore, inducers or inhibitors of CYP3A4 may affect estrogen drug metabolism. Inducers of CYP3A4, such as St. John's Wort (*Hypericum perforatum*) preparations, phenobarbital, carbamazepine, and rifampin, may reduce plasma concentrations of estrogens, possibly resulting in a decrease in therapeutic effects and/or changes in the uterine bleeding profile.

Inhibitors of CYP3A4, such as erythromycin, clarithromycin, ketoconazole, itraconazole, ritonavir and grapefruit juice, may increase the exposure of CE resulting in an increased risk of endometrial hyperplasia. Therefore, for chronically administered CYP3A4 inhibitors (>30 days) concurrently administered with DUAVEE, adequate diagnostic measures, including directed or random endometrial sampling when indicated by signs and symptoms of endometrial hyperplasia, should be undertaken to rule out malignancy in postmenopausal women with undiagnosed persistent or recurring abnormal genital bleeding.

Bazedoxifene undergoes little or no cytochrome P450 (CYP)-mediated metabolism. Bazedoxifene does not induce or inhibit the activities of major CYP isoenzymes. *In vitro* data suggest that bazedoxifene is unlikely to interact with co-administered drugs via CYP-mediated metabolism.

Uridine Diphosphate Glucuronosyltransferase (UGT)
Bazedoxifene undergoes metabolism by UGT enzymes in the intestinal tract and liver. The metabolism of bazedoxifene may be increased by concomitant use of substances known to induce UGTs, such as rifampin, phenobarbital, carbamazepine, and phenytoin. A reduction in bazedoxifene exposure may be associated with an increased risk of endometrial hyperplasia. Adequate diagnostic measures, including directed or random endometrial sampling when indicated, should be undertaken to rule out malignancy in postmenopausal women with undiagnosed persistent or recurring abnormal genital bleeding.

Atorvastatin
Concomitant administration of bazedoxifene (40 mg daily) and atorvastatin (20 mg, single-dose) to healthy postmenopausal women did not affect the pharmacokinetics of bazedoxifene, atorvastatin or its active metabolites.

USE IN SPECIFIC POPULATIONS
Pregnancy Pregnancy Category X *[see Contraindications]*

DUAVEE must not be used in women who are or may become pregnant.

No studies were performed on animals to evaluate the effects on reproduction with CE/bazedoxifene.

Administration of bazedoxifene to rats at maternally toxic dosages ≥ 1 mg/kg/day (≥ 0.3 times the human area under the curve (AUC) at the 20 mg dose) resulted in reduced numbers of live fetuses and/or reductions in fetal body weights. No fetal developmental anomalies were observed. In studies conducted with pregnant rabbits treated with bazedoxifene, abortion and an increased incidence of heart (ventricular septal defect) and skeletal system (ossification delays, misshapen or misaligned bones, primarily of the spine and skull) anomalies in the fetuses were present at maternally toxic dosages of ≥ 0.5 mg/kg/day (2 times the human AUC at the 20 mg dose).

Nursing Mothers
DUAVEE should not be used by lactating women *[see Contraindications]*. It is not known whether this drug is excreted in human milk. Detectable amounts of estrogens have been identified in the milk of mothers receiving CE. Estrogen administration to nursing mothers has been shown to decrease the quantity and quality of the milk.

Pediatric Use
DUAVEE is not indicated for use in children *[see Indications and Usage]*.

Geriatric Use
DUAVEE is not recommended for use in women greater than 75 years of age.

Of the total number of women in phase 3 clinical studies who received DUAVEE, 4.60% (n=224) were 65 years and over. DUAVEE was not studied in women aged 75 and over. No overall differences in safety or effectiveness were observed between women 65-74 years of age and younger women, and other reported clinical experience has not identified differences in responses between the elderly and younger women, but greater sensitivity of some older women cannot be ruled out.

An increased risk of probable dementia in women over 65 years of age was reported in the WHIMS ancillary studies of the WHI using daily CE (0.625 mg).

Renal Impairment
DUAVEE is not recommended for use in patients with renal impairment.

The pharmacokinetics, safety, and efficacy of DUAVEE have not been evaluated in women with renal impairment.

Hepatic Impairment
DUAVEE is contraindicated in patients with hepatic impairment *[see Contraindications]*.

The pharmacokinetics, safety, and efficacy of DUAVEE have not been evaluated in women with hepatic impairment. In a pharmacokinetics study of bazedoxifene 20 mg alone, the Cmax and AUC of bazedoxifene increased 67% and 143%, respectively, in women with mild hepatic impairment (Child Pugh Class A), compared to healthy women. The Cmax and AUC of bazedoxifene increased 32% and 109%, respectively, in women with moderate hepatic impairment (Child Pugh Class B). The Cmax and AUC of bazedoxifene increased 20% and 268%, respectively, in women with severe hepatic impairment (Child Pugh Class C).

No pharmacokinetic studies with CE were conducted in women with hepatic impairment.

Use in Women with Body Mass Index (BMI) > 27 kg/m^2
A 17% reduction in bazedoxifene exposure was predicted in women with BMI > 27 kg/m^2 (N=144) compared to those with BMI ≤ 27 kg/m^2 (N=93) after administration of DUAVEE, based on a population pharmacokinetic model using data from four Phase 1 studies. A reduction in bazedoxifene exposure may be associated with an increased risk of endometrial hyperplasia. Regardless of BMI, adequate diagnostic measures, including directed or random endometrial sampling when indicated, should be undertaken to rule out malignancy in postmenopausal women with undiagnosed persistent or recurring abnormal genital bleeding.

PATIENT COUNSELING INFORMATION See FDA-approved patient labeling (Patient Information).
Venous Thromboembolic Events
Advise patients to immediately report to their physician any signs or symptoms related to venous thrombosis and thromboembolic events *[see Warnings and Precautions]*.

Abnormal Vaginal Bleeding
Inform postmenopausal women of the importance of reporting abnormal vaginal bleeding to their healthcare provider as soon as possible *[see Warnings and Precautions]*.

Possible Serious Adverse Reactions with Estrogen Therapy
Inform postmenopausal women of possible serious adverse reactions of estrogen therapy including Cardiovascular Disorders, Malignant Neoplasms, and Probable Dementia *[see Warnings and Precautions]*.

Possible Less Serious Adverse Reactions with DUAVEE
Inform postmenopausal women of possible less serious but common adverse reactions of DUAVEE therapy such as muscle spasms, nausea, diarrhea, dyspepsia, upper abdominal pain, throat pain, dizziness and neck pain.

Calcium and Vitamin D Intake
Advise patients to add supplemental calcium and/or vitamin D to the diet if daily intake is inadequate.

This brief summary is based on the DUAVEE full prescribing information LAB-0582-1.0, October 2013.

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Inter@ctive

TRENDING NOW

2014 visionaries put patients first

Independent pharmacies are finding ways to thrive in the evolving healthcare landscape. Profiled here are three pharmacists — Tripp Logan, Ben Briggs, and Steve Adkins — who forged their own paths to success.

http://drugtopics.com/2014visionaries

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Twenty years of improving women's health

The FDA's Office of Women's Health recently celebrated its 20th anniversary. Marsha Henderson, assistant commissioner, Office of Women's Health, discusses the agency's priorities.

Using inventory software to streamline supply chains

Dallas Moore, regional director of pharmacy services, Intermountain Utah Valley Regional Medical Center, discusses how his employer uses Aesynt software to manage inventory.

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Voices

What a waste

Re: "Specialty pharmacy: David does the necessary" [David Stanley, View from the Zoo, September]:

A family member brought a patient's drugs in for disposal after he passed away. Included in this pile were 15 bottles of 120 Nexavar tablets, a "specialty" drug for several types of cancer that do not respond to conventional therapy. I discovered that each bottle's acquisition cost is over $10,000. That's more than $150,000 worth of meds.

A call to the specialty pharmacy produced no information as to how I could get this medication to a needy patient. E-mails to several oncologists who prescribe this drug were never answered.

What a waste of resources! First, no one followed this patient to see why there was noncompliance, and second, they continued to send bottle after bottle to the patient. There should be a way not to waste these products, which still have the seal on each bottle.

Mike Miller, RPh
DUNCANSVILLE, PENN.

We need another option

Re: "We're all in this together" [In My View, Jim Rawlings, September].

I am a 2014 grad who is also a career-changer. I want to thank Goose Rawlings for expressing an opinion I hold as well. The current system of training is geared to only certain types of pharmacists who can fit the mold. I went through pharmacy school with a wife and two kids! I cannot go for extended residency training. We need another option.

We *need* to make ASHP and APhA listen to this message. They will not see another dime out of me!

Matthew D. Balish, PharmD
SALISBURY, MD.

Where are the programs?

I graduated 24 years ago with a BS Pharm and would love to further my education and get a PharmD degree. I recently started looking around for a nontraditional PharmD program for practicing pharmacists and was surprised that there are so few to choose from. I found only six nontraditional PharmD programs accredited by ACPE, and the price tag for each one was more than $60,000. Each program requires at least four clinical rotations and about two years of part-time classwork. Some of these programs also require travel a couple times a year to the university where they are offered.

You would think with new pharmacy schools opening up every year that there would be many nontradional programs available for working pharmacists. Maybe ACPE should require all pharmacy schools to offer a nontraditional PharmD program in order to receive accreditation. That might also bring the price down and give us better quality courses that can teach us new skills and help us pass the BCPS once we complete the program.

Ellen Kozlowski
POSTED AT *DRUGTOPICS.COM*

22 years and ouch

Re: "Are legacy pharmacists an endangered species?" [Jim Plagakis, JP at Large, September]:

I am one of those legacy pharmacists, loyal, experienced, and hard-working — and let go after 22+ years of service. What do we do about it? Who is our voice?

Anonymous
POSTED AT *DRUGTOPICS.COM*

Second verse, same as the first

I thought I was reading my own comment; I experienced the same thing after 22+ years of service. Unfortunately, nothing will ever be done about it. So much for honoring your longtime employees ...

Anonymous
POSTED AT *DRUGTOPICS.COM*

Time for a grassroots movement?

Jim, I think you've just created a new column for *DT*: National Pharmacy Ombudsman. The professional organizations are worthless on this issue, so you'd probably get lots of choice work :)

Anonymous
POSTED AT *DRUGTOPICS.COM*

Jump now

Hopefully, some of the younger pharmacists will read the handwriting on the wall *before* it happens to them. They should jump ship now and work for themselves. Some of us in my generation are looking for young pharmacists to take over for us.

Richard McCoy
POSTED AT *DRUGTOPICS.COM*

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.

VIEW FROM THE ZOO David Stanley, RPh

HIPAA in Wonderland

"With the passage of this bill, we will enter a new era. A time when healthcare providers will encounter unnecessary obstacles when they seek information to care for their patients, when law enforcement investigations will be brought to a standstill, and when any healthcare entity can use this new law as an excuse to avoid an unwanted task. I am proud to be a part of this process that will hinder the operations of this country's already overworked and understaffed healthcare workforce."

I am pretty sure that no politician ever said anything like that when the bill we all know as HIPAA was wending its way through Congress, and I'd be willing to bet that President Clinton said no such thing when he signed it into law 18 years ago.

I think we can all agree that no politician in his right mind would be inclined to take a position that favored *blocking* the delivery of healthcare. And I'm sure that the intention behind HIPAA was *not* to provoke conversations like the one I was having with the insurance company help desk. Yet there I was.

Stonewall the provider

"I'm sorry, sir. Healthcare privacy laws prevent us from releasing that information."

"You mean HIPAA? Is that the law we're talking about?"

"That is correct."

"That's funny, because I have a copy of the HIPAA law right here in front of me."

This was my second call to try to resolve my patient's issue, and I had done my homework before I dialed that second time. "And it says right here, 'A covered entity may disclose protected health information for the treatment activities of any healthcare provider and the payment activities of another covered entity.' I'm the treater and you're the payer, so if you'll just answer my question now …"

"Healthcare privacy laws prevent us from releasing that information."

"Did you even hear what I just said?"

It will probably not surprise you to learn that I had to talk to a supervisor's supervisor to get my problem solved, as I'm sure you have had this type of conversation as well.

Defy the police

Nothing seems to frighten the healthcare world more than those five letters. Fear of the "H-word" all too often induces complete paralysis in certain people, as if an instant lifetime trip to a Siberian labor camp would be the fate of anyone who runs afoul of the HIPAA police.

Well, I have news for you. There are no special HIPAA agents lying in wait, watching for you to slip up.

And I wasn't trying to put one over on that help-desk worker. Those words were a direct quote from the actual law, as are these:

"Covered entities may disclose protected health information to law enforcement officials for law enforcement purposes under the following circumstances ... to identify or locate a suspect, fugitive, material witness, or missing person ... in response to a law enforcement official's request for information about a victim or suspected victim of a crime ..."

Seems pretty clear to me. Yet that didn't stop a Daytona Beach nursing home from invoking "privacy laws" to avoid giving information to police investigating a possible sexual assault on a 75-year-old Alzheimer's patient.

Imprison the next of kin

HIPAA's relationship to law enforcement, however, seems to depend a great deal on who's interpreting the law.

It was invoked to prevent police from acting in the Daytona Beach case, yet in Springfield, Missouri, it was cited as the reason hospital security went into overdrive to detain a woman who had crossed the line, in their view, by ... wait for it … taking a picture of her own son.

You can watch a video the mother made of her encounter at *http://bit.ly/unlawfuldetain*, and while you do, try to come up with a way that scenario can possibly square with the intention of the people who actually wrote the law.

Better yet, just go read the law yourself — something that apparently far too many people have yet to do. Anyone who actually reads the law will see that HIPAA is never to be used to hinder a patient's care, to protect rapists, or to persecute mothers taking pictures of their children.

Unless they are teaching kids some awfully funny things in law school these days, your chances of ending up in a Siberian work camp for doing your job to help patients are almost zero.

So please, Mr. Help-desk Person, next time I call, would you just answer the question? DT

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

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CVS Caremark changes name, ends tobacco sales early

CVS Caremark Corp. has decided to change its name to CVS Health, repositioning itself as a leader in healthcare innovation through services that include 7,700 community pharmacies, 900 walk-in medical clinics, pharmacy benefit management for some 65 million plan members, and specialty pharmacy services.

More than 100 million people annually take advantage of CVS Health's programs that help patients with chronic disease and connect them with pharmacists for better medication adherence. CVS Health has also forged alliances with doctors and health plans, providing through its pharmacies and medical clinics clinical services, medication counseling, chronic disease monitoring, and wellness programs for its members, a company statement said.

CVS Health also has stopped all tobacco sales at its pharmacies about one month earlier than previously stated.

"Along with the start of CVS Health, the sale of cigarettes and tobacco products at CVS/pharmacy ends today [September 3]," said President and CEO Larry J. Merlo in a prepared statement. "By eliminating cigarettes and tobacco products from sale in our stores, we can make a difference in the health of all Americans."

Sylvia Burwell, Health and Human Services secretary, commended CVS Health for ending tobacco sales one month ahead of the company's original deadline of October 1.

"CVS Health's tobacco-free policy is an unprecedented step in the retail industry and will have an impact in bringing our country closer to achieving a tobacco-free generation," Burwell said in a news release. "We hope others will follow CVS Health's lead."

HHS applauded CVS Health's national smoking cessation program, which includes four key components: an assessment to determine the smoker's readiness to quit, education and tools to help smokers quit, medication support to reduce the desire for tobacco products, and coaching services to prevent relapses.

— Julia Talsma, Content Channel Director

Tobacco purchases declined by 13% in Boston and San Francisco after CVS ended pharmacy tobacco sales.

FREE FLU SHOTS

Walgreens plans to open 27 new health clinics in Texas by year's end

Walgreens will be offering chronic and preventive health services at 13 new pharmacy locations in the Dallas-Fort Worth area by the end of this year. The company opened one new clinic at the end of July and plans 12 more Healthcare Clinics in the Dallas Metropolitan area, according to a company statement.

"Our expansion into Dallas-Fort Worth reflects our continued effort to enhance access to high-quality, affordable care and wellbeing services," said Suzanne Hansen, Walgreens group vice president for Healthcare Clinic. "There is an ever-increasing demand for healthcare resources in today's environment."

This is especially true in Texas, which was one of the states that decided to opt out of Medicaid expansion and the Health Insurance Marketplace under the Affordable Care Act, leaving 2.8 million Texas residents without health insurance, according to the U.S. Department of Health and Human Services.

"If Texas were to implement Medicaid expansion, 92% of all eligible uninsured Texans — or 4.5 million people — might qualify for premium tax credits, Medicaid, or CHIP [Children's Health Insurance Program]," an HHS brief stated.

Walgreens' Healthcare Clinics are also present in the Houston area, and the company plans to open another 14 clinics this year, bringing the number in that region to 29. By the end of 2014 the United States will have more than 400 Walgreens' clinics.

Walgreens' clinics accept most insurance plans, including Medicare and Medicaid. For individuals without insurance coverage, Walgreens offers affordable patient care, the company noted.

Free flu vaccinations

In other news, Walgreens will again provide vouchers for free flu vaccinations for individuals without health insurance or who cannot afford the vaccinations. The company is collaborating with the U.S. Department of Health and Human Services for distribution of the vouchers worth more than $10 million.

The vouchers can be used at any Walgreens pharmacy in the country, in Puerto Rico, and at Duane Reed pharmacies in New York. In addition, some Healthcare Clinics will also accept them.

"Since 2010, more than half a million individuals have received free flu shots and vouchers through this innovative partnership," said J. Nadine Gracia, MD, MSCE, director of the HHS Office of Minority Health. "In the face of persistent disparities in influenza vaccination coverage — especially among adults — this initiative reflects our ongoing commitment to expanding access to important preventive services for our most vulnerable and underserved communities."

