Consumer-Directed Care Could Test Front Office

BY ELAINE ZABLOCKI

Contributing Writer

SAN DIEGO — The growth of consumer-directed health plans means physicians and their staff will need to talk more with patients about their prices and the value of their services.

"Admitting-office conversations will change dramatically," said Gary Scott Davis, a health lawyer based in Miami, during the annual meeting of the American Health Lawyers Association. "Physicians need to develop systems that allow them to quote prices for services. 'Complexity' is no longer an excuse."

Consumer-directed health care is growing dramatically, Mr. Davis said. This means precertification and utilization review will become less important, while the financial interface will become more important. The consumer will be paying a higher percentage of the cost of care. The new system resembles traditional indemnity insurance, and the issue is no longer whether a physician is authorized to provide a service. Instead, the question becomes how much will be paid, and from whom will the fee be collected.

Consumer expectations will have to change dramatically. Patients now are used to paying a standard, minimal copayment for an office visit, medication, or hospitalization. Under consumer-directed care, when patients go in for elective surgery, they'll need to bring their credit cards with them and be prepared to spend thousands of dollars.

This shift from fixed copayments to high out-of-pocket payments means physicians and hospitals will need to develop systems to collect money from patients at the time of service and find out accurately and efficiently from third-party payers exactly how much to charge.

The dollar amounts are higher, so bad debt could accumulate and become a more significant percentage of the physician's bottom line," Mr. Davis said in an interview. "Physicians will need to become ever more vigilant."

Consumer-directed plans often include a tax-deductible health savings account to be used for medical expenses, but that doesn't necessarily mean the physician can access those funds, Mr. Davis explained. Some people, especially high earners, may choose to use the account as

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a tax-deferred savings vehicle and pay for services with other funds.

Consumerdirected care is structured to require the highest costsharing for services in which consumer decisions can make a difference,

such as outpatient elective procedures, Mr. Davis said.

Historically, consumers have trusted their physicians' advice and judgment. Now, health plans or third parties may provide information that gives consumers a different perspective.

In situations in which patients do have choices, physicians who offer different services for the same diagnosis are likely to find themselves in competition. For example, a patient with cardiac problems can seek outpatient angiography from an invasive cardiologist or get a 16-slice CT scan from an invasive radiologist. "In the past, consumers knew that all their friends had angiography, but now they are being given more information," Mr. Davis said in an interview. "As they become aware that the same diagnostic service is available as a less expensive, noninvasive procedure, and they're paying 20% of the bill, they will ask themselves whether they want to pay for the lower-cost or higher-cost procedure."

Physicians, too, may choose to provide information about the benefits of certain procedures. "If you are a physician who believes in your heart of hearts that mastectomy is the correct treatment for a certain stage of breast cancer, then you'll want information out there saying why you think your treatment recommendations are correct," Mr. Davis said.

However, he warned about potential liability for physicians and hospitals as consumer-directed care becomes more prominent. "You must provide information in a way a reasonably prudent person can understand," he said. "One of the great unknowns is potential liability.'

Combunox≻ (Oxycodone HCl and Ibuprofen) Tablets 5 mg/400 mg

COREST LABORATORIES CII Rx only the Summary: For complete details, please see full prescribing information for Combunox. NDICATIONS AND USAGE combunox tablets are indicated for the short term (no more than 7 days) management of acute, noderate to severe pain.

Patients known to be hypersensitive to other opinids may exhibit cross-sensitivity to oxycodone. WARNINGS Misuse Abuse and Diversion of Opioids Misuse Abuse and Diversion of Opioids Combunox contains oxycodone, which is an opioid agonist, and a Schedule II controlled substance. Opioid agonists have the potential for being abused and are sought by abusers and people with addiction disorders, and are subject to diversion. Combunox can be abused in a manner similar to other opioid agonists, legal or illicit. This should be considered when prescribing or dispensing Combunox in situations where the physi-cian or pharmacist is concerned about an increased risk of misuse, abuse or diversion (see DRUG ABUSE AND DEPENDENCE).

ensive Effect unox, like all opioid analgesics, may cause severe hypotension in an individual whose abil-maniahia blood pressure has been compromised by a depleted blood volume, or after con-nt administration with drups such as phenothiazines or other agents which compromise rotor tone. Combunox may produce orthostatic hypotension in ambulatory patients. unox, like all opioid analgesics, should be administered with caution to patients in circu-shock, since vasodilatation produced by the drug may further reduce cardiac output and pressure.

latory shock, since vasodilatation produced by the drug may may make the later of the pressure. Head ripury and increased intracranial Pressure. The respiratory depressant effects of opioids and their capacity to elevate cerebrospinal fluid pressure may be markedly exagerated in the presence of head injury, intracranial lesions or a pre-existing increase in intracranial pressure. Furthermore, opioids produce adverse reactions that may obscure the clinical course of patients with head injuries. Acute Abdominal Conditions.

