

nority health and health disparities at the National Institutes of Health.

But most importantly, the laws will expand coverage for millions of Americans who are currently uninsured, Ms. Sebelius said.

“In almost every case, populations who are currently underserved get relief [under the new laws], whether it’s minority Americans, women, early retirees, rural Americans, or Americans with disabilities,” she said.

The 2009 quality report showed that overall quality is improving at a rate of

about 2.3% annually. The speed of improvement varied across settings of care: Hospitals are improving more rapidly, at

‘While the Affordable Care Act isn’t a cure, we think it’s one of the most effective treatments we’ve had for these problems in a long time.’

a median rate of change of about 5.8%, whereas outpatient settings improved at a median rate of change about 1.4%.

As a result, improvements in prevention and chronic disease management are lagging behind improvements in acute care.

For example, of the nine process measures tracked in the report that worsened, eight related to either preventive services or chronic disease management, including mammography, Pap testing, and fecal occult blood testing.

“Although the trend is going in the right direction, which is good, the pace is unacceptably slow,” said Dr. Carolyn Clancy, director of the Agency for

Healthcare Research and Quality, which produced the reports.

On the disparities side, the report showed that many disparities have not decreased over time. For example, from 2000 to 2005, disparities in colorectal cancer screening have grown between American Indians and Alaska Natives vs. whites, increasing at a rate of 7.7% per year.

Additionally, blacks and Hispanics had worsening disparities in colorectal cancer mortality from 2000 to 2006.

The two reports are available online at www.ahrq.gov/qual/qdr09.htm.

HHS Begins Setting Up High-Risk Pools

State-based high-risk health insurance pools are among the first programs to be implemented under health reform, Health and Human Service department officials announced April 2.

These state-based pools, designed to provide coverage to uninsured adults with preexisting conditions, are scheduled to be up and running within 90 days and will operate until Jan. 1, 2014.

At that time, the new state-based health insurance exchanges would open, and coverage would be available to all individuals regardless of preexisting conditions.

“When it’s up and running, the new high-risk pool program provides immediate relief to potentially millions of Americans with preexisting conditions like diabetes or high blood pressure who have been shut out of the insurance system,” HHS Secretary Kathleen Sebelius said during a news conference.

The same day, Ms. Sebelius sent a letter to governors and state insurance commissioners asking how they plan to participate in the temporary high-risk pool program. Under the law, HHS has \$5 billion in federal funds to set up pools on its own or collaborate with states. HHS is asking states to respond with their plans by the end of April.

States will have a number of options for participation. For example, states that don’t currently operate a high-risk insurance pool could establish one with federal help. Those that do have a pool in place could set up a companion high-risk pool that meets the new federal standards. States also could contract with an insurer to provide subsidized coverage for eligible residents. In states that choose to do nothing, HHS will operate the program on their behalf.

More than 30 states currently have high-risk insurance pools, according to HHS, with premiums 25%-100% higher than standard rates. Under the health reform law, the federal government would require new high-risk pools to set premiums at a standard rate, which would vary by state. The standard rate should be equivalent to what a typical person shopping on the individual market would be offered, according to HHS.

—Mary Ellen Schneider

- Flector® Patch, like other NSAIDs, may cause GI discomfort and, rarely, serious GI side effects, such as ulcers and bleeding, which may result in hospitalization and even death. Although serious GI tract ulcerations and bleeding can occur without warning symptoms, patients should be alert for the signs and symptoms of ulcerations and bleeding, and should ask for medical advice when observing any indicative sign or symptoms including epigastric pain, dyspepsia, melena, and hematemesis. Patients should be apprised of the importance of this follow-up (see **WARNINGS, Gastrointestinal Effects: Risk of Ulceration, Bleeding, and Perforation**).
- Flector® Patch, like other NSAIDs, may cause serious skin side effects such as exfoliative dermatitis, SJS, and TEN, which may result in hospitalizations and even death. Although serious skin reactions may occur without warning, patients should be alert for the signs and symptoms of skin rash and blisters, fever, or other signs of hypersensitivity such as itching, and should ask for medical advice when observing any indicative signs or symptoms. Patients should be advised to stop the drug immediately if they develop any type of rash and contact their physicians as soon as possible.
- Patients should be instructed to promptly report signs or symptoms of unexplained weight gain or edema to their physicians (see **WARNINGS, Cardiovascular Effects**).
- Patients should be informed of the warning signs and symptoms of hepatotoxicity (e.g., nausea, fatigue, lethargy, pruritus, jaundice, right upper quadrant tenderness, and “flu-like” symptoms). If these occur, patients should be instructed to stop therapy and seek immediate medical therapy.
- Patients should be informed of the signs of an anaphylactoid reaction (e.g. difficulty breathing, swelling of the face or throat). If these occur, patients should be instructed to seek immediate emergency help (see **WARNINGS**).
- In late pregnancy, as with other NSAIDs, Flector® Patch should be avoided because it may cause premature closure of the ductus arteriosus.
- Patients should be advised not to use Flector® Patch if they have an aspirin-sensitive asthma. Flector® Patch, like other NSAIDs, could cause severe and even fatal bronchospasm in these patients (see **PRECAUTIONS, Preexisting asthma**). Patients should discontinue use of Flector® Patch and should immediately seek emergency help if they experience wheezing or shortness of breath.
- Patients should be informed that Flector® Patch should be used only on intact skin.
- Patients should be advised to avoid contact of Flector® Patch with eyes and mucosa. Patients should be instructed that if eye contact occurs, they should immediately wash out the eye with water or saline, and consult a physician if irritation persists for more than an hour.
- Patients and caregivers should be instructed to wash their hands after applying, handling or removing the patch.
- Patients should be informed that, if Flector® Patch begins to peel off, the edges of the patch may be taped down.
- Patients should be instructed not to wear Flector® Patch during bathing or showering. Bathing should take place in between scheduled patch removal and application (see **DOSAGE AND ADMINISTRATION**).
- Patients should be advised to store Flector® Patch and to discard used patches out of the reach of children and pets. If a child or pet accidentally ingests Flector® Patch, medical help should be sought immediately (see **PRECAUTIONS, Accidental Exposure in Children**).