— Julia Talsma, Content Channel Director

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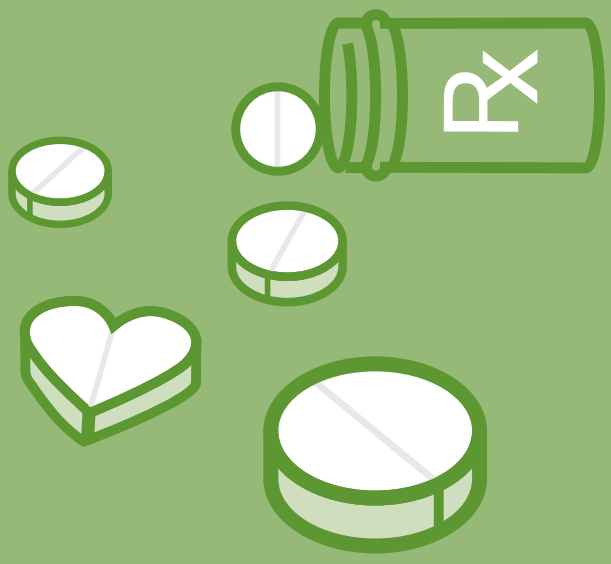

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EXPANDED TAKEBACK

DEA expands drug disposal options

Attorney General Eric Holder has announced a new Drug Enforcement Administration (DEA) regulation that allows pharmacies, hospitals, clinics, and other authorized collectors to accept unused prescription drugs. It took effect on October 9. The new rule also permits long-term-care facilities to accept controlled substances from residents and other consumers and to mail or otherwise return unused medications to authorized collection sites.

Public health crisis

Holder said the changes are an effort to reduce drug abuse, noting that nearly 40% of teenagers who abuse prescription drugs obtain them from their homes. "These shocking statistics illustrate that prescription drug addiction and abuse represent nothing less than a public health crisis," Holder said in a video posted at the U.S. Justice Department's website. "Every day, this crisis touches — and devastates — the lives of Americans from every state, in every region, and from every background and walk of life."

For the past several years, the DEA has held Take Back Days during which people could return unused medications to designated collection sites across the country. So far, more than 4.1 million pounds — or more than 2,100 tons — of prescription pills have been collected.

"The Department of Justice has taken aggressive steps to fight back, by targeting the illegal supply chain; by disrupting 'pill mills'; and by expanding public health, education, and law enforcement efforts," Holder said. "But much of this work must start at home."

Concerns

While supportive, both the National Community Pharmacists Association (NCPA) and the American Pharmacists Association (APhA) have expressed concerns.

"APhA has long supported the role of pharmacists in helping the public get unused or expired medications out of their homes. By expanding safe disposal locations, consumers will have more ways to dispose of their unused prescription medications and help keep them out of the wrong hands," said Thomas E. Menighan, APhA executive vice president and CEO, adding, "While APhA supports the expansion of public access to secure medication disposal options, we are concerned that issues of safety, liability and cost may affect participation of pharmacists and pharmacies."

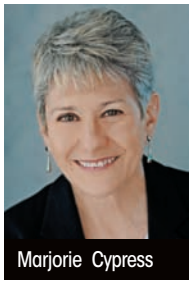
NCPA was still evaluating the new rule. "An initial reading reveals that some of the long-term-care facility issues we had raised about the proposed rule were addressed," said CEO B. Douglas Hoey, RPh, MBA. "In addition, it's important to note the program is completely voluntary for both retail and LTC pharmacies — as NCPA requested and the law required."

— Mark Lowery, Content Editor

DIABETES MANAGEMENT

Takeda, ADA create online resource guide for T2DM management

Takeda Pharmaceuticals and the American Diabetes Association (ADA) have launched ConnecT2Day, an online guide designed to help healthcare providers counsel patients in managing type 2 diabetes.


Marjorie Cypress

"Patients need educational and motivational information as they work each day to manage their disease," said Marjorie Cypress, PhD, C-ANP, CDE, ADA's president, healthcare and education. "Active self-management is key for people living with diabetes, and ConnecT2Day provides practitioners the resources they need to help them better connect and converse with their patients about their health."

The tools

Developed from data provided by providers and patients, ConnecT2Day resources include an online professional engagement portal (*http://professional.diabetes.org/ConnecT2Day_Home.aspx)* that features research findings, dial testing created from focus groups, and downloadable tools such as a Patient Conversation Toolkit. The toolkit provides a pocket reference card to which healthcare providers can refer when talking with diabetes patients, as well as a summary of research findings on the condition.

"Supporting healthcare professionals and patients is of utmost importance to us at Takeda, which is why we are delighted to collaborate with the [ADA] on ConnecT2Day," said Charles Baum, vice president and head, U.S. medical and scientific affairs, Takeda Pharmaceuticals International. "At Takeda, we recognize that healthcare professionals play a critical role in how their patients think about and manage this complex disease."

The tips

One tip offered at the website suggests emphasizing the benefits of better self-management rather than the threat of potential complications. Another tip suggests building trust with patients, as research has shown that patients are more committed to their treatment regimens when they believe their healthcare providers hear and understand them.

The website also suggests providing patients with type 2 diabetes straightforward, factual explanations of what is happening in their bodies, instead of metaphors or analogies.

To create the tips, Takeda and ADA researchers collected real-world messaging used by U.S. healthcare providers and measured that language to determine how it resonated with focus groups.

— Mark Lowery, Content Editor

Up front
In Depth

Christine Blank, Contributing Editor

Triggered by ACA, health-plan changes are mushrooming

The Affordable Care Act (ACA) is drastically changing the way patients and employers pay for healthcare and prescriptions, said speakers at this year's NACDS Total Store Expo, which took place in Boston, Aug. 23–26. And, they pointed out, pharmacists still have a lot to learn about the effects of the ACA on employer health plans.

In fact, when asked whether they understand the major provisions of the ACA, only 5.3% of pharmacists surveyed for a report titled "Research in Social and Administrative Pharmacy" said they "strongly agree."


Katy Spangler

To help shed some light, Katy Spangler, senior vice president of health policy for the American Benefits Council, and Michael Johnsrud, BS Pharm, PhD, senior vice president of Avalere Health PhD, briefed show attendees on aspects of the healthcare legislation in a presentation titled "ACA's Impact on Community Pharmacies."

Higher numbers

For example, Avalere Health predicts that pharmacy-covered enrollment in managed care organizations (MCOs) will increase by 37% between 2013 and 2016. And Express Scripts found that, from January through March, patients enrolled in healthcare exchanges had a 47% greater use of specialty medications than patients enrolled in commercial plans. "[There was] a greater volume in costs due to depression, pain, and seizure medications, and a higher cost-sharing as well. You think about who is using the exchanges: patients who are [having] a little more complex [health issues]," Johnsrud said.

In addition, the Centers for Medicare and Medicaid Services (CMS) estimates that 6.7 million individuals joined Medicaid between January and May of this year, a likely consequence of the ACA. "We are still seeing pretty hefty increases in the Medicaid population. Some of it could be related to the economy… We think it could be the exposure: the marketing and promotion under the ACA," Johnsrud said.

More business

Pharmacists may also obtain more business from Medicare patients because of the ACA. "The way that Medicare is structured to pay physicians, there is a really big emphasis on specialty care. As you see more people get insurance because of the healthcare law, you will see that become more of an issue, in that it is hard to see a primary care doctor," Spangler said.

As a result, policymakers will encourage medication therapy management programs at retail clinics and medical clinics where "you will see pharmacists, physician assistants, and nurse practitioners really practice at the top of their license," Spangler said. "You might see legislation on that at the federal or state level."

Plan changes

Many U.S. employers are changing their employee health benefit plans because they face a 40% excise tax on health coverage in excess of certain thresholds ($10,200 for self-only plans; $27,500 for family plans), which takes effect for taxable years beginning after December 31, 2017.

To avoid incurring the tax, many employers are adopting plans with higher deductibles and out-of-pocket costs. A recent survey from the National Business Group on Health found that there will be a nearly 50% increase in the number of employers who plan to offer a consumer-directed health plan as their only benefit-plan option next year.

"This means that the only plan available to nearly one-third of Americans getting coverage from employers is a high-deductible plan," Spangler said. These patients are also likely to pay 100% of their prescription costs for nonpreventive drugs until they meet their deductibles.

Some employers are also pursuing value-based insurance designs, eliminating or reducing co-pays on high-value prescriptions. Some plans have four or five different pharmacy tiers, in which the consumer is responsible for 25% to 35% of the cost of the specialty drug on the fourth or fifth tier.

A limited number of employers are also bypassing health insurance companies altogether and are contracting directly with providers. For example, in Seattle, Boeing contracts with Providence and the University of Washington for care provided directly to employees.

And, a few years ago, Lowes contracted with Cleveland Clinic for nonemergency heart care for its employees. "The employees loved it, and Lowes got a better value from Cleveland Clinic," Spangler said. "You will see more of these types of innovative [arrangements], as employers look to increase quality and lower cost." DT

Up front
In Depth

Christine Blank, Contributing Editor

PQA launches new quality improvement program

EPIQ (Educating Pharmacists in Quality), a program recently released by the Pharmacy Quality Alliance (PQA), is designed to help community pharmacists focus on issues of quality improvement in their practices.

"Community pharmacy leadership is really starting to understand quality measurement, its importance in the marketplace, why they need to focus on quality improvement, and why they have to meet their quality goals," said Samuel Stolpe, director of quality strategies for PQA. "However, one of the challenges we have seen in community pharmacy is getting the message to the front lines. We are interested in developing efficiencies in getting that message, along with the knowledge and tools to improve quality, delivered straight to the front lines."


Samuel Stolpe

The training program can be used to improve quality and raise Medicare Part D Star Ratings.

"Health insurers are using community pharmacies to improve their Star Ratings, partnering with them to target their quality goals. The onus is on community pharmacies to make sure they understand and address their quality numbers. Medication adherence, medication use, and safety measures account for a fairly substantial part — 50% — of Star Ratings, so focusing on pharmacy quality is essential," Stolpe said.

CE training modules

To that end, PQA's new EPIQ training program, available for free download from the PQA website (*www.PQAalliance.org*), is designed to train pharmacists, healthcare professionals, and pharmacy students in methods to measure, improve, and report the quality of care in pharmacy practice.

The EPIQ program is set up as 26 continuing education (CE) modules, each one featuring an online unit and corresponding training video.

"We have also grouped modules by pharmacy practice sector, with eight modules recommended for community pharmacy," Stolpe said.

Pharmacy schools can download the modules in full for live CE or professional development training. According to a statement from PQA, "EPIQ materials are available for pharmacy faculty and students as a turnkey, 26-session course, which can either be used in its entirety as one-hour lectures within a full-semester course or separated into individual sessions to be integrated into an existing class."

Educational versatility

"EPIQ contains educational resources that can be used by individual pharmacists, preceptors, or pharmacy educators," said lead developer Terri Warholak, PhD, RPh, associate professor and investigator in the Center for Health Outcomes and Pharmacoeconomic Research at the University of Arizona College of Pharmacy.


Terri Warholak

The EPIQ modules are also designed for pharmacy school students, "who need to be able to understand quality standards and hit the ground running once they enter practice," Stolpe said. "This is part of the way we are doing business now as pharmacists. "

The program sessions are tailored for use in a variety of settings, including community pharmacies, health systems, and managed-care settings.

"Its major subsections cover the critical quality topics facing today's practitioner, such as quality improvement, medication safety and error reduction, and quality measures," Warholak said.

Modules include subject areas such as "Understanding problems in the use of medications," "The business case for pharmacy quality," "What is quality improvement?" "Statistical process control," "Team building," "EQUIPP and pharmacy quality reporting," "Medication errors prevention lab," and "Health information technology and quality."

Each session contains a PowerPoint lecture, an instructor guide, an interactive activity set, and assessment questions.

Successful launch

PQA introduced the EPIQ program at NACDS's Total Store Expo conference in August.

"We met with quite a few leaders and had remarkable success. There is a lot of excitement around this training, since many pharmacy executives are exploring how to get quality improvement tools into the hands of their pharmacists," Stolpe said.

To download individual EPIQ modules or take the course online, visit *www.PQAalliance.org*. Practicing pharmacists who register for CE credit by entering their NABP numbers will be directed to the EPIQ portal. DT

During this flu season, you have an opportunity to help protect more of your adult patients against herpes zoster

Actor portrayal.

The CDC suggests vaccinating patients against zoster when they're in for their flu vaccine visits[1]

ZOSTAVAX is recommended for patients aged ≥60 years at the first available clinical encounter.

About ZOSTAVAX

ZOSTAVAX is a live attenuated virus vaccine indicated for prevention of herpes zoster (shingles) in individuals 50 years of age and older. ZOSTAVAX is not indicated for the treatment of zoster or postherpetic neuralgia. ZOSTAVAX should not be used for prevention of primary varicella infection (Chickenpox).

Select Safety Information

Vaccination with ZOSTAVAX does not result in protection of all vaccine recipients.

ZOSTAVAX is contraindicated in: persons with a history of anaphylactic or anaphylactoid reaction to gelatin, neomycin, or any other component of the vaccine; persons with a history of primary or acquired immunodeficiencies; persons on immunosuppressive therapy; pregnant women or women of childbearing age.

A reduced immune response to ZOSTAVAX was observed in individuals who received concurrent administration of PNEUMOVAX®23 (Pneumococcal Vaccine Polyvalent) and ZOSTAVAX compared with individuals who received these vaccines 4 weeks apart. Consider administration of the two vaccines separated by at least 4 weeks.

Serious vaccine-related adverse reactions that have occurred following vaccination with ZOSTAVAX include asthma exacerbation and polymyalgia rheumatica. Other serious adverse events reported following vaccination with ZOSTAVAX include cardiovascular events (congestive heart failure, pulmonary edema). Common adverse reactions occurring in ≥1% of vaccinated individuals during clinical trials include injection-site reactions (erythema, pain/tenderness, swelling, hematoma, pruritus, warmth) and headache.

Transmission of vaccine virus may occur between vaccinees and susceptible contacts.

Deferral should be considered in acute illness (for example, in the presence of fever) or in patients with active untreated tuberculosis.

Please see the adjacent Brief Summary of the Prescribing Information.

CDC=Centers for Disease Control and Prevention.

Reference: 1. Centers for Disease Control and Prevention (CDC). Prevention of herpes zoster: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Recomm Rep.* 2008;57(RR-5):1–30.

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VACC-1123879-0003 07/14

ZOSTAVAX® (Zoster Vaccine Live)

BRIEF SUMMARY OF PRESCRIBING INFORMATION

INDICATIONS AND USAGE

ZOSTAVAX is a live attenuated virus vaccine indicated for prevention of herpes zoster (shingles) in individuals 50 years of age and older.

Limitations of Use of ZOSTAVAX:

- ZOSTAVAX is not indicated for the treatment of zoster or postherpetic neuralgia (PHN).
- ZOSTAVAX is not indicated for prevention of primary varicella infection (Chickenpox).

CONTRAINDICATIONS

Hypersensitivity: Do not administer ZOSTAVAX to individuals with a history of anaphylactic/anaphylactoid reaction to gelatin, neomycin or any other component of the vaccine. Neomycin allergy manifested as contact dermatitis is not a contraindication to receiving this vaccine.

Immunosuppression: ZOSTAVAX is a live, attenuated varicella-zoster vaccine and administration may result in disseminated disease in individuals who are immunosuppressed or immunodeficient. Do not administer ZOSTAVAX to immunosuppressed or immunodeficient individuals including those with a history of primary or acquired immunodeficiency states, leukemia, lymphoma or other malignant neoplasms affecting the bone marrow or lymphatic system, AIDS or other clinical manifestations of infection with human immunodeficiency viruses, and those on immunosuppressive therapy.

Pregnancy: Do not administer ZOSTAVAX to pregnant women. It is not known whether ZOSTAVAX can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. However, naturally occurring varicella-zoster virus (VZV) infection is known to sometimes cause fetal harm. Therefore, ZOSTAVAX should not be administered to pregnant women, and pregnancy should be avoided for 3 months following administration of ZOSTAVAX.

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions: Serious adverse reactions, including anaphylaxis, have occurred with ZOSTAVAX. Adequate treatment provisions, including epinephrine injection (1:1,000), should be available for immediate use should an anaphylactic/anaphylactoid reaction occur.

Transmission of Vaccine Virus: Transmission of vaccine virus may occur between vaccinees and susceptible contacts.

Concurrent Illness: Deferral should be considered in acute illness (for example, in the presence of fever) or in patients with active untreated tuberculosis.

Limitations of Vaccine Effectiveness: Vaccination with ZOSTAVAX does not result in protection of all vaccine recipients.

The duration of protection beyond 4 years after vaccination with ZOSTAVAX is unknown. The need for revaccination has not been defined.

ADVERSE REACTIONS

The most frequent adverse reactions, reported in ≥1% of subjects vaccinated with ZOSTAVAX, were headache and injection-site reactions.

Clinical Trials Experience: Because clinical trials are conducted under widely varying conditions, rates of adverse reactions observed in the clinical trials of a vaccine cannot be directly compared to rates in the clinical trials of another vaccine and may not reflect the rates observed in practice.

ZOSTAVAX Efficacy and Safety Trial (ZEST) in Subjects 50 to 59 Years of Age: In the ZEST study, subjects received a single dose of either ZOSTAVAX (N=11,184) or placebo (N=11,212). The racial distribution across both vaccination groups was similar: White (94.4%); Black (4.2%); Hispanic (3.3%) and Other (1.4%) in both vaccination groups. The gender distribution was 38% male and 62% female in both vaccination groups. The age distribution of subjects enrolled, 50 to 59 years, was similar in both vaccination groups. All subjects received a vaccination report card (VRC) to record adverse events occurring from Days 1 to 42 postvaccination.

In the ZEST study, serious adverse events occurred at a similar rate in subjects vaccinated with ZOSTAVAX (0.6%) or placebo (0.5%) from Days 1 to 42 postvaccination.

In the ZEST study, all subjects were monitored for adverse reactions. An anaphylactic reaction was reported for one subject vaccinated with ZOSTAVAX.

Most Common Adverse Reactions and Experiences in the ZEST Study: The overall incidence of vaccine-related injection-site adverse reactions within 5 days post-vaccination was greater for subjects vaccinated with ZOSTAVAX as compared to subjects who received placebo (63.6% for ZOSTAVAX and 14.0% for placebo). Injection-site adverse reactions occurring at an incidence ≥1% within 5 days post-vaccination are shown in Table 1.