Acute Abdominal Conditions

The administration of opioids may obscure the diagnosis or clinical course of patients with acute abdominal conditions.

out risk.
Dis should be prescribed with extreme caution in those with a prior history of ulcer disease astrointestinal bleeding. Most spontaneous reports of fatal GI events are in elderly or debild patients and, therefore, special care should be taken in treating this population. To minite the potential risk for an adverse GI event the treatment period should be of the shortest sible duration. For high risk patients, alternate therapies that do not involve NSAIDs should

Pregnancy
As with other NSAID-containing products, Combunox should be avoided in late pregnancy
because it may cause premature closure of the ductus arteriosus.
Interactions with Alcohol and Drugs of Abuse
Oxycodone may be expected to have additive effects when used in conjunction with alcohol,
other oploids, or illicit drugs that cause central nervous system depression.

PREFAITINDS.

and the possibility of respiratory depression, postural hypotension, and aftered mental states should be kept in mind.

Isse in Pancreaticellising ratc Disease combunox may cause spasm of the sphincter of Oddi and should be used with caution in patients with biliary tract disease, including acute pancreatitis. Opioids like Combunox may cause increases in the serum amylase level.

Cough Reflex

nex e suppresses the cough reflex; as with other opioid containing products, caution should ed when Combunox is used postoperatively and in patients with pulmonary disease.

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us diministring une design and a conditions, spatic Effects cubios, noninfammatory painful conditions, spatic Effects vivil nother NSAIDs, ibuprofen has been reported to cause borderline elevations of one or ore liver enzymes; this may occur in up to 15% of patients. These abnormalities may progress, any remain essentially unchanged, or may be transient with continued therapy, Notable 16 sines ie upper limit of normal) elevations of SGPT (ALT) or SGOT (AST) occurred in controlled clinal trials in less than 1% of patients. A patient with symptoms and/or signs suggesting liver situnction, or in whom an abnormal liver test has occurred, should be evaluated for evidence the development of more severe hepatic reactions, including jaundice and cases of fatal hepatitis, have been reported with suprofen as with other NSAIDs. Although such reactions are rare, if abnormal liver tests persist rovosen, if clinical signs and symptoms consistent with liver disease develop, or if system canifestations occur (e.g. eosinophilia, rash, etc.), Combunox should be discontinued.

Caution is also recommended in patients with pre-existing kidney disease (see WARNINGS -Advanced Renal Disease).

As with other NSAIDs, long-term administration of ibuprofen has resulted in renal papillary necrosis and other renal pathologic changes. Renal toxicity has also been seen in patients in which renal prostaglandins have a compensatory role in the maintenance of renal perfusion. In these patients, administration of a nonsteroidal anti-inflammatory drug may cause a dose-dependent reduction in prostaglandin formation and, secondarily, in renal blood flow, which may

precipitate overt renal decompensation. Patients at greatest risk of this reaction are those with impaired renal function, heart failure, liver dysfunction, those taking diuretics and ACE inhibitors, and the elderly. Discontinuation of nonsteroidal anti-inflammatory drug therapy is usually followed by recovery to the pretreatment state. Duporfore metabolites are eliminated primarily by the kidneys. The extent to which the metabolites may accumulate in patients with renal failure has not been studied. Patients with significantly impaired renal function should be more closely monitored. Hermatological Effects
Ibuprofen. Ike other NSAIDs, can inhibit platelet aggregation but the effect is quantitatively less and of shorter duration than that seen with asprin. Ibuprofen has been shown to prolong bleeding time in normal subjects. Because this prolonged bleeding effect may be exaggerated in patients with underlying hemostacid defects. Combinance should be used with caution in persons with intrinsic caegulation defects and those on anticoagulant therapy. Anemia is sometimes seen in patients receiving NSAIDs, including buprofen. This may be due to fluid retention, Gl toss, or an incompletely described effect upon erythropolesis.
Fluid Retention and Ederna.

loss, or an incompletely described effect upon enympage.