Laboratory Tests
Because serious GI tract ulcerations and bleeding can occur without warning symptoms, physicians should monitor for signs or symptoms of GI bleeding. Patients on long-term treatment with NSAIDs, should have their CBC and a chemistry profile checked periodically. If clinical signs and symptoms consistent with liver or renal disease develop, systemic manifestations occur (e.g., eosinophilia, rash, etc.) or if abnormal liver tests persist or worsen, Flector® Patch should be discontinued.

Drug Interactions
ACE-inhibitors
Reports suggest that NSAIDs may diminish the antihypertensive effect of ACE-inhibitors. This interaction should be given consideration in patients taking NSAIDs concomitantly with ACE-inhibitors.

Aspirin
When Flector® Patch is administered with aspirin, the binding of diclofenac to protein is reduced, although the clearance of free diclofenac is not altered. The clinical significance of this interaction is not known; however, as with other NSAIDs, concomitant administration of diclofenac and aspirin is not generally recommended because of the potential of increased adverse effects.

Diuretics
Clinical studies, as well as post marketing observations, have shown that Flector® Patch may reduce the natriuretic effect of furosemide and thiazides in some patients. This response has been attributed to inhibition of renal prostaglandin synthesis. During concomitant therapy with NSAIDs, the patient should be observed closely for signs of renal failure (see **WARNINGS, Renal Effects**), as well as to assure diuretic efficacy.

Lithium
NSAIDs have produced an elevation of plasma lithium levels and a reduction in renal lithium clearance. The mean minimum lithium concentration increased 15% and the renal clearance was decreased by approximately 20%. These effects have been attributed to inhibition of renal prostaglandin synthesis by the NSAID. Thus, when NSAIDs and lithium are administered concurrently, subjects should be observed carefully for signs of lithium toxicity.

Methotrexate
NSAIDs have been reported to competitively inhibit methotrexate accumulation in rabbit kidney slices. This may indicate that they could enhance the toxicity of methotrexate. Caution should be used when NSAIDs are administered concomitantly with methotrexate.

Warfarin
The effects of warfarin and NSAIDs on GI bleeding are synergistic, such that users of both drugs together have a risk of serious GI bleeding higher than users of either drug alone.

Carcinogenesis, Mutagenesis, Impairment of Fertility
Carcinogenesis
Long-term studies in animals have not been performed to evaluate the carcinogenic potential of either diclofenac epolamine or Flector® Patch.

Mutagenesis
Diclofenac epolamine is not mutagenic in *Salmonella Typhimurium* strains, nor does it induce an increase in metabolic aberrations in cultured human lymphocytes, or the frequency of micronucleated cells in the bone marrow micronucleus test performed in rats.

Impairment of Fertility
Male and female Sprague Dawley rats were administered 1, 3, or 6 mg/kg/day diclofenac epolamine via oral gavage (males treated for 60 days prior to conception and during mating period, females treated for 14 days prior to mating through day 19 of gestation). Diclofenac epolamine treatment with 6 mg/kg/day resulted in increased early resorptions and postimplantation losses; however, no effects on the mating and fertility indices were found. The 6 mg/kg/day dose corresponds to 3-times the maximum recommended daily exposure in humans based on a body surface area comparison.