Table 1
Injection-Site Adverse Reactions Reported in ≥1% of Adults Who Received ZOSTAVAX or Placebo Within 5 Days Post-Vaccination in the ZOSTAVAX Efficacy and Safety Trial

Injection-Site Adverse Reaction	ZOSTAVAX (N = 11094) %	Placebo (N = 11116) %
*Solicited**		
Pain	53.9	9.0
Erythema	48.1	4.3
Swelling	40.4	2.8
Unsolicited		
Pruritis	11.3	0.7
Warmth	3.7	0.2
Hematoma	1.6	1.6
Induration	1.1	0.0

*Solicited on the Vaccination Report Card

Systemic adverse reactions and experiences reported during Days 1-42 at an incidence of ≥1% in either vaccination group were headache (ZOSTAVAX 9.4%, placebo 8.2%) and pain in the extremity (ZOSTAVAX 1.3%, placebo 0.8%), respectively.

The overall incidence of systemic adverse experiences reported during Days 1-42 was higher for ZOSTAVAX (35.4%) than for placebo (33.5%).

Shingles Prevention Study (SPS) in Subjects 60 Years of Age and Older: In the SPS, the largest clinical trial of ZOSTAVAX, subjects received a single dose of either ZOSTAVAX (n=19,270) or placebo (n=19,276). The racial distribution across both vaccination groups was similar: White (95%); Black (2.0%); Hispanic (1.0%) and Other (1.0%) in both vaccination groups. The gender distribution was 59% male and 41% female in both vaccination groups. The age distribution of subjects enrolled, 59-99 years, was similar in both vaccination groups.

The Adverse Event Monitoring Substudy of the SPS, designed to provide detailed data on the safety profile of the zoster vaccine (n=3,345 received ZOSTAVAX and n=3,271 received placebo) used vaccination report cards (VRC) to record adverse events occurring from Days 0 to 42 postvaccination (97% of subjects completed VRC in both vaccination groups). In addition, monthly surveillance for hospitalization was conducted through the end of the study, 2 to 5 years postvaccination.

The remainder of subjects in the SPS (n=15,925 received ZOSTAVAX and n=16,005 received placebo) were actively followed for safety outcomes through Day 42 postvaccination and passively followed for safety after Day 42.

Serious Adverse Events Occurring 0-42 Days Postvaccination: In the overall SPS study population, serious adverse events occurred at a similar rate (1.4%) in subjects vaccinated with ZOSTAVAX or placebo.

In the AE Monitoring Substudy, the rate of SAEs was increased in the group of subjects who received ZOSTAVAX as compared to the group of subjects who received placebo (Table 2).

Table 2
Number of Subjects with ≥1 Serious Adverse Events (0-42 Days Postvaccination) in the Shingles Prevention Study

Cohort	ZOSTAVAX n/N %	Placebo n/N %	Relative Risk (95% CI)
Overall Study Cohort (60 years of age and older)	255/18671 1.4%	254/18717 1.4%	1.01 (0.85, 1.20)
60-69 years old	113/10100 1.1%	101/10095 1.0%	1.12 (0.86, 1.46)
70-79 years old	115/7351 1.6%	132/7333 1.8%	0.87 (0.68, 1.11)
≥80 years old	27/1220 2.2%	21/1289 1.6%	1.36 (0.78, 2.37)
AE Monitoring Substudy Cohort (60 years of age and older)	64/3326 1.9%	41/3249 1.3%	1.53 (1.04, 2.25)
60-69 years old	22/1726 1.3%	18/1709 1.1%	1.21 (0.66, 2.23)
70-79 years old	31/1383 2.2%	19/1367 1.4%	1.61 (0.92, 2.82)
≥80 years old	11/217 5.1%	4/173 2.3%	2.19 (0.75, 6.45)

N=number of subjects in cohort with safety follow-up
n=number of subjects reporting an SAE 0-42 Days postvaccination

Among reported serious adverse events in the SPS (Days 0 to 42 postvaccination), serious cardiovascular events occurred more frequently in subjects who received ZOSTAVAX (20 [0.6%]) than in subjects who received placebo (12 [0.4%]) in the AE Monitoring Substudy. The frequencies of serious cardiovascular events were similar in subjects who received ZOSTAVAX (81 [0.4%]) and in subjects who received placebo (72 [0.4%]) in the entire study cohort (Days 0 to 42 postvaccination).

Serious Adverse Events Occurring Over the Entire Course of the Study: Rates of hospitalization were similar among subjects who received ZOSTAVAX and subjects who received placebo in the AE Monitoring Substudy, throughout the entire study.

Fifty-one individuals (1.5%) receiving ZOSTAVAX were reported to have congestive heart failure (CHF) or pulmonary edema compared to 39 individuals (1.2%) receiving placebo in the AE Monitoring Substudy; 58 individuals (0.3%) receiving ZOSTAVAX were reported to have congestive heart failure (CHF) or pulmonary edema compared to 45 (0.2%) individuals receiving placebo in the overall study.

In the SPS, all subjects were monitored for vaccine-related SAEs. Investigator-determined, vaccine-related serious adverse experiences were reported for 2 subjects vaccinated with ZOSTAVAX (asthma exacerbation and polymyalgia rheumatica) and 3 subjects who received placebo (Goodpasture's syndrome, anaphylactic reaction, and polymyalgia rheumatica).

Deaths: The incidence of death was similar in the groups receiving ZOSTAVAX or placebo during the Days 0-42 postvaccination period; 14 deaths occurred in the group of subjects who received ZOSTAVAX and 16 deaths occurred in the group of subjects who received placebo. The most common reported cause of death was cardiovascular disease (10 in the group of subjects who received ZOSTAVAX, 8 in the group of subjects who received placebo). The overall incidence of death occurring at any time during the study was similar between vaccination groups: 793

ZOSTAVAX® (Zoster Vaccine Live)

BRIEF SUMMARY OF PRESCRIBING INFORMATION (*continued*)

deaths (4.1%) occurred in subjects who received ZOSTAVAX and 795 deaths (4.1%) in subjects who received placebo.

Most Common Adverse Reactions and Experiences in the AE Monitoring Substudy of the SPS: Injection-site adverse reactions reported at an incidence ≥1% are shown in Table 3. Most of these adverse reactions were reported as mild in intensity. The overall incidence of vaccine-related injection-site adverse reactions was significantly greater for subjects vaccinated with ZOSTAVAX versus subjects who received placebo (48% for ZOSTAVAX and 17% for placebo).

Table 3
Injection-Site Adverse Reactions* in ≥1% of Adults Who Received ZOSTAVAX or Placebo Within 5 Days Postvaccination from the AE Monitoring Substudy of the Shingles Prevention Study

Adverse Reaction	ZOSTAVAX (N = 3345) %	Placebo (N = 3271) %
Solicited†		
Erythema	35.6	6.9
Pain/Tenderness	34.3	8.3
Swelling	26.1	4.5
Unsolicited		
Hematoma	1.6	1.4
Pruritis	6.9	1.0
Warmth	1.6	0.3

*Patients instructed to report adverse experiences on a Vaccination Report Card
†Solicited on the Vaccination Report Card

Headache was the only systemic adverse reaction reported on the vaccine report card between Days 0-42 by ≥1% of subjects in the AE Monitoring Substudy in either vaccination group (ZOSTAVAX 1.4%, placebo 0.8%).

The numbers of subjects with elevated temperature (≥38.3ºC [≥101.0ºF]) within 42 days postvaccination were similar in the ZOSTAVAX and the placebo vaccination groups [27 (0.8%) vs. 27 (0.9%), respectively].

The following adverse experiences in the AE Monitoring Substudy of the SPS (Days 0 to 42 postvaccination) were reported at an incidence ≥1% and greater in subjects who received ZOSTAVAX than in subjects who received placebo, respectively: respiratory infection (65 [1.9%] vs. 55 [1.7%]), fever (59 [1.8%] vs. 53 [1.6%]), flu syndrome (57 [1.7%] vs. 52 [1.6%]), diarrhea (51 [1.5%] vs. 41 [1.3%]), rhinitis (46 [1.4%] vs. 36 [1.1%]), skin disorder (35 [1.1%] vs. 31 [1.0%]), respiratory disorder (35 [1.1%] vs. 27 [0.8%]), asthenia (32 [1.0%] vs. 14 [0.4%]).

VZV Rashes Following Vaccination: Within the 42-day postvaccination reporting period in the ZEST, noninjection-site zoster-like rashes were reported by 34 subjects (19 for ZOSTAVAX and 15 for placebo). Of 24 specimens that were adequate for Polymerase Chain Reaction (PCR) testing, wild-type VZV was detected in 10 (3 for ZOSTAVAX, 7 for placebo) of these specimens. The Oka/Merck strain of VZV was not detected from any of these specimens. Of reported varicella-like rashes (n=124, 69 for ZOSTAVAX and 55 for placebo), 23 had specimens that were available and adequate for PCR testing. VZV was detected in one of these specimens in the ZOSTAVAX group; however, the virus strain (wild-type or Oka/Merck strain) could not be determined.

Within the 42-day postvaccination reporting period in the SPS, noninjection-site zoster-like rashes were reported by 53 subjects (17 for ZOSTAVAX and 36 for placebo). Of 41 specimens that were adequate for Polymerase Chain Reaction (PCR) testing, wild-type VZV was detected in 25 (5 for ZOSTAVAX, 20 for placebo) of these specimens. The Oka/Merck strain of VZV was not detected from any of these specimens.

Of reported varicella-like rashes (n=59), 10 had specimens that were available and adequate for PCR testing. VZV was not detected in any of these specimens.

In clinical trials in support of the initial licensure of the frozen formulation of ZOSTAVAX, the reported rates of noninjection-site zoster-like and varicella-like rashes within 42 days postvaccination were also low in both zoster vaccine and placebo recipients. Of 17 reported varicella-like rashes and non-injection site zoster-like rashes, 10 specimens were available and adequate for PCR testing, and 2 subjects had varicella (onset Day 8 and 17) confirmed to be Oka/Merck strain.

Postmarketing Experience

The following additional adverse reactions have been identified during postmarketing use of ZOSTAVAX. Because these reactions are reported voluntarily from a population of uncertain size, it is generally not possible to reliably estimate their frequency or establish a causal relationship to the vaccine.

Gastrointestinal disorders: nausea
Infections and infestations: herpes zoster (vaccine strain)
Skin and subcutaneous tissue disorders: rash
Musculoskeletal and connective tissue disorders: arthralgia; myalgia
General disorders and administration site conditions: injection-site rash; pyrexia; injection-site urticaria; transient injection-site lymphadenopathy
Immune system disorders: hypersensitivity reactions including anaphylactic reactions

Reporting Adverse Events: The U.S. Department of Health and Human Services has established a Vaccine Adverse Event Reporting System (VAERS) to accept all reports of suspected adverse events after the administration of any vaccine. For information or a copy of the vaccine reporting form, call the VAERS toll-free number at 1-800-822-7967 or report online to **www.vaers.hhs.gov**.

DRUG INTERACTIONS

Concomitant Administration with Other Vaccines: In a randomized clinical study, a reduced immune response to ZOSTAVAX as measured by gpELISA was observed in individuals who received concurrent administration of PNEUMOVAX® 23 (Pneumococcal Vaccine Polyvalent) and ZOSTAVAX compared with individuals who received these vaccines 4 weeks apart. Consider administration of the two vaccines separated by at least 4 weeks *[see Clinical Studies (14.3)]*.

For concomitant administration of ZOSTAVAX with trivalent inactivated influenza vaccine, *[see Clinical Studies (14.3)]*.

Antiviral Medications: Concurrent administration of ZOSTAVAX and antiviral medications known to be effective against VZV has not been evaluated.

USE IN SPECIFIC POPULATIONS

Pregnancy: Pregnancy Category: Contraindication *[see Contraindications (4.3)]*.

ZOSTAVAX should not be administered to pregnant females since wild-type varicella can sometimes cause congenital varicella infection. Pregnancy should be avoided for three months following vaccination with ZOSTAVAX *[see Contraindications (4.3) and Patient Counseling Information (17)]*.

Pregnancy Registry

From 1995 to 2013, Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., maintained a Pregnancy Registry to monitor fetal outcomes following inadvertent administration of VARIVAX® during pregnancy or within three months prior to conception. In 2006, reports of exposure to two other varicella (Oka/Merck)-containing vaccines, ProQuad® (Measles, Mumps, Rubella and Varicella Virus Vaccine Live) and ZOSTAVAX, were added to the Registry. The Pregnancy Registry has been discontinued. As of March 2011, 811 women with pregnancy outcome information available for analysis were prospectively enrolled following vaccination with VARIVAX, within three months prior to conception or any time during pregnancy. Of these women, 170 were seronegative at the time of exposure and 627 women had an unknown serostatus. The remaining women were seropositive. Nine exposures to either ProQuad or ZOSTAVAX have been reported that met criteria for inclusion into the Registry.

None of the 820 women who received a varicella-containing vaccine delivered infants with abnormalities consistent with congenital varicella syndrome.

All exposures to VARIVAX, ProQuad, or ZOSTAVAX during pregnancy or within three months prior to conception should be reported as suspected adverse reactions by contacting Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., at 1-877-888-4231 or VAERS at 1-800-822-7967 or www.vaers.hhs.gov.

Nursing Mothers: ZOSTAVAX is not indicated in women who are nursing. It is not known whether VZV is secreted in human milk. Therefore, because some viruses are secreted in human milk, caution should be exercised if ZOSTAVAX is administered to a nursing woman.

Pediatric Use: ZOSTAVAX is not indicated for prevention of primary varicella infection (Chickenpox) and should not be used in children and adolescents.

Geriatric Use: The median age of subjects enrolled in the largest (N=38,546) clinical study of ZOSTAVAX was 69 years (range 59-99 years). Of the 19,270 subjects who received ZOSTAVAX, 10,378 were 60-69 years of age, 7,629 were 70-79 years of age, and 1,263 were 80 years of age or older.

CLINICAL STUDIES

Concomitant Use Studies: In a double-blind, controlled substudy, 374 adults in the US, 60 years of age and older (median age = 66 years), were randomized to receive trivalent inactivated influenza vaccine (TIV) and ZOSTAVAX concurrently (N=188), or TIV alone followed 4 weeks later by ZOSTAVAX alone (N=186). The antibody responses to both vaccines at 4 weeks postvaccination were similar in both groups.

In a double-blind, controlled clinical trial, 473 adults, 60 years of age or older, were randomized to receive ZOSTAVAX and PNEUMOVAX 23 concomitantly (N=237), or PNEUMOVAX 23 alone followed 4 weeks later by ZOSTAVAX alone (N=236). At four weeks postvaccination, the VZV antibody levels following concomitant use were significantly lower than the VZV antibody levels following nonconcomitant administration (GMTs of 338 vs. 484 gpELISA units/mL, respectively; GMT ratio = 0.70 [95% CI: 0.61, 0.80]).

PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information).

- Question the patient about reactions to previous vaccines.
- Provide a copy of the patient information (PPI) and discuss any questions or concerns.
- Inform patient of the benefits and risks of ZOSTAVAX, including the potential risk of transmitting the vaccine virus to susceptible individuals, such as immunosuppressed or immunodeficient individuals or pregnant women who have not had chickenpox.
- Instruct patient to report any adverse reactions or any symptoms of concern to their healthcare professional.

For more detailed information, please read the Prescribing Information.

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Up front
In Depth

Julia Talsma, Content Channel Director

Retail pharmacists can help health plans with CMS Star Ratings measures

Starting next year, Medicare health plans that have achieved three, four, or five stars in the Medicare Star Rating system are in a good position to continue to serve their beneficiaries. Health plans that have not scored at least three stars for the last three consecutive years will be vulnerable to elimination from the Medicare system.

The Medicare star rating program, created in 2007 by the Centers for Medicare and Medicaid Services (CMS), enumerated quality measures for health plans to meet and for Medicare beneficiaries to use in making informed decisions about healthcare enrollment. Of the performance measures now in place, half can be directly affected by community pharmacists working with the health plan.

"If anybody can say anything positive about the Affordable Care Act, we are finally putting accountability into the system. We are trying to get all the different health professionals that are operating in silos to start coordinating with each other, with the ultimate focus on better care for the patient," said Dan Benamoz, RPh, founder and CEO of Pharmacy Development Services (PDS), a consulting services company for independent pharmacy owners. "So the government is going to hold people accountable for results."


Dan Benamoz

Weighted performance measures

In 2012, a new weighting system for performance measures was instituted for Medicare Advantage plans and Medicare prescription drug plans. Of the 10 triple-weighted measures, eight are related to medication therapy and can be influenced directly and indirectly by pharmacist interventions. Three measures that pertain to chronic disease management in Medicare Advantage plans are health services measures (Medicare Part C). They include:

- Diabetes care and blood sugar, controlled
- Diabetes care and cholesterol, controlled
- Controlled blood pressure

The five triple-weighted performance measures of the Medicare prescription drug plan (Part D) that pharmacists can influence are:

- High-risk medications in the elderly. This measure is adapted from the HEDIS measure, which involves a list of medications that places adults older than 65 years at high risk of adverse drug-related side effects. It was derived from the Beers criteria and updated in 2012 by the American Geriatrics Society.
- Diabetes treatment for individuals who also need treatment for hypertension. This performance measure demonstrates the percentage of patients with diabetes and hypertension who are receiving a renin-angiotensin system antagonist: ACE inhibitor, angiotensin-receptor blocker, or direct renin inhibitor.
- Medication adherence to oral antidiabetic medications
- Medication adherence to renin-angiotensin system antagonists
- Medication adherence to statins

High medication adherence is defined as more than 80% of days covered by a patient receiving the medications.

Preparing for Star Ratings

Last year, Health Mart launched a series of town hall meetings across the United States, inviting more than 2,500 of its participating pharmacists to learn about value-based reimbursement, the quality measures, and CMS Star Ratings.