Fluid Retention and Edema
Fluid retention and edema have been reported in association with ibuprofen; therefore, the drug should be used with caution in patients with a history of cardiac decompensation, hypertension

Pre-existing Asthma Patients with asthma may have aspirin-sensitive asthma. The use of aspirin in patients with aspirin-sensitive asthma has been associated with severe bronchospasm, which may be falsal. Since cross-reactivity between aspirin and other NSAIDs has been reported in such aspirin-sensitive patients, Combunox should not be administered to patients with this form of aspirin sensitivity and sould be used with caution in patients with pre-existing asthma. Aseptic Meningitis

existing various or exist with caution in patients with pre-existing asthma. Aseptic Mennights
Aseptic

uently than prescribed, and so as it is prescribed, in the amounts prescribed, and no more lubnox, like other drugs containing ibuprofen, is not free of side effects. The side effects of ed rugs can cause discomfort and, rarely, there are more serious side effects, such as one testinal bleeding, which may result in hospitalization and upa aun uause unscommon ann, rarey, tinere are more serious side effects, such as inal bleeding, which may result in hospitalization and even fatal outcomes. Pati e instructed to report any signs or symptoms of gastrointestinal bleeding, blurred vi eye problems, skin rash, weight gain, or edema.

of other eye processes, see the control of the cont

anddepressants), such blockade has not yet been shown to be of clinical significance with this agent However, clinicians should be aware of this possible interaction. Anticholinergies: The concurrent use of anticholinergies with oxycodone preparations may produce parafylic list.

CNS Depressants: Patients receiving narcotic analgesics, general anesthetics, phenothiazines, CNS obpressants: Patients receiving narcotic analgesics, general anesthetics, phenothiazines, their tranquilizers, sedative-hyponics or other CNS depressants (including alcohol) concomitantly with oxycodone may exhibit an additive CNS depression. Interactive effects resulting in respiratory depression, hypotension, proflound sedation, or comma may result if these drugs are taken in combination with the usual dosage of oxycodone. When such combined therapy is contemplated, the dose of one or both apents should be reduced.

Mixed Agonist/Antagonist Opicid Analgesics: Agonist/antagonist analgesics (i.e., pentazocine, analbuphine, buttorphanol and buprenorphine) should be administered with caution to patients who have received or are receiving a course of therapy with a pure opicid agonist analgesic site. pentazocine as oxycodone, in this situation, mixed agonist/antagonist analgesics may reduce the analgesic effect of oxycodone and/or may precipitate withdrawal symptoms in these patients. Monoamine Oxidase Inhibitors (Makol): AMOIs these been reported to intensity the effects of a least one opicid drug causing anxiety, confusion and significant depression of respiration or coma. The use of oxycodone is not recommended for patients taking MAOIs or within 14 days of stopping such treatment.

Neuromuscular Blocking Agents: Oxycodone, as well as other opicid analgesics, may enhance the neuromuscular blocking action of skeletal muscle relaxants and produce an increased degree of respiratory depression.

degree of respiratory depression.
Duprofen
ACE-inhibitors: Reports suggest that NSAIDs may diminish the antihypertensive effect of
ACE-inhibitors. This interaction should be given consideration in patients taking Combunox
concomitantly with ACE-inhibitors.
Aspirin As with other products containing NSAIDs, concomitant administration of Combunox
and aspirin is not generally recommended because of the potential of increased adverse effects.
Burstless: bluprofen has been shown to reduce the natirurative effect of furosamide and thizaides
in some patients. This response has been attributed to inhibition of renal prostaglandin synthesis. During concomitant therapy with Combunox the patient should be observed closely for
Signs of renal failure (see PRECAUTIONS - Penal Effects), as well as duretic efficacy.
Lithium: Ibuprofen has been shown to elevate plasma lithium concentration and reduce renal
lithium clearance. This effect has been attributed to inhibition of renal prostaglandin synthesis
by ibuprofen. Thus, when Combunox and lithium are administered concurrently, patients should
enharment for some of lithium toxicity.

profen. Thus, when Combiunox and lithium are administered concurrently, patients should served for signs of lithium toxicin, otreazle: libuprofen, as well as other NSAIDs, has been reported to competitively inhibit otreazle accumulation in rabbit kidney slices. This may indicate that ibuprofen could nee the toxicity of methotreazle. Caution should be used when Combiunox is administered to the toxicity of methotreazle. Caution should be used when Combiunox is administered to the toxicity of methotreazle. Caution should be used when Combiunox is administered to the toxicity of methotreazle.