This year, Health Mart is offering another series of town hall meetings to focus on the five medication-related quality measures noted above and to help pharmacists create action plans for their practices and communities, said Tony Willoughby, vice president and chief pharmacist, Health Mart.


Tony Willoughby

First, he noted, it is important for pharmacists to leverage the long-term relationships they have with patients and to embrace behavioral coaching to improve outcomes.

"All the Medicare Part D performance measures, whether for medication adherence, the addition of medication, or a suggestion for alternative

therapy, involve a behavioral change for patients. They have to do something differently," Willoughby said. "What we find is that patients who come into our pharmacies are much more open to that type of coaching from pharmacists because of the long-term relationships that they have with them."

This year's ideaShare meeting introduced motivational interviewing techniques to help pharmacists communicate with patients and overcome barriers to medication adherence.

"We have taken pharmacists' testimonials and leveraged those in a playbook released at our meeting that walks them through the patient encounter. In addition to providing education and intervention resources, we also understand the power of coaching. That is why we have formed an exclusive partnership with PDS to offer Health Mart pharmacies access to PDS coaching services," Willoughby said.

Medication synchronization

Medication synchronization — the process of coordinating a patient's medications so that they are filled and dispensed at the same time every month — has been demonstrated to have a positive impact on medication adherence. This in turn will help boost the pharmacy's the medication adherence performance measures for the CMS star rating program.

The average patient with a chronic condition picks up his medication approximately seven to eight times in a 12-month period. With the implementation of a medication synchronization program, the patient picks up his prescriptions approximately 10 to 11 times during the 12-month time frame.

"By taking control of when the prescriptions need to be filled within your store by a certain date, you understand your productivity day by day. This not only frees up time to provide other patient-centered services, but most importantly gives the pharmacist a better view of the patient's pharmacy record to allow the pharmacist to identify medication-related interventions," said Willoughby.

"If a diabetes patient is taking a diabetic medication and a hypertensive agent, but it is not the right one from the guidelines, this is a great opportunity to have that conversation with the patient. It facilitates a lot of positive principles in the way that we practice," he said.

MTM

Benamoz of PDS offers his members the SyncRx medication synchronization program for improved medication adherence and SyncRx+ — a system for increasing the five quality measures by adding a medication therapy management (MTM) component. SynchRx+ allows the pharmacist to do a comprehensive medication review in just seven minutes.

In addition to SyncRx and SyncRx+, Benamoz recommends providing patients with compliance packaging, so that all medications are organized for different administration times.

"Any time you want to change anybody's behavior, you have to make it as simple as possible. That is what compliance packaging is," Benamoz said. "I have yet to meet in five years an owner who wishes he could go back to the old way of dispensing. They all love it. They can organize their workflow and it allows them to shift the bottlenecks to off-peak hours."

Pharmacists who haven't yet implemented medication synchronization need to start by focusing on their Medicare Part D patient population, Benamoz said. He suggested identifying Medicare beneficiaries who are taking 10 or more medications and working with them on medication synchronization.

"Start with 10 to 15 patients when starting a medication synchronization program. To do all your patients overnight is a recipe for failure," he said.

Benchmarking

It is also necessary to examine pharmacy performance using the EQuIPP scores. EQuIPP stands for the Electronic Quality Improvement Platform for Plans and Pharmacies.

According to the authors of a report about the Medicare Star Ratings published in the May/June 2014 *Journal of the American Pharmacists Association*, EQuIPP is a performance information management platform that "brings a level of standardization to the measurement of the quality of medication use and makes this information accessible and easy to understand."

EQuIPP is available to health plans and community pharmacies at *www.equipp.org/default.aspx*.

All the triple-weighted Part D performance measures have been included in EQuIPP, so pharmacists can compare their pharmacy's performance to the performances of other pharmacies in their region or state.

Once pharmacists know the patients who are having difficulty with medication adherence, they can initiate conversations to uncover barriers to adherence and also use motivational interviewing during MTM sessions.

Pharmacists need to rise to the challenge of helping to improve medication adherence — and ultimately the Medicare Star Rating scores, said Benamoz. This will become important as health plans evaluate their pharmacy partners and reward pharmacies that perform well on the Star Ratings measures.

"Independent pharmacists need to embrace change, because that is where most of the opportunities come from," he said. DT

Jill Sederstrom

Rising Stars

Three women entrepreneurs share their paths to pharmacy success

For decades men have outnumbered women in pharmacy, but the tides are shifting, and not only are women in the profession growing in numbers; they're leading the way.

In 1970, according to the Department of Health and Human Services (HHS), women accounted for only 13% of the pharmacy workforce; however, the latest data from the 2009 National Pharmacist Workforce Survey, prepared by the Midwest Pharmacy Workforce Research Consortium, show that by 2009 that number had increased to 46.4%.

It's a trend that is only expected to grow. HHS has estimated that by 2020, a majority — approximately 62% — of active pharmacists will be women.

As the numbers of women practicing pharmacy increase, so do the numbers of women assuming leadership roles in the industry, whether through owning their own stores, assuming corporate roles, or advocating for change in Washington, D.C.

The 2009 National Pharmacist Workforce Survey found that the number of women pharmacists in positions of pharmacy ownership or partnership had grown from 2.3% in 2000 to 8.1% in 2009.

Compensation is also growing. The latest research shows that the median salary for a woman working full-time as a pharmacist is now 92 cents for every dollar a man earns.

Greater opportunity

According to Eden Sulzer, director of the Cardinal Health Women in Pharmacy initiative, as more male pharmacy owners reach retirement age, greater opportunity develops for women to become pharmacy owners.

"There is still a need — and I think a growing need — for people to be able to go into a community pharmacy and get that custom and personal level of care, especially for those who are dealing with chronic conditions," she said. "We decided that, hey, this is a moment in time when we need to jump into this and try some things, and see what we can do to help these women overcome some barriers and some myths around business ownership, and give them some tools to succeed."

Cardinal Health created its Women in Pharmacy initiative to help inspire, facilitate, and support women in all stages of their careers by providing opportunities for education, mentoring, networking, and more to women who want to advance their careers.

"These women — and the women I get to spend my time with who own pharmacies in their communities — really become community leaders, and in urban and rural areas, the community pharmacy is often like the community center," she said. "They have great influence, they are touching people's lives, they are really filling in the gap in the level of care that we are getting."

While new opportunities for leadership and professional education continue to grow for women in pharmacy, some women are already making their mark in the industry, including three women who have found unique avenues through which to bring about positive change in their communities and the profession.


Staci Hubert

Staci Hubert, PharmD

Staci Hubert found her pharmacy mentor even before she earned her high school diploma. Now the Ashland, Neb., pharmacy owner not only advocates for her profession; she also helps other women in the industry reach their own goals.

Her first exposure to community pharmacy came in high school, when she landed a part-time job at Stangel Pharmacy in her small town of Onawa, Iowa. It was clear to Hubert that the pharmacist, Jim Stangel, was integral to the residents' overall healthcare.

"He was really an incredible business owner," she said. "I probably lucked out to begin with by having such a good pharmacist to work with, one who encouraged me to go to pharmacy school."

In college, Hubert explored various forms of pharmacy practice, including chain pharmacy, hospital pharmacy, and even nuclear pharmacy, but when one of the pharmacists she worked with at the hospital asked whether she'd be interested in returning to the community pharmacy setting to work in an independent pharmacy with a view toward ownership, she couldn't pass up the opportunity.

Within two years she had become a partial owner, gradually taking on a larger and larger portion of the business.

"I basically worked into ownership," she said.

Today, with a partner, she owns Ashland Pharmacy, and she opened her own closed-door compounding pharmacy down the street in 2002. Unlike Ashland Pharmacy, the compounding pharmacy isn't open to the public. Instead, it serves its customers over the phone and delivers medications by mail, delivery, or patient pickup from the Ashland Pharmacy location.

"I felt more comfortable opening that up on my own, since I had been running this community pharmacy," Hubert said.

Keys to success

While initially she found the idea of owning her own pharmacy a bit daunting — especially the need to keep up with all the laws and regulations governing independent pharmacies — Hubert said, the key to success is hiring the right people to support the business.

"You don't have to have an accounting degree or a personnel management degree, but you need to hire good people," she said.

Throughout her career she has worked hard at both Ashland Pharmacy and Silver Street Compounding pharmacy to address needs within the community, whether she's selling diabetic shoes or compounding bio-identical hormones in cream or capsule form to replace low hormones in patients with imbalances.

Hubert also has devoted time to her community, serving at one point as the president of Ashland's Chamber of Commerce. She also gives time to her industry. Currently she serves on the Cardinal Health National Retail Advisory Board. And she went to Washington, D.C., this year to speak with lawmakers about the dangers of legislating the use of mail-order pharmacies, as well as about the important role small independent pharmacies can play in a community.

"I think pharmacists, a lot of times, just step back and let whatever is happening to them happen. I think we have to be more vocal," she said.

Mentoring and leadership

Along with other owners of independent pharmacies in the area, Hubert volunteers her time, meeting with pharmacy students who may be considering ownership for themselves.

"It helps to have a support system. We wanted these gals in the pharmacy schools to know that they would have a contact, that we would be there for them if they had any questions," she said.

Through it all, Hubert has also raised a family. She is the devoted mother of three; her youngest is now entering her senior year of high school.

Balancing it all wasn't always easy, Hubert said, but it was always possible.

"I raised my kids through here," she said. "If they were sick, we'd pick them up and they'd come and sleep on the pharmacy floor."

Having an ownership role in the pharmacy also allowed her to schedule her time in the pharmacy around school plays and athletic events, something she tries now to do for her staff as well.

"We can make it work on short staff, so we kind of have a family environment here," she said.


Miranda Rochol

Miranda Rochol

Miranda Rochol never imagined that she'd end up in pharmacy. The Wisconsin resident knew from the time she was in high school that she wanted to be a neonatal nurse practitioner. But after injuring her back while she was in nursing school, Rochol was forced to consider other options.

"I started working as a pharmacy technician because I knew I wanted to do healthcare and I didn't know what else to do," she said.

It might not have been the career she imagined as a teenager, but it became a passion. Rochol, who later went back to school to earn a degree in healthcare administration, soon found herself creating training programs for pharmacy technicians, developing and implementing strategies for Walgreens' electronic prescription program, and helping launch the retail giant's accountable care organizations.

Up through the ranks

Although Rochol started as a pharmacy technician, she was able to move quickly through corporate ranks, thanks to networking and what she describes as her aggressive and persistent nature.

"I also strongly believe that I want to continue to better myself and improve myself, and I love learning new things," she said. "I don't shy away from a challenge, and in fact, I think I tend to shine when there is a challenge."

Less than a year after accepting a job in one of Walgreens' retail stores, she was promoted to the district office, where she developed a training program for her technicians that caught the eye of the corporate home office.

She soon accepted a position within the corporate office's new electronic prescribing department.

"When I started inside that department, we had 100,000 scripts a month, and when I left, we had 10 million scripts a month. It was pretty amazing to see that growth," she said.

She also spent time helping the company launch its ACOs before leaving Walgreens to accept her current position as vice president of product and strategy for Healthcare Data Solutions, a company that specializes in supplying provider organization data to the chain pharmacy, dental, pharma, and healthcare markets.

Unique experience

Her unique experience within the pharmacy industry has helped her in her position today. For instance, her time as a pharmacy technician has helped her understand how critical it is for products to fit into the pharmacy's existing workflow.

"We know our pharmacy product almost has to be so seamless that it's less than half a millisecond, because if our products are going to take one second, that's too long. I would not have directly known that if I had never worked in pharmacy," she said.

Rochol attributes part of her success in the industry to the many wonderful mentors she's had along the way.

"I've learned so much from them," she said.

While most of her mentors were males, Rochol said, she hopes her story illustrates the leadership potential of women in the industry as well.

"I think that there are more opportunities today than there were even 10 years ago for women inside pharmacy, but I strongly believe there's still an opportunity for growth in that area," she said.


Jenna Gresens

Jenna Gresens, RPh

Pharmacy is continually evolving, and Jenna Gresens has fully embraced the process.

The independent pharmacy owner readily incorporates new technology, regularly sets new goals for her pharmacy, Edgerton Pharmacy in Edgerton, Wis., and continues to find ways to improve patient care and attract new customers.

"We like to always have another goal to keep us challenged and motivated and engaged, and keep us visioning," she said.

The first goal for Gresens and her husband, Eric, who is also a pharmacist, was to own their own pharmacy. That goal, Gresens readily admits, was initially more of a passion for her husband.

"He was the one who really had the independent spirit to want to do this," she said.

After they purchased their store in 2003, Gresens' husband ran the pharmacy while Gresens continued to work as a hospital pharmacist. But soon her husband needed more help at the store, and Gresens left her hospital job to join him.

She soon found that she too liked the benefits of independent ownership. And they were also able to start their own family.

"I am kind of a jack-of-all-trades. I prefer to do a little bit

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Rising Stars

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of everything rather than do one thing and get really, really into it. Community pharmacy fits well with my work style, because I am able to do a little bit of everything — and sometimes it's a lot of everything," she said.

Cooperative endeavors

In 2009, the couple joined forces with the owners of several other independent pharmacies to create the RockMed LTC Pharmacy.

The group of pharmacies wanted a way to combine the business each was doing with assisted living facilities and long-term-care facilities.

"We thought if we were able to combine that business into one spot, it would lead to greater efficiencies, so we tried that and it started growing. At that location we are now serving more patients, caring for more patients, than we are doing at any of the other facilities," she said.

Her husband now runs the RockMed LTC Pharmacy while Gresens spends her days leading the team at the Edgerton Pharmacy.

It's the perfect fit for Gresens, who has been able to exercise her artistic side through development of the store's attached gift shop. Over the 12 years since the couple purchased the pharmacy, it has become a regional destination.

The pharmacy building is 14,000 square feet. The previous owner had filled the space by creating a general store of sorts, selling everything from toasters to automotive parts. After doing some research, Gresens found that customers weren't really buying the products, so she decided to refine their selection and focus on gift items.

"We have a lot of greeting cards and candles, fashion, jewelry. We are big on the seasonal décor. And I think we're finally getting to the point where we are able to really refine our selection," she said.

When she isn't at the store or taking care of her children, Gresens can often be found onstage; she serves as a co-founder of the Rock River Repertory Theatre Company.

"It's important to get involved in something you are passionate about. Women in pharmacy don't have to be passionate only about pharmacy. I think just being out there and being present helps build bridges with the community," she said.

For her, business ownership has allowed her to strike a balance — although sometimes an imperfect one — between being a mother and being a pharmacist.

"I would not be able to be the mother that I am, or the business person that I am, if I didn't own my own business and have a little bit of flexibility and autonomy to do what I feel is the best thing to do in the moment," she said. DT

Jill Sederstrom *is a freelance writer based in Kansas City.*

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Third weight-loss drug approved for obese, overweight adults

FDA has approved a third weight-management drug for use by obese and overweight adults who need to lose weight. More than one third of U.S. adults are obese, according to the Centers for Disease Control and Prevention.

Contrave (Orexigen Therapeutics), a pill combining naltrexone HCl and bupropion HCl in an extended-release formulation, joins two other obesity drugs — Belviq (locarserin HCl; Arena/Eisai) and Qysmia (phentermine and topiramate extended-release capsules; Vivus) — as treatment options for obesity.

Contrave can be prescribed for patients with a body mass index (BMI) of 30 kg/m^2 or more and those with a BMI of 27 kg/m^2 or more who have at least one of the following conditions — hypertension, type 2 diabetes, or dyslipidemia — to help them lose excess pounds along with exercise and diet.

Additional treatment options

Lee Kaplan, MD, PhD, is a fellow of The Obesity Society, and director of Obesity, Metabolism, and Nutrition Institute, Massachusetts General Hospital.

"The Obesity Society researchers and clinicians agree that losing weight solely by altering lifestyle changes, while effective for some people, can often be difficult to accomplish, and even more difficult to maintain. Additional treatment strategies, such as antiobesity medications like Contrave, are important tools in the clinician's toolbox for treating obesity," Kaplan said.

Clinical trials

Contrave's efficacy was demonstrated in clinical trials of approximately 4,500 obese and overweight patients who also had weight-related conditions. They were treated for one year. Exercise and diet were part of their treatment regimens. Three different clinical trials showed an average weight loss range of 2% to 5% in a higher percentage of patients who received Contrave than placebo.

Patients prescribed Contrave should be evaluated 12 weeks after starting therapy to determine if they have lost 5% of their baseline weight. The drug should be stopped if this goal of 5% weight loss has not been achieved, according to FDA.

Because it contains the antidepressant bupropion, Contrave carries a boxed warning for suicidal ideation and behavior associated with antidepressants. It also carries a warning of serious neuropsychiatric events that have occurred in individuals taking bupropion for smoking cessation. The drug also should not be used by patients with seizure disorders or with uncontrolled hypertension.

Several post-marketing studies will evaluate risks and interactions. DT

Kathryn Foxhall

FDA panel backs liraglutide for obesity

An FDA advisory committee voted 14 to 1 on September 11 in favor of approval of liraglutide for injection (Novo Nordisk) for chronic weight management in some obese patients.

Committee members called for further study of risks connected with cancer, cardiovascular disease, and other conditions. But they generally agreed with FDA's decision that the drug's weight-loss efficacy has been demonstrated across trials and patient populations, despite the fact that information about the magnitude of the treatment effect is affected by missing data.

Use of the drug is proposed as an adjunct to diet and exercise in adults who have an initial body mass index (BMI) of 30 kg/m^2 or more, or who have a BMI of 27 kg/m^2 or more with at least one weight-related co-morbidity.

In January 2010, FDA approved the drug to improve glycemic control in adult patients with type 2 diabetes, with a maximum approved dose of 1.8 mg daily. It is marketed under the trade name Victoza.

Lack of long-term research

After trials examined several dosage levels, the sponsor submitted data in support of 3-mg daily dose for obesity treatment.

During public testimony, several pleas were made for better treatment options for obesity. But committee members were concerned about the lack of long-term research into the drug's efficacy and safety.

One of the public witnesses who opposed approval, Sammy Almashat, MD, MPH, of the Public Citizen group, said that, among other issues, there is a lack of long-term evidence on cardiovascular risk, and "cardiovascular risks have been consistently seen in diet drugs over time." He noted that a long-term study with Victoza will not be completed for two more years and that the study will be of a lower dose and in a different patient population.

REMS

In its presentation, Novo Nordisk included a plan for a risk evaluation and mitigation strategy (REMS) that informs health professionals about the risk of medullary thyroid cancer and acute pancreatitis, and about appropriate patient selection. The company says it will send a series of letters at intervals to healthcare professionals likely to prescribe liraglutide 3 mg, will provide a website, and will assess the REMS effectiveness at one, two, three, and seven years after approval. DT

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NEW DRUG REVIEW Diana M. Sobieraj, PharmD

New antiplatelet therapy approved for secondary prevention of CVD

In May 2014, FDA approved vorapaxar (Zontivity; Merck, Sharp and Dohme) to decrease thrombotic cardiovascular events in patients with a history of myocardial infarction (MI) or with peripheral arterial disease (PAD).

An antiplatelet, vorapaxar is a first-in-class antagonist on the protease-activated receptor-1 (PAR-1). The major human platelet receptor, PAR-1 is activated by thrombin. Vorapaxar blocks thrombin-mediated activation of PAR-1 without interfering with fibrin cleavage and therefore does not impact the coagulation cascade.

Owing to increased risk of intracranial hemorrhage (ICH), vorapaxar is contraindicated in patients with a history of a stroke, transient ischemic attack, or ICH, as well as in patients with active pathologic bleeding.

Efficacy

The efficacy of vorapaxar was based on a randomized controlled trial (TRA 2P-TIMI 50) of 26,449 patients who were considered to have stable atherosclerotic disease and were receiving standard therapy. Qualifying diagnoses included a history of MI, ischemic stroke, or PAD. The qualifying diagnosis for the majority of enrolled patients was MI (67%); 94% of enrolled patients were taking aspirin and thienopyridine was common, especially among MI patients (78%).

Patients were randomized to receive vorapaxar 2.5 mg daily or placebo. Patients treated with vorapaxar 2.5 mg daily compared to placebo for a median of 30 months had a reduced risk of the composite outcome of death from cardiovascular cause, myocardial infarction, or stroke [hazard ratio (HR) 0.87 (0.80 to 0.94)]. When the individual components of the composite outcome were evaluated separately, only the risk of MI was significantly different between the two treatments, favoring vorapaxar vs. placebo [HR 0.83 (0.74 to 0.93)].

The major secondary outcome was a composite of cardiovascular death, MI, stroke, or urgent revascularization, which was significantly reduced with vorapaxar compared to placebo [HR 0.88 (0.82 to 0.95)].

Death due to any cause was not significantly different between the two groups, [HR 0.95 (0.85 to 1.07)].

Safety

The risk of major or minor bleeding according to GUSTO criteria was significantly greater in patients treated with vorapaxar vs. placebo [HR 1.66 (1.43 to 1.93)]. ICH was also higher in vorapaxar-treated patients compared to placebo [HR 1.94 (1.39 to 2.70)].

In patients with a history of stroke, the rate of ICH was even greater with vorapaxar treatment compared to placebo than in patients without a history of stroke.

An antiplatelet, vorapaxar is a first-in-class antagonist on the protease-activated receptor-1, blocking its thrombin-mediated activation without interfering with fibrin cleavage.

After two years of follow-up, the data safety and monitoring board suggested stopping therapy in patients with a history of stroke due to the higher risk of ICH, hence the current contraindication on the drug label.

Aside from bleeding events, adverse reactions reported in at least 2% of patients treated with vorapaxar and at a rate greater than 10% above the placebo group include anemia, depression, and rashes/eruptions/exanthems. Iron deficiency, retinopathy or retinal disorders, and diplopia/oculomotor symptoms occurred in at least 40% more patients treated with vorapaxar vs. placebo.

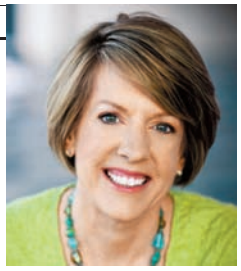
Dosing

Vorapaxar is dosed 2.08 mg daily, which is equivalent to 2.5 mg of vorapaxar sulfate. Vorapaxar should be used in combination with aspirin and/or clopidogrel according to their indications or standard of care, since experience using vorapaxar in other ways is limited.

According to the drug label, vorapaxar should not be used in combination with strong CYP3A inhibitors and inducers.

There are no dose reductions specific to renal insufficiency. Vorapaxar is metabolized by the liver and excreted via the fecal route. No unchanged vorapaxar has been detected in urine. DT

Diana M. Sobieraj *is assistant professor of Pharmacy Practice, University of Connecticut School of Pharmacy, Storrs, Conn.*



ANTICOAGULATION THERAPIES Anna D. Garrett, PharmD, BCPS

Poorly managed anticoagulation may contribute to risk of dementia

Excellent anticoagulation management appears to lower the risk of dementia over the long term in patients with atrial fibrillation (AF). A study of 2,605 patients tracked an average of four years found an inverse relationship between the percentage of time in the therapeutic range (TTR) of international normalized ratio (INR) and long-term risk of a dementia diagnosis in AF patients.

Patients in the study were managed on warfarin with a target INR of 2 to 3. Their mean age was 74, and 54% were male; 30.5% had a $CHADS_2$ score of 0 or 1, and about 70% had a $CHADS_2$ score of 2 or 3.

Over a median of four years of follow-up, the percentage of TTR averaged 63.1%; mean time in INR <2 was 25.6% and mean time in INR >3 was 16.2%. The rate of a dementia diagnosis was 4.2%. The risk of dementia went up 1.7% for each percentage-point increase in time with an INR <2, and by 1.8% for each percentage-point increase in time with an INR >3.

The authors suggested that these results may be due to the possibility that chronic overanticoagulation and underanticoagulation can produce repeated microemboli and microbleeds that may be below detection thresholds of standard brain imaging but eventually contribute to dementia.

Source: Jacobs V, Woller SC, Stevens S, et al. Time outside of therapeutic range in atrial fibrillation patients is associated with long-term risk of dementia. Heart Rhythm *2014. Published online August 8, 2014.* http://bit.ly/ttrAFdement.

Peri-op AF increases long-term risk of stroke

A new study suggests that new-onset perioperative atrial fibrillation during surgery is linked to an increased risk of stroke within a year. New-onset AF is estimated to occur in 1% to 40% of surgeries and is often considered to be a transient response to stress.

Perioperative AF during cardiac surgery has repeatedly been linked with an increased risk of perioperative stroke. However, the risk of ischemic stroke in the long term after new-onset AF during cardiac and noncardiac surgery is unclear.

Of the 1,729,360 eligible patients identified, 24,711 (1.43%) had new-onset perioperative AF during hospitalization and 13,952 (0.81%) experienced an ischemic stroke after discharge, during a mean follow-up of 2.1 years.

Perioperative AF during both cardiac and noncardiac surgery was associated with a greater long-term risk of stroke; however the association of perioperative AF with stroke was significantly stronger with noncardiac surgery.

Source: Gialdini G, Nearing K, Bhave P, et al. Perioperative atrial fibrillation and the long-term risk of ischemic stroke. JAMA. *2014; 312(6):616–622.* http://bit.ly/periopAF.

Discharge aspirin dosing does not match latest U.S. guidelines

American doctors may be putting their myocardial infarction (MI) patients at risk because they have not kept up with changes in practice guidelines pertaining to aspirin dose post-MI. Many U.S. patients who have an MI are discharged with high-dose aspirin, even though the latest evidence-based practice guidelines support the use of low-dose (81 mg) aspirin.

Earlier U.S. guidelines recommended higher doses, but the 2012–2013 guidelines now advocate low-dose aspirin.

Researchers in this study identified 221,199 patients, 40% with STEMI and 60% with non-STEMI, who were seen in 525 centers from 2007 to 2011 and received aspirin on discharge. Most patients (60.9%) received high-dose aspirin; fewer (35.6%) received low-dose aspirin. Patients receiving doses other than 81 mg or 325 mg were excluded from analysis.

Patients undergoing PCI had the highest prevalence of high-dose aspirin at discharge (73%), followed by patients receiving PTCA alone (66%), CABG (48%), and medical management alone (44%). Post-CABG treatment is among the only cardiovascular situations where high-dose aspirin continues to be endorsed by guidelines (100–325 mg daily, class 1A).

Previous U.S. guidelines recommended high-dose aspirin at discharge for patients receiving intracoronary stents, based on protocols from early pivotal stent trials, and these were likely a major contributor to the practice pattern, the researchers said.

Source: Hall HM, de Lemos JA, Enriquez JR, et al. Contemporary patterns of discharge aspirin dosing after acute myocardial infarction in the United States: Results From the National Cardiovascular Data Registry. Circulation: Cardiovascular Quality and Outcomes *2014. Published online before print August 12, 2014.* http://www.ncbi.nlm.nih.gov/pubmed/25116897. 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.*

Julia Talsma, Content Channel Director

New device takes fear out of influenza vaccinations

Adults can protect themselves against flu with a needle-free option

Starting this fall, pharmacists will be able to provide influenza vaccinations to adults 18 to 64 years of age with the first needle-free delivery device approved by FDA.

In mid-August, PharmaJet Inc., the company that developed the technology, and bioCSL Inc., the manufacturer of Afluria, an inactivated influenza vaccine, received FDA approval for the PharmaJet Stratis 0.5mL Needle-Free Jet Injector for administration of Afluria in patients who want protection during this year's flu season.

"We hope that this option can facilitate broader immunization coverage," said James A. Bowman, PharmaJet's president and chief commercial officer, who spoke with *Drug Topics* during the 2014 NACDS Total Store Expo meeting in Boston.

James A. Bowman

"The CDC recommends that all citizens over six months old get a flu shot, but for the last five years the flu vaccine rate has been hovering at about 40%. Of those who forgo immunization, about one-third do so through aversion to or fear of needles," Bowman said.

The CDC's surveillance of influenza vaccination coverage in the United States showed an increase in uptake for adults ≥18 years from 33% in 2007–2008 to 38% in 2011–2012. Influenza vaccination coverage tends to increase as patients reach middle age and retirement age, the CDC reported.

Coverage in the 2011-2012 season was about 26% for young adults between the ages of 18 and 49 years. The rate reached 44% among individuals age 50 to 64 years, and climbed higher to almost 70% in patients age 65 and older. However, this is far below the *Healthy People 2020* target of 70% for all adults 18 years of age and older.

The needle-free PharmaJet Stratis 0.5 mL Jet Injector can be used to administer Afluria vaccine to patients 18-to-64 years old.

How it works

A reusable injector, the PharmaJet device delivers a single dose of Afluria in a disposable cartridge without the need of an external power source. When the PharmaJet is in contact with the patient's upper arm, a steady stream of fluid penetrates the skin, delivering an intramuscular injection in about one-tenth of a second. With a vial adapter, the device can be used with vaccine vials.

During the 2012-2013 influenza season, in one of the largest injector studies ever made, 1,250 individuals received vaccination with Afluria either by means of the needle-free jet injector (627) or by needle and syringe (623).

"The immune response to Afluria given by needle-free injector met the criteria for noninferiority for all six coprimary endpoints," wrote investigator Linda McAllister and her colleagues in a report published online in *The Lancet*.

"The jet injector group met the geometric mean titre criterion for noninferiority for the A/H1N1, A/H2N2, and B strains," McAllister wrote. She noted that the jet injector group also met the seroconversion rate criterion for noninferiority for the three strains.

In the clinical study, participants who received the inactivated influenza vaccination by jet injection experienced more localized reactions than those who received their vaccinations by needle and syringe. Immediate complaints of pain, tenderness, itching, redness, and swelling were more frequent in the jet injector group. However, most were mild reactions that did not prevent daily activities.

In addition to a good safety and acceptability profile for patients, the needle-free jet injector also offers greater safety to vaccine administrators through elimination of possible needlestick injuries.

"With broader use of the PharmaJet injector, we eliminate those needles and the possibility for needle-stick injuries, eliminate the risk of needle reuse or cross-contamination," Bowman said. "So it is safe for the patient and for the caregiver." DT

Dr. Smith's Diaper Rash Spray and Dr. Smith's Rash + Skin Spray sooth irritated tissues gently and easily.

The Always Discreet product line offers adult options that include a panty liner, a pad, and underwear.

IMAGES COURTESY OF MISSION PHARMACAL / PROCTER & GAMBLE

OTC

Undercover in the personal care aisle

JULIANNE STEIN, CONTENT CHANNEL MANAGER

Let's be honest. There are some products that patients are embarrassed to ask for and shoppers bury under their other purchases. These generally correspond to the parts of our anatomy that we keep hidden from public view. It's a cultural thing. And, come to think of it, an aesthetic one. Nonetheless, whether young or old, as long as we inhabit bodies, we will need help keeping them healthy and happy. Fortunately, an array of products has been designed with that in mind. Here are some of the latest.

Diaper rash

For the young of the species, there's **Boudreaux's Butt Paste**, created by a pharmacist and presented in three formulations. **Boudreaux's Original** was designed for use with every diaper change, to prevent and treat rash. It spreads on easily and wipes off quickly, with a pleasant scent that the manufacturer claims "you won't smell on your baby from a mile away." Ingredients include zinc oxide, castor oil, mineral oil, paraffin, petrolatum, and Peruvian balsam. **All-Natural Boudreaux's** was formulated with the enviro-mom in mind. It treats and helps protect against rash using such ingredients as aloe vera, zinc oxide, beeswax, castor oil, citric acid, and Peruvian balsam. Then there's **Maximum Strength Boudreaux's,** which ups the zinc oxide content from 16% to 40%. It still applies and wipes off easily, and has the same pleasant aroma as the other products have. These products can be used liberally and often to make Baby comfortable and fend off diaper rash. They are available at Target, Kmart, and Toys "R" Us, and online at *walmart.com*, *amazon.com*, *drugstore.com*, and other sites. **(www.buttpaste.com)**

Two Mission Pharmacal products also were formulated to address the problem of diaper rash. For babies, **Dr. Smith's Diaper Rash Spray** easily applies, hands-free, to create a moisture barrier that treats diaper rash and protects even the most sensitive skin from wetness. Spraying it on does it all; no need to rub it in and perhaps irritate Baby's tender bottom. The propellant is free of hydrofluorocarbons (HFCs) and volatile organic compounds (VOCs). The spray should not cake or run, and the company says that the technology of the actuator and propellant minimizes the possibility of overspray, as does the product's rich consistency. This new spray is currently available at *Walgreens.com* and *Drugstore.com*, as well as on store shelves at retailers such as Schnucks, Dierbergs, Kroger stores, and others. **(www.doctorsmiths.com)**

For adults, there's **Dr. Smith's Rash+Skin Spray**, to help treat and prevent rashes and skin irritations arising from adult incontinence. It also can relieve chapped or cracked skin, chafing due to skin-on-skin contact, skin irritations associated with athletic activity, and skin irritated from laser dermabrasion or by superficial cuts, scrapes, and burns. This spray uses the same HFC- and VOC-free propellant, said by the manufacturer to be one of the most environmentally preferable aerosol technologies available today. **(www.doctorsmiths.com)**

Continued on pg. 49

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References: 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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Personal care

Continued from pg. 47

Bladder leakage

For women dealing with sensitive bladders and bladder leakage, Procter & Gamble has designed a line of panty liners, pads, and underwear it has dubbed **Always Discreet**. Company literature describes the **liners** as flexible and ultra-thin, with an odor-neutralizer and a leak-resistant core. Very light and ultra-thin versions are available. To stop bladder leaks, the **pads** feature two soft "leakguards," said to absorb twice as much as may be necessary. Like the liners, the pads are very thin and flexible, and have the same capacity to neutralize odor. Users can choose between Moderate, Maximum, and Ultimate options. Constructed in a soft cottonlike fabric, the curve-hugging Always Discreet **underwear** features a three-layer anti-leak core, double leakguards, and odor-less technology. Moderate and Maximum options are available. Always Discreet is available at major supermarkets, pharmacies, and mass retail locations nationwide. **(www.alwaysdiscreet.com)**

While we're on the subject of protective underclothes, more products to consider come from Kimberly-Clark: **Depend for Women Underwear** and **Depend for Men Underwear**, both featuring what the manufacturer has termed Fit-Flex Protection. Styled in small/medium, large, and extra-large, Depend for Women Underwear is specially made to fit comfortably in a slip-on style that features oval-cut leg openings. The Lycra strands in the Fit-Flex Protection ensure a smooth, body-hugging fit. The men's product, Depend for Men Underwear, is available in two sizes, small/medium and large/extra-large, styled with more Lycra strands for a discreet, comfortable, and close-to-body fit. With snug, brief-like leg openings and up-front protection, they pull on and off for easy use. Products are available at major retailers nationwide. **(www.depend.com)**

There is hope for sensitive bladders. One new option is **AZO Bladder Control**, a drug-free dietary supplement that helps users control the urge to urinate. Ingredients include a blend of pumpkin-seed extract and soybean isoflavones, said to help optimize normal bladder activity and strength, which can help alleviate the fear, worry, and potential embarrassment caused by occasional frequent urges. According to company literature, pumpkin seed supports the integrity and function of the bladder muscles, while isoflavones help to relax the bladder muscle and to sustain muscular strength in the pelvic floor — the muscles used to control urinary flow. [*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat ,or cure any disease.*] This product can be found at Walmart, Target, and Walgreens stores nationwide. **(www.azobladder.com)**

The new line of Monistat Complete Care products includes a home test, probiotics, and a long-lasting freshness gel.