enhance the toxicity of methotrexate. Caution should be used when Combunox is administered concomitantly with methotrexate. Warfarin: The effects of warfarin and NSAIDs on GI bleeding are synergistic, such that users of both drugs topether have a greater risk of serious GI bleeding than users of either drug alone. Carcinogenicity, Mutagenicity and Impairment of Fertility Studies to evaluate the potential effects of the combination of oxycodone and ibuprofen on carcinogenicity, mutagenicity or impairment of fertility have not been conducted.

carcinogenicity, mutagenicity of impairment of retniny have not oeen conducted.

Pregnancy

Teratogenic Effects

Pregnancy Category C

Animal studies to assess the potential effects of the combination of oxycodone and ibuprofen on embryo-fetal development were conducted in the rat and rabbit model.

Pregnant rats were treated by oral gavage with combination doses of oxycodone:buprofen mylkyday (0.252, 0.0.54.0.1.08b, or 20.166) on days 7-16 of gestation. There was no evidence for developmental toxicity or teratogenicity at any dose, although maternal toxicity was noted at doses of 0.5-40 and above. The highest dose tested in the rat (20.1660 mylday) or a body surface area (mylm²) asis. This dose was associated with maternal toxicity (death, clinical signs, decreased BM).

face area (mg/m²) basis. This dose was associated with maternal toxicity (death, clinical signs, decreased BW). Prepnant rabbits were treated by oral gavage with combination doses of oxycodone/fluprofie (0.38.30, 0.75.60, 1.50.120 or 3.00.240 mg/kg/day) on gestation days 7-19. Oxycodone/fluprofien treatment was not tratogenic under the conditions of the assay. Maternal toxicity was noted at doses of 1.5.120 (reduced body weight and food consumption) and 3.240 mg/kg/day (mortality). The no adverse effect level (NOAEL) for maternal toxicity, 0.75.60 mg/kg/day, is 0.75 fold the proposed maximum daily human dose based upon the body surface ana Developmental toxicity, as evidenced by delayed ossification and reduced felal body weights, was noted at the highest dose, which is approximately 2 times the MRHD on a mg/m² basis. and is likely due to maternal toxicity, the fetal NOAEL of 1.50.120 mg/kg/day is approximately 1.5 times the MRHD on an mg/m² basis.

There are no adequate and well-controlled studies in pregnant women. Combunox should be used during gregnancy only if the potential benefit justifies the potential risk to the tetus. Because of the buprofen component, Combunox should not be used during the third trimester of pregnancy because it could cause problems in the unborn child (premature closure of the ductus arteriosus and pulmonary hypertension in the fetus/heonate).

ductus arteriosus and pulmonary hypertension in the tetus/neonare).

Labur and Delivery
Combunos should not be used during the third trimester of pregnancy due to the potential for ibuprofen is inhibit prosalsgaland syntheticae which may prolong pregnancy and inhibit bloor Oxycodone is not recommended for use in vomen during and immediately prior to labor and delivery because or all opioids may cause respiratory depression in the newborn. Mursing Mothers
Buptrofen is not transferred to breast milk in significant quantities. The American Academy of Pediatrics cassing the upper of the properties of the production of th

effects in the nursing infant have not been documented, withdrawal can occur in breast-feeding infants when maternal administration of an opioid analgesic is discontinued. Because of the potential for serious adverse reactions in nursing infants from the oxycodone present in Combunox, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mouth. Pediatric Use In the placebo-controlled, clinical studies of pain following dental surgery, 109 patients between the ages of 14 and 17 years were administered a single dose of Combunox. No apparent differences were noted in the safety of Combunox in paleints below and above 17 years of age. Combunox has not been studied in patients under 14 years of age.

priatric Use
the total number of subjects in clinical studies of Combunox, 89 patients were 65 and over,
lile 37 patients were 75 and over. No overall differences in safety were observed between
ses subjects and younger subjects, and other reported clinical experience has not identified
freences in responses between the elderly and younger patients, but greater sensitivity of
me older individuals cannot be ruled out.
wever, because the elderly may be more sensitive to the renal and gastrointestinal effects of
insteroidal anti-inflammatory agents as well as possible increased risk of respiratory depreson with oploids, extra caution should be used when treating the elderly with Combunox.