Relief and support

Relief for sensitive anatomy also motivated the design of a trio of new products from Insight Pharmaceuticals' new **Monistat Complete Care** line. The **Vaginal Health Test** is a one-step pH test that can determine whether an infection is present and help women decide whether they need to seek care from a healthcare professional. **Probiotics Plus Antioxidants** provide the only antioxidant strains that have been clinically proven to help maintain both urinary tract and vaginal health. Each capsule combines immune-support vitamins A and C with *Lactobacillus reuteri* and *Lactobacillus rhamnosus*, which have shown to be effective in managing recurrent urinary tract infections and recurrent yeast infections. **Stay Fresh Feminine Freshness Gel** is an easy-to-use, odor-neutralizing gel that is specially formulated to maintain vaginal pH balance. One application lasts for up to three days. The three new products join Monistat's Chafing Relief Powder Gel and Instant Itch Relief Cream to round out the Complete Care product line. Available at major retailers nationwide. **(www.monistat.com)** DT

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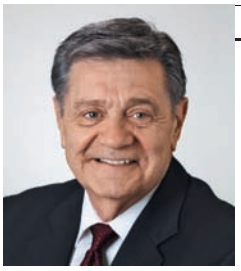

ETHICAL DECISION-MAKING IN PHARMACY Kenneth R. Baker, BS Pharm, JD

Multilingual drug labels required?

When I read Mark Lowery's article "Should states require bilingual drug labels?" [July 31; *http://bit.ly/bilinguallabels*] and the follow-up article, which included comments from pharmacists and pharmacy technicians across the country ["Bilingual drug labels: Pharmacists speak out"; August 11; *http://bit.ly/labelspeakout*], I was intrigued by the dual concepts of quality best practices and government mandates.

The article noted that the "California State Board of Pharmacy is considering new regulations that would require pharmacies throughout the state to provide translated labels on prescription drug bottles." New York passed a similar rule last year.

Such a rule, while well-intentioned, may stifle a better way to accomplish the purpose. Such regulations undoubtably have some benefits. However, compliance will be expensive, the rules will be of only marginal value to most patients, and implementing them might expose pharmacies to legal risks.

Who benefits?

Proponents of the label changes believe they would make prescription drug use easier to manage for state residents who do not speak English. An estimated 44% of California residents speak a language other than English at home.

In Arizona, where I live, ballots are printed in both Spanish and English. That makes sense, but it is of no value for voters whose first language is French or Vietnamese or one of many African languages.

Voting is not a matter for private business. It is a function of government, and it is up to government workers to devise the best system to accomplish the goals of government.

Who decides?

Who is to decide how a pharmacy can best communicate with its patients? The answer is that it is the patients who can best make that decision.

At one pharmacy in Minnesota, the first language on the after-hours telephone message is Hmong (*www.sunpharmacymn.com*). (There are other Hmong-speaking pharmacies in Minnesota, as well.)

No governmental agency dictated to the pharmacy that it hire Hmong speakers or give prescription directions in Hmong. What spoke to the pharmacy was a combination of the American free enterprise system and the patients' pocketbooks. And Hmong patients from across Minneapolis take their business to that pharmacy and spend their money there.

This pharmacy provides a lesson in how bilingual communications can best be accomplished. Hmong speakers across Minnesota come to this pharmacy because someone told them "Hmong is spoken here." Among other means, they find out through word of mouth and through the pharmacy's own advertisements. And they choose for themselves.

Communication is the cornerstone

Increasingly, the art of communication is becoming the cornerstone of the practice of pharmacy. Pharmacists have knowledge of drugs and a deep understanding of how they can best be used. They need to use this expertise to help their patients manage medication risks. This is accomplished through appropriate communication.

The role of the boards of pharmacy is not to dictate in which or in how many languages a pharmacy should communicate. A better role would be to educate the public about which pharmacy offers communication services. On their web pages, boards can post lists of the pharmacies that can communicate in Spanish, Hmong, Vietnamese, French, or any other language a pharmacy can certify that it offers. The board could also list the pharmacies that communicate only in English.

Once informed, patients can decide which services are important to them and which they are willing to pay for. That is the American system, doing what it does best. DT

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.

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LEGAL COMPLIANCE Ned Milenkovich, PharmD, JD

OIG finds proposed per-fill fee arrangements suspect

Advisory Opinion 14-06 critical of pharmacy payment structure

The Office of the Inspector General (OIG) for the United States Department of Health and Human Services (HHS) recently issued an opinion rejecting a proposed per-fill arrangement between a specialty pharmacy and local retail pharmacies.

Although Advisory Opinion No. 14-06 is limited to the situation presented to the OIG, it provides insight into how the OIG might treat similar per-fill contractual agreements. Pharmacies should review their current per-fill arrangements to determine whether they contain a pattern of facts similar to the those described in the opinion and below.

The specialty-pharmacy requestor that is the subject of the opinion comprises a nationwide distribution channel and several freestanding pharmacies. The specialty pharmacy dispenses drugs for cancer, HIV/AIDS, multiple sclerosis, and hemophilia that are reimbursable by federal healthcare programs and are not available at all retail pharmacies.

Kickback? Or fee for services rendered?

Under the arrangement presented to the OIG, the specialty pharmacy would have compensated retail pharmacies for "support services" provided on a per-fill basis. In other words, the specialty pharmacy would have paid the retail pharmacies upon receiving:

- The initial prescription for the specialty drug
- Each subsequent refill request

Under the arrangement, the retail pharmacies would have provided support services, including collection of patient information, patient counseling, and acceptance and transfer of the prescription to the specialty pharmacy.

The retail pharmacy would have been required to inform the patient presenting the specialty-drug prescription that pharmacies other than the specialty pharmacy could fill the patient's prescription. However, if the specialty pharmacy did not receive a patient's specialty-drug prescription, the specialty pharmacy would not have paid the retail pharmacy for any support services rendered.

Violations of the anti-kickback statute can occur when remuneration — anything of value — is "paid purposefully to induce or reward referrals" of prescriptions payable by a federal healthcare program. Penalties for violating the anti-kickback statute include fines of up to $25,000, imprisonment for up to five years, or both, as well as automatic exclusion from Medicare, Medicaid, and other federal healthcare programs.

Can't pay to generate business

The OIG concluded that the proposed arrangement was a potential violation of the federal anti-kickback statute because the per-fill fee would reward referrals for specialty prescription drugs payable by a federal healthcare program.

In its opinion, the OIG found that a significant risk existed that the per-fill fees paid by the specialty pharmacy would compensate the local retail pharmacies for generating business, as opposed to payment for legitimate, "commercially reasonable services." The OIG found that per-fill fees are "inherently subject to abuse" because of their direct tie to the number of patient prescriptions referred to the specialty pharmacy.

As the proposed arrangement would create financial incentives that could influence a retail pharmacy's referral decisions, the OIG determined that it posed more than a minimal risk of fraud and abuse under the anti-kickback statute.

Any portion of payment

The OIG also cautioned that courts have held that the anti-kickback statute covers arrangements where a portion of the payment is to induce referrals. In other words, courts have found that the anti-kickback statute was violated if any portion of a payment is for a referral of services.

According to the opinion, the specialty pharmacy asserted that, if not for the proposed arrangement, local retail pharmacies would not know where to direct patients seeking to fill a prescription for a specialty drug. The OIG expressed doubt at this statement and advised that the specialty pharmacy could describe its services to the local retail pharmacies without providing remuneration for specialty-drug prescription referrals received. 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 health, drug, and pharmacy legal practice at Roetzel and Andress LPA. He is also a member of the Illinois State Board of Pharmacy. Contact him at 312-582-1676 or at nmilenkovich@ralaw.com.*

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EDUCATIONAL OBJECTIVES

Goal: To educate pharmacists, particularly in the outpatient setting, regarding the clinical principles, techniques, and benefits of using motivational interviewing to improve cardiovascular outcomes in their patients.

After participating in this activity, pharmacists will be able to:

- Identify how motivational interviewing differs from our everyday mode of communicating with patients with cardiovascular disease
- Describe the motivational interviewing communication "tools" that can be used to explore patient resistance and ambivalence
- Identify adherence issues for cardiovascular disease management
- Describe motivational interviewing skills for a cardiovascular disease management conversation with a patient who does not adhere to the treatment regimen

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

Pharmacists are eligible to participate in the knowledge-based activity, and will receive up to 0.2 CEUs (2 contact hours) for completing the activity, passing the quiz with a grade of 70% or better, and completing an online evaluation. Statements of credit are available via the online system and your participation will be recorded with CPE Monitor within 72 hours of submission.

ACPE# 0009-9999-14-011-H01-P

Grant Funding: None

Activity Fee: There is no fee for this activity.

Initial release date: 10/10/2014

Expiration date: 10/10/2016

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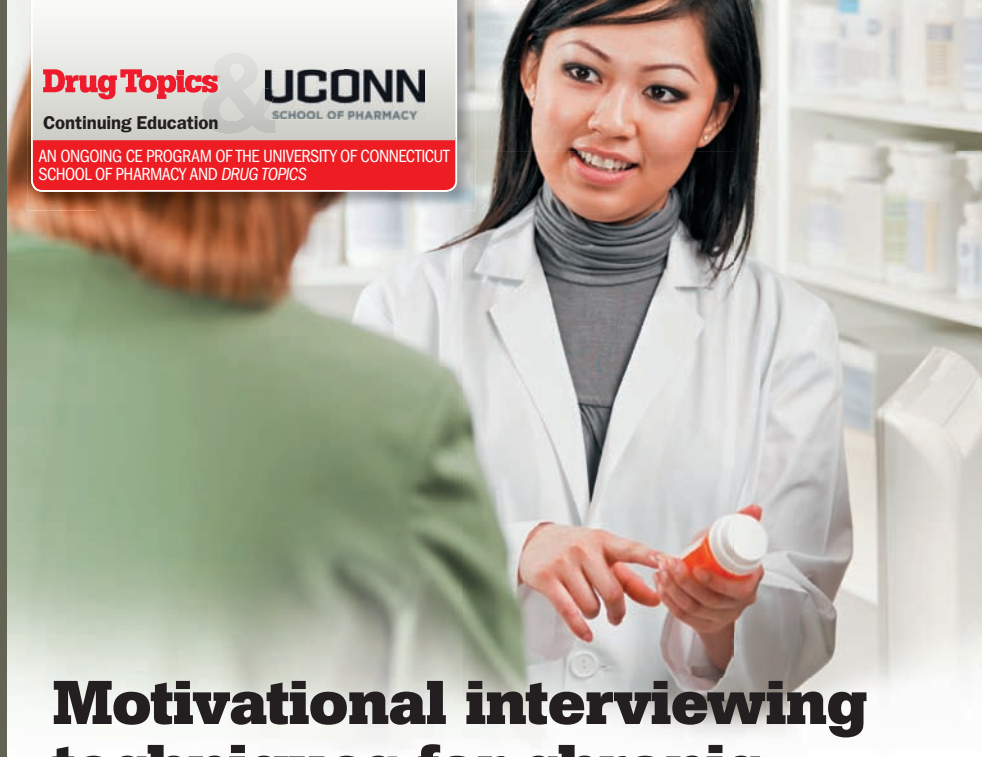

Motivational interviewing techniques for chronic disease management: Focus on cardiovascular disease

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Abstract

Pharmacists are uniquely positioned healthcare professionals with direct patient contact who not only play an integral role in making pharmacological recommendations and providing disease state management, but can also assist with changing patients' health-related behaviors such as diet, exercise, and smoking cessation. With the shift in health care to a more patient-centered approach, patients need to be and feel empowered to become active participants in their health care. Although there are various ways for healthcare providers to assist patients in changing their health-related behaviors, motivational interviewing is one approach that has been well studied and has led to positive health outcomes.

Faculty: Thomas M. Matta, PharmD and Danielle M. Miller, PharmD
Dr. Matta is an assistant clinical professor, Northeastern University School of Pharmacy, Boston, Mass., and ambulatory care clinical pharmacy specialist, Harbor Health Services, Inc., Boston, Mass. Dr. Miller is an assistant clinical professor, Northeastern University School of Pharmacy, Boston, Mass., and ambulatory care clinical pharmacy specialist, Boston Medical Center, Boston, Mass.

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

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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 motivational interviewing techniques for chronic disease management with a focus on CVD. In November and December, the activities include weight management and smoking cessation. The knowledge-based part of the series ends in January 2015 with an activity about MTM opportunities in caring for the patient with CVD.

The series also offers application-based and practice-based activities. There will be online case studies in CVD, providing up to 4 CPE credits later this year and next.

Live meetings are scheduled for next year, focusing on communicaton skills development for health behavior change in CVD management and case discussions.

Introduction

Pharmacists are healthcare professionals with direct patient contact who are in a unique position that allows them to address patient health conditions as well as medication and lifestyle management. In particular, the role of pharmacists in outpatient ambulatory care clinics and community settings is becoming increasingly focused on preventive care and keeping patients out of the hospital. To achieve these ends, pharmacists are being encouraged to assist with managing various chronic disease states, such as diabetes, hypertension, hyperlipidemia, asthma, and chronic obstructive pulmonary disease. Pharmacists not only play an integral role in making pharmacological recommendations and providing disease state management, but they can also assist with changing their patients' health-related behaviors such as diet, exercise, and smoking cessation.

With the shift in health care to a more patient-centered approach, patients must and should feel empowered to become active participants in their health care. Although there are various ways to assist in changing health-related behaviors, motivational interviewing is one approach that has been well studied and has led to positive health outcomes.[1,2] Motivational interviewing is a patient-centered style of collaboratively engaging with patients to empower them to make changes by creating a certain mindset. Because motivation is considered a mental state that is subject to change, motivational interviewing can be used to help patients feel ready to improve their health outcomes.[3] Pharmacists can use this method to help patients realize the necessity of change and to help facilitate that change process through collaboration and conversation.[4,5] Therefore, motivational interviewing is a means of constructive, unbiased communication between patients and healthcare professionals. The use of this approach in chronic disease state management is not a novel concept. Although first introduced to address substance abuse, this technique has been rapidly expanded to the management of chronic diseases such as diabetes, hypertension, and dyslipidemia. Motivational interviewing has also been shown to be beneficial in helping patients make lifestyle changes such as smoking cessation and improved medication adherence.[6] Because pharmacists holistically treat a patient's overall health, health behaviors factor into the aforementioned chronic diseases, especially in terms of cardiovascular health.

Cardiovascular disease is an umbrella term for multiple conditions such as heart failure, coronary artery disease, stroke, and myocardial infarction. Such conditions, which are largely preventable, can occur when chronic disease states such as hypertension, dyslipidemia, and diabetes mellitus go untreated or uncontrolled. Cardiovascular disease remains the number one leading cause of death in the United States.[7] The enormity of this problem has not gone unnoticed. In September 2011, the Department of Health and Human Services launched the Million Hearts campaign with the goal of preventing one million myocardial infarctions and strokes by 2017.[8] The role of pharmacists in this initiative is vital, particularly in the outpatient and community settings where preventive care is fundamental. Pharmacists in these settings can use motivational interviewing to engage patients in their health, in turn leading to improved cardiovascular outcomes.

What is motivational interviewing?

Motivational interviewing is a style of communication that involves eliciting enthusiasm for change in a patient's life. It is defined as "patient-centered and collaborative, using a directive counseling style that elicits and strengthens the patient's internal motivation for change."[6] Motivational interviewing works under the premise that a patient's behavior is influenced by what he or she thinks or says and that these feelings directly affect his or her ability to change to a healthier lifestyle.[9] The goal of this type of interviewing is to remove any ambivalence a patient may have toward change and to build upon his or her predisposition toward change. This process allows pharmacists to help the patient target and reach his or her own healthcare

goals rather than using the deterioration of a health condition as an external motivating factor.[10]

Motivational interviewing relies on three essential components: collaboration, evocation, and autonomy. Together, this triad is known as the "spirit" of motivational interviewing.[6] When these components are used as the foundation, patient interaction becomes more patient centered, collaborative, nonjudgmental, and directive.[6,11] The pharmacist, whether working in a community pharmacy or an ambulatory care practice setting, should understand that the patient's opinions and perceptions direct the changes needed, rather than what the pharmacist decides is important for the patient's health. Because the patient will be the one who makes the final decision regarding his or her health care, the pharmacist's goal is to alter the dynamic of the patient-pharmacist relationship into one that involves collaborating as a team, helping the patient understand his or her own motivations for change.

This collaborative approach is different from the more traditional patient-provider relationship, in which the pharmacist or other healthcare professional simply gives the patient an abundance of information and the patient is expected to understand and follow the directions given. In these scenarios, the patient is passive in the decision-making process, which in turn may lead to more resistance to change. For example, a 52-year-old man is coming to the clinic after recently being discharged from the hospital for a myocardial infarction. The patient is obese, smokes one to two packs of cigarettes daily, and drinks four beers daily. He is now taking aspirin, simvastatin, and a couple of new blood pressure medications. Rather than going through his list of medications to assess medication adherence and then recommending lifestyle changes to prevent another myocardial infarction, the pharmacist needs to take a step back and consider the "spirit" of motivational interviewing. Together, the patient will help the pharmacist identify realistic lifestyle changes.

Evocation is used to elicit an internal or intrinsic motivation from the patient. For this to work, the pharmacist should allow the patient to communicate and discuss his or her beliefs, attitudes, and values.[6] Pharmacists must understand the patient's views before collaborating on the next appropriate step. Because it is assumed that the resources and motivation for change reside within the patient, pharmacists can use motivational interviewing to glean the necessary information from the patient instead of simply giving directions to follow at home. It is safe to assume that many healthcare professionals, including pharmacists, have encountered patients whom they truly believed would make the necessary behavioral changes and be fully adherent with their medications only to be let down at the next interaction when the patient admits that nothing has changed. This never-ending cycle will continue until patient barriers are identified and properly addressed.

The pharmacist's goal is to alter the dynamic of the patient-pharmacist relationship into one that involves collaborating as a team, helping the patient understand his or her own motivations for change.

Autonomy also plays an important role in motivational interviewing. Both the patient and the healthcare professional must understand and accept that change is the responsibility of the patient. It is the patient who works with the pharmacist to identify solutions for current barriers or problems and who then modifies his or her behavior based on the solution reached. Pharmacists should support and respect patient autonomy by affirming the patient's rights and ability to make self-directed healthcare decisions.[6,12] One way for pharmacists to support patient autonomy is by asking his or her permission to provide information rather than just giving the information in an authoritative, traditional counseling-style format.

Many people have tried to make health-related changes in their lives and realized just how difficult this process is. Oftentimes, a patient is told he or she

Pause&Ponder

Scenario #1
Martha is a new patient in your ambulatory care clinic. She was diagnosed 4 months ago with hypertension and has had adherence issues with her medications. She has been referred to pharmacy for disease education and medication adherence and management. You introduce yourself to Martha, obtain her vital signs, quickly explain why hypertension is known as the silent killer, and educate her on contributing factors to hypertension.

After chatting, you ask her if she has any questions, to which she responds "No." You schedule her for a follow-up visit, and before she leaves, you tell her to "Watch the salt!"

Does this seem like a typical interaction for you? Do you feel as though the information given will have fruitful outcomes for the patient? Do you think this approach works or do you believe there are better alternatives available?

needs to make a change and is given an ultimatum of "complete a, b, and c or x, y, and z will happen." Fortunately, there are patients who, once effectively motivated, are successful in making these positive health-related changes. However, for those who need extra encouragement, the use of motivational interviewing as a method of communication allows the pharmacist to collaborate with the patient to help develop his or her own motivation, commitment, and plan for change. This approach can be especially useful for working with patients on medication adherence and lifestyle changes (**Table 1**).[12,13]

Motivational interviewing helps a patient realize the need for health-related behavior changes and provides a way to prepare for such changes. Once patients have achieved this level of readiness, the role of the pharmacist transforms from facilitator to coach. As Miller stated, motivational interviewing is "a prelude to coaching."[12] Assessing a patient's readiness is necessary to determine his or her confidence and ability to change a targeted behavior. Proper assessment of readiness can be achieved through targeted questions. The pharmacist can also use a numeric rating score to better understand how important making a particular change may be to a patient or his or her confidence level in successfully making that change. For example, in assessing cardiovascular health, the pharmacist may ask, "On a scale of 1 to 10, with 1 being least likely and 10 being most likely, how confident are you that you will be able to quit smoking?" Once the patient's concerns and thoughts are revealed, the pharmacist may then provide a tailored approach to each patient.

Clinical principles of motivational interviewing

To be effective in using motivational interviewing as a communication style, a pharmacist should practice the following four clinical principles: empathy, discrepancy, rolling with resistance, and supporting self-efficacy.[6,9,12]

Empathy is vital to motivational interviewing. It encourages patient-centered care and allows the interviewer to promote behavioral changes when faced with patient ambivalence or a self-perceived inability to change. The empathetic pharmacist goes beyond simply relating to a patient on a superficial level; he or she is able to recognize and have respect for a patient's personal situation, beliefs, and values. Expressing empathy demonstrates to patients that the pharmacist is listening and genuinely trying to understand the patient from his or her personal perspective. In turn, this sense of being understood helps alleviate patient anxiety and build trust in the patient-pharmacist relationship. Remember, empathy is not sympathizing with the patient and simply saying, "I'm sorry you feel that way." Rather, empathy focuses on the patient and his or her uncertainty in any given situation. You may encounter a patient who is frustrated that he or she is not losing weight even after starting to exercise and work on healthier food choices. Instead of saying "I understand," it may be more beneficial to say, "It sounds like you have been working out more frequently but still not losing weight; this must be discouraging to you."[11] This display of empathy allows the patient to understand that he or she is in a nonjudgmental and collaborative environment, and the patient is then more likely to candidly communicate personal costs and challenges he or she may be facing. Candid communication early in the patient-pharmacist relationship allows the pharmacist to more quickly, efficiently, and thoroughly address the patient's needs.

For many pharmacists, expressing empathy is a learned skill set. It takes a conscious effort to truly understand a patient's feelings without passing judgment. However, with practice, the use of empathetic statements such as "It appears you are frustrated" or "It sounds like the situation has been upsetting to you" will become an unconscious effort. One statement all pharmacists and all healthcare professionals in general should be wary of using is "I understand." Patients may feel belittled by this phrase because it is unlikely that a pharmacist or other healthcare provider actually understands what the patient is feeling as a unique individual. Furthermore, this phrase negates the spirit of motivational interviewing by causing a shift from a patient-centered dynamic to a provider-centered one.[13]

TABLE 1

GUIDELINES FOR MOTIVATIONAL INTERVIEWING

Guidelines
Acknowledge the patient's motivation to change
Listen
Empower
Facilitate conversation
Roll with resistance
Understand patient ambivalence
Develop discrepancy
Respect and support patient autonomy

Source: Ref 12, 13

The principle of discrepancy involves understanding a patient's ambivalence towards change and works to resolve those barriers. In practice, a patient may have mixed emotions about change—agreeing to it at times and then deciding against it for fear of not wanting to unbalance the status quo. Patients may not even realize that a difference in mindset exists. Discrepancy allows the patient to see any inconsistencies that he or she may not otherwise recognize. The pharmacist's main role in this situation is to listen to the patient as he or she relays his or her personal goals for health care and what he or she values most, paying special attention to any concerns or difficulties with change the patient may have. One way to do this is to ask the patient what is important to him or her and what he or she feels are positives and negatives of changing his or her behavior. Pharmacists should help patients identify the discrepancy of where they want to be and where they are now by asking the right questions. Once this is done, patients must then verbalize the reasons for change, which ultimately leads to an increased likelihood of successful change. Remember, change is more likely to occur when it is the idea of the patient, not of the pharmacist.

The next clinical principle in motivational interviewing is the ability to roll with resistance. Imagine speaking to a patient with a recent myocardial infarction who communicates that he has not been taking his metoprolol succinate as prescribed. The

TABLE 2

TYPES OF PATIENT RESISTANCE

Type of patient resistance	Examples
Arguing The accuracy, knowledge, or integrity of the provider is questioned by the patient	• Challenging the accuracy of what the provider says • Discounting the authority and knowledge of the provider • Expressing hostility directly toward the provider for what he or she is saying
Interrupting The patient explicitly interrupts the provider in a defensive manner	• Talking over the provider without waiting for an appropriate break or pause in conversation • Cutting off the provider intentionally with phrases such as, "OK, I got it, I've had enough."
Denying The patient's inability to recognize problems, accept responsibility for his or her actions, cooperate with providers, or take appropriate action to make a change	• Blaming everyone else for his or her problems • Disagreeing with a provider's recommendation without offering a constructive alternative • Making excuses for poor behavior • Minimizing the risks/dangers of a particular behavior and suggesting that the provider is making a bigger deal of the issue than is necessary • Expressing ambivalence/reluctance about information or advice • Showing unwillingness to change or lack of desire to change
Ignoring The patient has no intention of following the guidance of the provider	• Not paying attention to the provider • Not responding (verbally or nonverbally) to questions asked by the provider • Diverting the conversation to another topic • Not answering the question or providing a totally unrelated response

Source: Ref 15,16

initial reaction for most pharmacists is to address the issue of nonadherence. This is often achieved by giving the patient as much information as possible regarding why he or she should be taking the medication rather than listening to the patient and understanding his or her reservations to using or even obtaining the medication. That initial reaction to address or "fix" what is wrong with the situation is known as the "righting reflex."[14] To roll with resistance, the pharmacist must resist the urge to make things "right." This is often the most difficult part of motivational interviewing because the pharmacist generally wants to provide a patient with the best advice to improve his or her health. Unfortunately, forcing information on patients can lead to a caustic relationship—one that is not patient centered, and one in which the patient refuses to openly discuss any issues he or she may be experiencing. Most pharmacists have experienced an encounter with a patient in which resistance has occurred. A common form of resistance is denial, often expressed as excuses for not making a health-related behavior change. Denial is just one of several types of patient resistance (**Table 2**).[15,16] Therefore, the pharmacist must learn to identify and roll with various types of resistance, resisting the righting reflex or the urge to argue with the patient.

Lastly, supporting self-efficacy is vital to effective motivational interviewing. Pharmacists can demonstrate support by affirming any changes the patient has made—even if the change seems as simple as discerning a discrepancy in his or her behavior. This final step acknowledges a patient's ability to change, and the confidence this instills in the patient will encourage even more progress. A patient must believe that he or she is capable of altering his or her behavior and committing to change. The effective pharmacist will help the patient brainstorm a plan of action, using the patient's own experiences and skills to find positive ways to implement the changes. For example, a patient who smokes identifies this behavior as a poor choice and voices concern about having a myocardial infarction and passing away just as her father did. Thus, the patient identifies the dangerous association between smoking and myocardial infarctions herself. This self-directed "ah-ha" moment now drives her internal motivation for changing her poor health-related behavior. The role of the pharmacist throughout this interaction is to provide affirmation (e.g., "I appreciate you sharing your concern with me") to build patient confidence in following through with the change process.

Both the patient and the health care professional must understand and accept that change is the responsibility of the patient.

Techniques of motivational interviewing

To be successful in employing motivational interviewing, clinicians need to employ techniques that will facilitate dialogue and foster collaboration in a positive, empathetic, and nonjudgmental environment. Such techniques include open-ended questions, affirmation, reflective listening, and summarization (OARS).[6]

To facilitate change in a patient's health, clinicians must first understand the patient's views and opinions surrounding the health behavior change. Use of open-ended questions is a commonly employed technique to elicit conversation between the pharmacist and patient. Open-ended questions such as "What is most difficult about making this behavior change?" or "How do

you think changing this behavior will make you feel?" help the pharmacist understand a patient's apprehensions, fears, or ambivalence to change. Knowing the patient's standpoint is essential not only to evoke patient buy-in, but also to allow the pharmacist to adequately guide the conversation. Examples of open-ended questions can be found in **Table 3**.[11]

Recognizing patient ambivalence is a key step during the interview session. It is human nature to doubt and resist change. However, the pharmacist must be able to use a patient's ambivalence to guide the conversation. Patients must see for themselves the difference in what their current behavior is and where they want to be. Pharmacists can then assist with how patients are going to make the change from point A to point B. In implementing this approach, pharmacists should guide the conversation to allow the patient to identify the discrepancy between his or her views or beliefs and reality. Moreover, beginning with open-ended questions will aid the pharmacist in tailoring his or her guidance to the patient, thereby more efficiently addressing the patient's health concerns. Allowing patients to advocate for themselves has been shown to result in a greater commitment to change and more successful outcomes.[17]

Motivational interviewing also relies on reflective listening. Using reflective listening, the pharmacist will listen intently to what the patient has to say and repeat back the information. The benefit of this technique is two-fold. First, it gives the patient an opportunity to correct any errors the pharmacist may have made in trying to understand the patient. Second, it allows the patient to develop a rapport with the pharmacist while reinforcing that he or she is in control of the conversation. To be effective, reflective listening requires empathy; the listener must have respect for the patient's motivations without judgment. During this portion of the conversation, it is imperative for the pharmacist to listen for opportunities of "change talk." Change talk is a pivotal opportunity during the conversation that occurs when the individual patient is self-influenced by something he or she says versus something the pharmacist says.[18,19] Again, asking open-ended questions enables the individual to think or speak out loud about a behavior change, ultimately creating that opportunity for change talk.[14]

TABLE 3

EXAMPLES OF CLOSED-ENDED VERSUS OPEN-ENDED QUESTIONS

Closed-ended questions	Open-ended questions
Have you ever tried to quit smoking before?	What concerns you most about quitting smoking?
Do you know what this medication is for?	What you are taking this medication for?
Are you exercising every day?	How often do you exercise per week?
Have you been avoiding adding salt to foods for better blood pressure control?	Can you tell me what you know about eating too much salt and your blood pressure?
Do you ever forget to take your medications?	In the past week, how many times did you forget to take your medication?
Are you taking your [drug name] every day?	How do you take your [drug name]?
Can you tell me what your doctor told you about diabetes?	What do you know about diabetes?

Source: Ref 11

Throughout the conversation, often during reflective listening, the pharmacist should summarize what the patient is saying. Summarization provides a recap of the conversation and gives the patient the opportunity to agree with, modify, or clarify what the pharmacist is saying. However, when providing a summary, the pharmacist should explicitly indicate that he or she is doing so. The pharmacist should mention any patient ambivalence observed, receive permission to ask additional questions, and conclude with an invitation to the patient to provide any clarification, make comments, ask questions, or voice concerns. This creates another opportunity for change talk and allows the patient to lead the conversation, potentially in a different direction. This may allow the patient to identify a topic that he or she is struggling with and prompt the pharmacist to focus on this area.

Although the patient is responsible for directing and communicating change, the pharmacist or other healthcare professional is still responsible for guiding and filtering the patient's thoughts to encourage change. The pharmacist must understand what the patient's beliefs and opinions about his or her health are and show acceptance and affirmation. Additionally, once the pharmacist has identified the patient's beliefs and opinions, he or she must then navigate the conversation to appropriately tailor suggestions for health changes.

Beginning with open-ended questions will aid the pharmacist in tailoring his or her guidance to the patient, thereby more efficiently addressing the patient's health concerns.

Affirmations are "genuine statements of recognition of and appreciation for the patient's efforts and perspective."[6] Recognizing, congratulating, and providing continual support to patients' changes in health behaviors are key to maintaining a collaborative patient-pharmacist relationship while continually instilling positive health behavior changes in patients. It is also necessary to provide affirmation regardless of the magnitude of change to

prevent patient discouragement or resistance. One example is congratulating a patient with heart failure for adhering to his or her regimen of a beta-blocker, angiotensin-converting enzyme inhibitor, diuretic, and mineralocorticoid receptor antagonist. At the same time, pharmacists must recognize past health behavior changes a patient may have struggled with and respect how past behavior will influence future behavior. Providing affirmation to patients focused on past failed attempts at behavior change has been found to be particularly pivotal in breaking the behavior.[12,20] With these techniques for motivational interviewing, a pharmacist may more readily elicit necessary information so that he or she may encourage and guide his or her patients into a healthier lifestyle.

Barriers and pitfalls of effective motivational interviewing

Common barriers to effective motivational interviewing include lack of time, lack of reimbursement for services, and lack of adequate training or support for motivational interviewing. Although pharmacists may be hesitant to embrace motivational interviewing because of concerns about time constraints, it has been shown that as little as a few minutes can effectively promote change.[17,21] Currently, pharmacists remain unrecognized as healthcare providers, and as with all services rendered in an ambulatory care setting, pharmacists will not be reimbursed for patient encounters involving motivational interviewing. Lastly, there may be some concern about lack of training for motivational interviewing; however, motivational interviewing is a growing trend in patient-centered care, and the use of this technique is increasingly a topic in healthcare publications.

Other barriers may include a pharmacist's uncertainty about a patient's ability to change or a patient's unwillingness to participate.[22] Pharmacists must be cognizant of patient pushback and aware of potential pitfalls that may result in patient resistance. Clinicians should keep in mind that motivational interviewing is different from traditional counseling. A significant part of a pharmacist's job is to counsel but also to avoid doing all of the talking. Pharmacists must remember that motivational interviewing is a collaborative, patient-centered conversation. Asking too many questions may revoke a patient's autonomy, resulting in disengagement. Similarly, pharmacists should refrain from giving unsolicited advice or recommendations. Despite the everyday workflow of an ambulatory care pharmacist in assessing patients and implementing patient care plans, motivational interviewing is not passive. Patients must partner with their pharmacist in the decision-making process when identifying discrepancy, developing goals, and creating a plan of action. Pharmacists can gain credibility and patient respect by asking permission before providing advice, thoughts, or recommendations. As any other healthcare professional, pharmacists enjoy helping their patients. However, they should be careful not to think through the patient's problem out loud. Pharmacists should guide the conversation so that the patient develops discrepancy in his or her behavior and makes his or her own realization about changing a health behavior. It is essential to obtain patient buy-in to be successful. Common pitfalls can be avoided by remembering OARS: use open-ended questions, affirm a patient's efforts or opinions, practice reflective listening, and summarize the conversation.[6]

> Patients must see for themselves the difference in what their current behavior is and where they want to be.

Integration of motivational interviewing into clinical practice

Once the principles and techniques of motivational interviewing are understood

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Pause&Ponder

Scenario #2
Given the information you have now, consider this patient scenario:

Harold is a patient with a medical history of hypertension and myocardial infarction. He comes to your pharmacy to pick up his medications, after having not refilled his metoprolol succinate in almost 4 months.

Would your typical approach to this resistance be to tell Harold about all of the benefits of taking his medication and the risks associated with nonadherence? After reading about motivational interviewing, what kind of questions would you ask him now?

When you ask Harold various open-ended questions, he reveals to you that he has made dietary changes and feels as though he does not need to take his heart medication anymore. He goes on to tell you that he is only here because his wife has been nagging him lately to start taking his medication again. He tells you that his blood pressure has been great, and he doesn't understand why he needs to keep taking this medication. How would you handle this situation? How could you incorporate empathy and self-efficacy into this conversation?

TEST QUESTIONS

1. Which of the following best describes the dynamic of motivational interviewing?
- **a.** The pharmacist acts in an authoritative role.
- **b.** The pharmacist gives motivation to the patient.
- **c.** The relationship is centered on the patient.
- **d.** The patient serves as a passive participant.

2. BD is a 46-year-old woman who comes to the pharmacy counter requesting a refill on her simvastatin. You notice that she has not refilled her prescription in more than a month. Using motivational interviewing techniques, which of the following questions is most appropriate to ask BD?
- **a.** Do you ever forget to take your simvastatin?
- **b.** How do you take your simvastatin?
- **c.** Do you take your simvastatin every day?
- **d.** Are you taking your simvastatin as prescribed?

3. All of the following are common pitfalls during motivational interviewing EXCEPT for:
- **a.** Allowing the patient to develop discrepancy in health behaviors
- **b.** Providing patients with a provider-directed care plan
- **c.** Asking too many questions and not listening enough
- **d.** Revoking patient's autonomy by being authoritative

4. Which of the following is TRUE about integrating motivational interviewing into pharmacy practice?
- **a.** It takes more time than traditional counseling.
- **b.** It has resulted in a more passive patient-provider relationship.
- **c.** It is eventually going to replace traditional counseling.
- **d.** It empowers patients to actively participate in their health.