VIPERSF PRACTIONS

Sion with Opiolis, extra caution should be used when usualing use every wint connection.

ADVERSE REACTIONS

Listed below are the adverse event incidence rates from single dose analgesis trials in which a total of 247 patients received either Combunox, ibuprofen (400 mg), oxycodone HCI (5 mg), or placebo. Adverse event information is also provided from an additional 304 patients who were exposed to Combunox in a multiple dose analgesis trial, without placebo or active component comparison arms, given up to four times daily for up to 7 days.

Adverse Events Which Occurred at a Frequency of 2 1% and at a Higher Incidence than in the Deschool Count in Station Boxes Multies.

the Placebo Group in Single Dose Studies				
	5/400 mg	400 mg	5 mg	Placebo
	(n=923)	Ibuprofen	Oxycodone HCI	(n=315)
		(n=913)	(n=286)	
Digestive				
Nausea	81 (8.8%)	44 (4.8%)	46 (16.1%)	21 (6.7%)
Vomiting	49 (5.3%)	16 (1.8%)	30 (10.5%)	10 (3.2%)
Flatulence	9 (1.0%)	7 (0.8%)	3 (1.0%)	0
Nervous System				
Somnolence	67 (7.3%)	38 (4.2%)	12 (4.2%)	7 (2.2%)
Dizziness	47 (5.1%)	21 (2.3%)	17 (5.9%)	8 (2.5%)
Skin and Appenda	iges			
Sweat	15 (1.6%)	7 (0.8%)	4 (1.4%)	1 (0.3%)

Swiri auf rypieniages

Sweat

15 (1.6%) 7 (0.8%) 4 (1.4%) 1 (0.3%)

Adverse events that were reported by at least 1% of patients taking Combunox but were observed at greater incidence in the placebor breated patients were fever, headache and purritus. Adverse events that occurred in less than 1% and in at least two Combunox treated patients in Single Does studies not listed above include the following: Body as Mohe: addominals ain, asthenia, chest pain, enlarged abdomen. Cardiovascular System: hypotension, syncope, tably-cardia, vasoridation Oligisetties System: constpation (by morth, dyspepsia, enrotation), elius. Hernic and Lymphatic System: semia, Metabolic and Nutritional Disorders: derma, Nervous System: europation (by morth, dyspepsia, enrotation), elius. Hernic and Lymphatic System: uninary retention.

Adverse events that occurred in the Multiple Does study in at least 2%, of patients treated with Combunox include the following: Body as Whole: asthenia (3.3%), fever (3.0%), headens (1.2%). Cardiovascular Systems: vasoridation (3.0%), Dispettive System: constpation (4.5%), diarribas (2.1%), dyspepsia (2.1%), nausea (2.5.4%), vomiting (4.5%). Nervous System: dizziness (1.2%), despense study not listed previously include the following: Body as Whole: asthenia (3.0%). Nervous System: dizziness (1.2%), opense study not listed previously include the following: Body as Whole to such a final fi

DRUG ARUSE AND DEPENDENCE

Carturysound toxers, measure of property.

Treatment:
In the treatment of opioid overdosage, primary attention should be given to the re-establishment of a patent airway and institution of assisted or controlled ventilation. Supportive measures (including oxygen and vasopressors) should be employed in the management of ircituatory shock and pulmonary edema accompanying overdose, as indicated. Cardiac arrest or arrhythmias may require cardiac massage or defibrilation. The narcotic antagonist nations the ydrochloride is a specific antidote against respiratory depression, which may result from overdosage or unusual sensitivity to narcotics including oxygodone. An appropriate dose of national hydrochloride should be administered intravenously with simultaneous efforts at respiratory expensions. Since the duration of action of oxygodone may exceed that of the natione, the patient should be kept under continuous surveillance and repeated doses of the antagonist should be administered as needed to manifatian adequate respiration. Management of hypotension, acidosis and gastrointesthal bleeding may be necessary. In cases of acute overdose, the stomach should be emplied through ipecas-induced emissis or gastric lavage. Orally administered activated characoal may help in reducing the absorption and reabsorption of buprofen. Emissis is most effective if initiated within 30 minutes of ingestion. Induced emiss is not recommended in platients with imigrated consciousness or overdoses greater than 400 maying of the ibuprofen component in children because of the risk for convulsions and the potential for aspiration of gastric contents.

A Schedule CII Narcotic

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