5. Which of the following techniques allows patients to assess a provider's understanding of the conversation?
- **a.** Open-ended questions
- **b.** Reflective listening
- **c.** Affirmations
- **d.** Summarization

6. Successful communication between patients and pharmacists relies on which of the following principles of effective motivational interviewing?
- **a.** Sympathy
- **b.** Discrepancy
- **c.** Creating resistance
- **d.** Disregarding self-efficacy

7. You are a pharmacist engaging in motivational interviewing with a patient; however, you catch yourself asking too many questions and the patient is becoming distant. Which of the following is an effective way to overcome this common pitfall?
- **a.** Allow the patient to talk, and reflectively listen.
- **b.** Reassure the patient you are in control of the conversation.
- **c.** Be sure to ask closed-ended questions.
- **d.** Disregard the patient's distance; you know what you are doing.

8. Which of the following is/are barriers to implementing motivational interviewing in clinical practice?
- **a.** Lack of time **b.** Lack of reimbursement
- **c.** Lack of proper training **d.** All of the above

9. The phrase "It sounds like you are frustrated about not being able to lose weight," is an example of:
- **a.** Reflective listening **b.** Sympathy
- **c.** Affirmation **d.** Developing discrepancy

10. Which of the following terms best describes the role of the patient as the key resource of identifying need for change, developing goals, and creating a plan to change health behavior?
- **a.** Passive **b.** Autonomous
- **c.** Submissive **d.** Defiant

11. What is the purpose of "change talk" during motivational interviewing?
- **a.** For the pharmacist to persuade patients to make a change
- **b.** For the pharmacist to seize an opportunity to shift the conversation
- **c.** For patients to self-influence a need for change by something they say
- **d.** For patients to challenge the pharmacist about what is being said

12. Refer to the "Pause and Ponder" scenario involving Harold. Considering motivational interviewing techniques, which of the following questions is MOST appropriate?
- **a.** When was the last time you took metoprolol?
- **b.** What made you decide to stop taking your metoprolol?
- **c.** Do you feel any different since not taking your metoprolol?
- **d.** Are you concerned about having another heart attack?

13. "Your commitment to a heart-healthy lifestyle really shows by your weight loss so far" is an example of:
- **a.** Reflective listening
- **b.** Change talk
- **c.** Developing discrepancy
- **d.** Affirmation

14. Which of the following increases a patient's risk for cardiovascular disease?
- **a.** Nonsmoker
- **b.** Uncontrolled diabetes mellitus
- **c.** Daily exercise
- **d.** Controlled hypertension

15. Identification of patient resistance during a conversation is important to:
- **a.** Understand the patient's concern about change
- **b.** Confront the patient with his/her problem(s)
- **c.** Correct unwanted behaviors immediately
- **d.** Determine if a patient will succeed in changing

16. PJ is a 58-year-old obese man with a medical history of coronary artery disease, hypertension, uncontrolled type 2 diabetes mellitus, and hypertriglyceridemia. He smokes 1 pack per day and drinks a 6-pack of beer per day. He presents to the clinic for a blood pressure check. During your visit, which of the following statements best reflects motivational interviewing?
- **a.** "I'm worried your poor lifestyle choices are going to give you a heart attack."
- **b.** "Let me tell you how to make the necessary changes to get you healthy."
- **c.** "I think you are not going to take better care of yourself unless something bad happens."
- **d.** "You expressed some concern about having a heart attack. Can you tell me more about this?"

17. A common mistake made by healthcare providers during motivational interviewing is to identify and correct what is wrong in patients. Such a desire is known as:
- **a.** Righting reflex **b.** Autonomy
- **c.** Evoking change **d.** Sustaining talk

18. JD is referred to the pharmacy for smoking cessation. During your visit, JD voices concern about quitting because she is afraid of gaining weight. Which one of the following pharmacist responses is MOST consistent with the principles of motivational interviewing?
- **a.** "Yes, weight gain is a possibility and this can be a concern. With a proper exercise regimen, you should be just fine, though."
- **b.** "Some patients will gain weight, but it doesn't happen to all. Plus, quitting is better for your overall health in the long run."
- **c.** "It sounds like you're worried about gaining weight if you quit smoking. May I share some information with you?"
- **d.** "Gaining weight should be the least of your worries. You will be lowering your risk for having a heart attack."

19. The "spirit" of motivational interviewing is best described by which of the following terms?
- **a.** Authority **b.** Evocation
- **c.** Ambivalence **d.** Education

20. Which one of the following best characterizes the clinical principles of motivational interviewing?
- **a.** Ask open-ended questions to elicit conversation and support patient anonymity.
- **b.** Find out what the patient knows about the identified behavior by asking multiple questions; then provide education.
- **c.** Support self-efficacy by giving the patient internal motivation by instilling fear in the patient about his or her poor health behavior.
- **d.** Resist the "righting reflex" and roll with resistance to avoid arguing with the patient.

Continued from pg. 59

FIGURE 1

MOTIVATIONAL INTERVIEWING OVERVIEW

Strategies

- Open-ended questions
- Affirmation
- Reflective listening
- Summarization

Principles

- Empathy
- Discrepancy
- Roll with resistance
- Support self-efficacy

Spirit

- Collaboration
- Evocation
- Autonomy

Source: Ref 6, 9, 12

(**Figure 1**), the next step is integrating motivational interviewing into everyday clinical practice.[6,9,12] Although a change in practice may cause apprehension from the pharmacist's standpoint, particularly regarding time constraints, motivational interviewing has been shown to work within the same time allowances as traditional counseling.[3] However, motivational interviewing leads to greater health outcomes through its patient-centered and collaborative approach.[3] Because this communication style works best as a continuum of conversation to evoke change, ambulatory care pharmacists are likely best positioned to conduct multiple motivational interviewing sessions over a period of time. Regardless of the practice setting, pharmacists should be mindful of the power of motivational interviewing when interacting with patients. Pharmacists should refrain from employing all of these strategies with every encounter and instead focus on the needs of the patient, potential time restraints, and their experience with motivational interviewing. With practice, motivational interviewing will become an unconscious effort to promote positive health behavior changes while establishing positive patient-pharmacist relationships.

Conclusion

Motivational interviewing has been shown to be an effective, evidence-based form of communication. It can foster a patient-centered, collaborative patient-pharmacist relationship. This technique empowers patients to make positive health-related behavior changes such as the reduction of cardiovascular complications. Although it may be a challenge to initially incorporate this style into everyday practice, continued use will allow pharmacists to better encourage and enable heart-healthy changes in their patients.•

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RX & OTC

New products

JULIANNE STEIN, CONTENT CHANNEL MANAGER

RX CARE

New Rx

FDA has approved **dulaglutide [1]** (Trulicity; Eli Lilly), a once-weekly subcutaneous injection to improve glycemic control, along with diet and exercise, in adults with type 2 diabetes, which affects about 26 million people and accounts for more than 90% of U.S. diabetes cases. A glucagon-like peptide-1 (GLP-1) receptor agonist, dulaglutide for injection is a new treatment option that can be used alone or added to existing regimens to control patients' blood-sugar levels. It is not indicated for patients with type 1 diabetes or diabetic ketoacidosis, or as first-line therapy for patients who cannot be managed with diet and exercise. A boxed warning notes tumors of the thyroid gland. Post-marketing studies will be required, as well as a REMS to warn healthcare providers about serious risks. **(www.trulicity.com)**

Genzyme has announced FDA approval of **eliglustat** (Cerdelga), a glucosylceramide synthase inhibitor indicated for the long-term treatment of adult patients with Gaucher disease type 1. Gaucher disease can cause severe and debilitating symptoms that include enlargement of the liver and spleen, various forms of bone disease, easy bruising, and anemia. FDA awarded eliglustat capsules orphan drug status as this product represents a new treatment option for a rare condition — estimates put type 1 U.S. patients at about 6,000. **(www.cerdelga.com)**

ViiV Healthcare has announced FDA approval of the fixed-dose combination of **abacavir 600 mg, dolutegravir 50 mg,** and **lamivudine 300 mg tablets** (Triumeq) for treatment of HIV-1 infection, providing patients with the first single-pill option containing dolutegravir. If patients have shown resistance to any of the ingredients, the product should not be used alone. All patients should be screened for the presence of the HLA-B*5701 allele; those who carry it are not candidates for this therapy. A boxed warning notes risk of hypersensitivity reactions, lactic acidosis, and severe hepatomegaly, and exacerbations of hepatitis B. **(us.triumeq.com)**

New Indications

Pfizer and Protalix Biotherapeutics have announced FDA approval of a pediatric indication for **taliglucerase alfa [2]** (Elelyso), for injection in the treatment of type 1 Gaucher Disease. Of three degrees of severity, Gaucher type 1 is found at a higher frequency among individuals who are of Ashkenazi Jewish ancestry. Elelyso recently received kosher certification by the Orthodox Union. **(www.elelyso.com)**

GlaxoSmithKline has received FDA approval of an additional indication for **eltrombopag [3]** (Promacta). This is a new first-in-class treatment option for use with patients with severe aplastic anemia who have had an insufficient response to immunosuppressive therapy. Eltrombopag is also indicated for the treatment of patients with chronic immune (idiopathic) thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy and patients with chronic hepatitis C whose degree of ITP prevents the initiation or maintenance of interferon-based therapy. Full prescribing information, including a boxed warning of risk to liver function, will be available at **http://bit.ly/promacta**. **(www.promacta.com)**

Biogen Idec has announced FDA approval of **peginterferon beta-1a**

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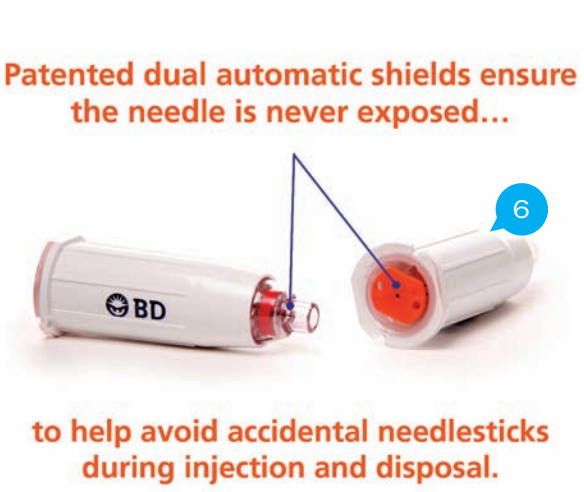

(Plegridy), a twice-monthly subcutaneous injection that patients can administer themselves. Reports say this is the latest version of Avonex, the company's once-weekly interferon beta treatment for patients with relapsing forms of multiple sclerosis. **(www.plegridy.com)**

New Generic

Teva has announced the U.S. launch of **entecavir tablets**, 0.5 mg and 1 mg, its generic equivalent to Bristol-Myers Squibb's Baraclude tablets for treatment of chronic hepatitis B. Teva was first to file, making the product eligible for 180 days of marketing exclusivity. **(www.teva.com)**

New OTC

Bee Bald has launched **Smooth Plus**, its daily moisturizer with broad-spectrum SPF 30 sunscreen for men and a "TSA-ready" **Five-Piece Travel Kit**. Other items in this all-natural product line for men include Clean (a daily cleanser), Scrub (a pre-shave exfoliating scrub), Shave (a premium shaving cream), Heal (a post-shave balm), Smooth (a daily moisturizer) and two types of Refresh Wipes (30 scented cleansing wipes). **(www.beebald.com)**

Pure Encapsulations has launched **ProbioMood**, the latest in its probiotic line. Intended to support emotional well-being and lessen occasional stress, the product comes in single-serving stick packs blending 3 billion CFU of *Lactobacillus helveticus* and *Bifidobacterium longum* per pack. **(www.pureencapsulations.com)**

Zarbee's Naturals has launched an **immune support line** for children and teenagers. These products include Mighty Bee Immune Support gummies that are free of animal by-products and safe for kids two years of age and up; Daily Bee Immune Support gummies formulated for everyday use by children four years old and up; Baby Immune Support + Vitamins, said to be the only immune support product on the market for babies as young as 2 months; and Elderberry Immune Support gummies for teens, designed to help support the maturing immune system. **(www.zarbees.com)**

Perfecta Products has announced the launch of **Zim's Advanced Cold Sore Kit [4]**, which includes an ointment for treatment and a lip balm for maintenance. The products both use natural ingredients, including propolis. **(www.zimsusa.com)**

Nordic Naturals has announced the launch of **Ultimate Omega D3 Sport Liquid [5]**, "The first liquid omega-3 to be 'Certified for Sport' by NSF International." One teaspoon of lemon-flavored liquid provides 2,900 mg of the omega-3s EPA and DHA, as well as 1,000 I.U. of natural vitamin D3.

According to a company statement, this product "offers high-intensity support for heart, brain, joints, and bones — optimizing fitness performance; promotes cardiovascular and respiratory function; promotes fat metabolism and improved body composition; and may enhance endurance." **(www.nordicnaturals.com)**

New device

BD has announced the retail pharmacy launch of the **BD AutoShield Duo [6]** pen needle for people with diabetes. The company describes the device as "the only pen needle to feature dual front- and back-end shields that ensure the needle is never exposed," helping users to avoid accidental needle sticks during insulin injection and needle disposal (no recapping is necessary). It is compatible with all diabetes injection pens on the market today. **(www.bd.com)** DT

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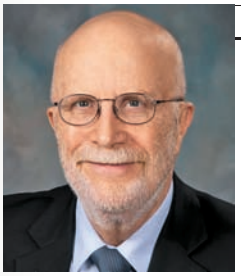

VIEWPOINT Robert L. Mabee, RPh, JD, MBA

The pharmacist's role in a changing healthcare landscape

If the Affordable Care Act collapses, as many think it will, it will create a crisis in healthcare delivery for many Americans. Most Americans seeking ambulatory care services will lack insurance; they will need quality care at affordable prices. It is essential that all American pharmacists prepare for these patients, because they will play a crucial role in helping patients get the care they need.

Routine visits to the emergency room have been and will continue to be cost-prohibitive. In the past, many patients with "good insurance" sought routine care after hours in the ER. For patients without insurance, that is not a viable option.

Expanded pharmacy services

Pharmacists will need to make sure that they have comprehensive data on primary care providers in their service areas. Patients with a sore throat and no (or very low) fever can be directed to family-practice physicians, PAs, and nurse clinicians who will be able to assess them and provide care during normal business hours at substantially lower prices.

Symptomatic treatment of coughs and colds can be handled by pharmacists as they always have been. The patient can also treat simple dermatological and minor trauma with advice from the pharmacist.

Pharmacists are already authorized to administer routine vaccinations in a number of states. They also can easily manage simple contact dermatitis, bug bites, and small abrasions or lacerations not requiring stitches.

In most states, pharmacists can be compensated as providers of these services. Many pharmacists already have a provider ID, and a schedule for cash reimbursement for consultations can be developed.

Expect pushback

There will be significant resistance from chains, big-box stores, and pharmaceutical manufacturers who have aggressively tried to eliminate pharmacy services from patient-care choices.

For example, they have sought to maximize purchase dollars by encouraging patients to buy medication supplies for three months at a time instead of 30 days, using the incentive of "cost savings" through a reduced number of co-pays.

The corporate practice of pharmacy combined with the corporate practice of medicine has created an anomaly in patient care that holds profit and quantity more important than quality care and patient welfare.

Yet today more than ever, cash-paying patients need their pharmacists to assist family-practice physicians and other primary caregivers in meeting their healthcare needs. The community pharmacist as part of the team of primary caregivers will be able to provide affordable care to patients at reasonable prices. This team approach can provide more efficient care, control costs, and reduce drug shortages.

Changing the paradigm

Large corporate retailers have been using pharmacists and their patients to increase their customer count and total sales. Large hospitals need family-practice doctors and other primary care providers to funnel patients into the referral chain to maximize income by providing additional services, even when they are not needed. Cost was no object as long as the funds came from other people, such as third-party payers.

The reemergence of patients as "cash customers" changes the paradigm. It will return the country to a rational approach to healthcare, with healthcare spending cut in half and quality of care substantially improved. High-priced corporate executives, hospital administrators, PBMs, and insurance companies will no longer be able to drain money from the system.

Oddly enough, a collapse of the ACA would actually produce real savings. It would provide the country with a path to affordable care, which is something that the troubled legislation could never do. Patients who identify themselves as consumers and not beneficiaries would become more cost-conscious. Since paying cash for routine care is the only way to actually reduce healthcare spending, the collapse of the ACA would put the country on the road back to affordable care.

The traditional role of the pharmacist, providing just the right amount of the correct medication at the best price, will restore control of healthcare spending to the patients and the providers, where it belongs. DT

Robert L. Mabee *is a pharmacist and attorney practicing in Sioux Falls, S.D. He also holds an MBA. Contact him at rlmabee@midconetwork.com.*

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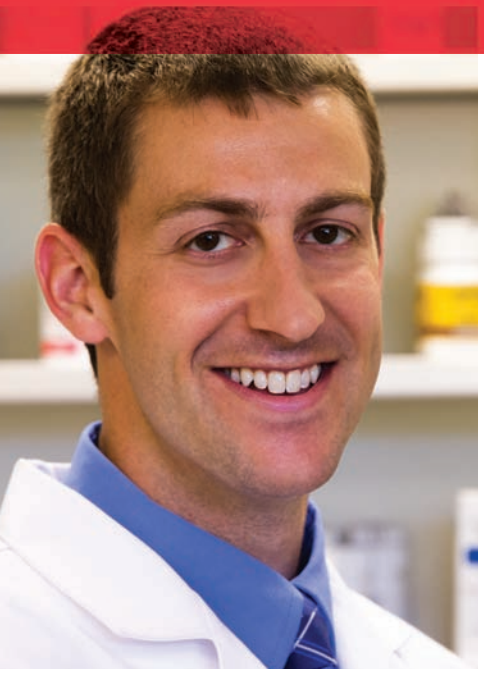

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