Pregnancy
Teratogenic Effects. Pregnancy Category C.
Pregnant Sprague Dawley rats were administered 1, 3, or 6 mg/kg diclofenac epolamine via oral gavage daily from gestation days 6-15. Maternal toxicity, embryotoxicity, and increased incidence of skeletal anomalies were noted with 6 mg/kg/day diclofenac epolamine, which corresponds to 3-times the maximum recommended daily exposure in humans based on a body surface area comparison. Pregnant New Zealand White rabbits were administered 1, 3, or 6 mg/kg diclofenac epolamine via oral gavage daily from gestation days 6-18. No maternal toxicity was noted; however, embryotoxicity was evident at 6 mg/kg/day group which corresponds to 6.5-times the maximum recommended daily exposure in humans based on a body surface area comparison. There are no adequate and well-controlled studies in pregnant women. Flector® Patch should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nonteratogenic Effects
Because of the known effects of nonsteroidal anti-inflammatory drugs on the fetal cardiovascular system (closure of ductus arteriosus), use during pregnancy (particularly late pregnancy) should be avoided. Male rats were orally administered diclofenac epolamine (1, 3, 6 mg/kg) for 60 days prior to mating and throughout the mating period, and females were given the same doses 14 days prior to mating and through mating, gestation, and lactation. Embryotoxicity was observed at 6 mg/kg diclofenac epolamine (3-times the maximum recommended daily exposure in humans based on a body surface area comparison), and was manifested as an increase in early resorptions, post-implantation losses, and a decrease in live fetuses. The number of live born and total born were also reduced as was F1 postnatal survival, but the physical and behavioral development of surviving F1 pups in all groups was the same as the deionized water control, nor was reproductive performance adversely affected despite a slight treatment-related reduction in body weight.

Labor and Delivery
In rat studies with NSAIDs, as with other drugs known to inhibit prostaglandin synthesis, an increased incidence of dystocia, delayed parturition, and decreased pup survival occurred. The effects of Flector® Patch on labor and delivery in pregnant women are unknown.

Nursing Mothers
It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human-milk and because of the potential for serious adverse reactions in nursing infants from Flector® Patch, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use
Safety and effectiveness in pediatric patients have not been established.

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

Diclofenac, as with any NSAID, is known to be substantially excreted by the kidney, and the risk of toxic reactions to Flector® Patch may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken when using Flector® Patch in the elderly, and it may be useful to monitor renal function.

ADVERSE REACTIONS
In controlled trials during the premarketing development of Flector® Patch, approximately 600 patients with minor sprains, strains, and contusions have been treated with Flector® Patch for up to two weeks.

Adverse Events Leading to Discontinuation of Treatment
In the controlled trials, 3% of patients in both the Flector® Patch and placebo patch groups discontinued treatment due to an adverse event. The most common adverse events leading to discontinuation were application site reactions, occurring in 2% of both the Flector® Patch and placebo patch groups. Application site reactions leading to dropout included pruritus, dermatitis, and burning.

Common Adverse Events
Localized Reactions

Overall, the most common adverse events associated with Flector® Patch treatment were skin reactions at the site of treatment. Table 1 lists all adverse events, regardless of causality, occurring in ≥ 1% of patients in controlled trials of Flector® Patch. A majority of patients treated with Flector® Patch had adverse events with a maximum intensity of “mild” or “moderate.”

Table 1. Common Adverse Events (by body system and preferred term) in ≥1% of Patients treated with Flector® Patch or Placebo Patch¹

	Diclofenac (N=572)		Placebo (N=564)	
	N	%	N	%
<i>Application Site Conditions</i>	64	11	70	12
Pruritus	31	5	44	8
Dermatitis	9	2	3	<1
Burning	2	<1	8	1
Other²	22	4	15	3
<i>Gastrointestinal Disorders</i>	49	9	33	6
Nausea	17	3	11	2
Dysgeusia	10	2	3	<1
Dyspepsia	7	1	8	1
Other³	15	3	11	2
<i>Nervous System Disorders</i>	13	2	18	3
Headache	7	1	10	2
Paresthesia	6	1	8	1
Somnolence	4	1	6	1
Other⁴	4	1	3	<1

¹ The table lists adverse events occurring in placebo-treated patients because the placebo-patch was comprised of the same ingredients as Flector® Patch except for diclofenac. Adverse events in the placebo group may therefore reflect effects of the non-active ingredients.

² Includes: application site dryness, irritation, erythema, atrophy, discoloration, hyperhidrosis, and vesicles.

³ Includes: gastritis, vomiting, diarrhea, constipation, upper abdominal pain, and dry mouth.

⁴ Includes: hypoaesthesia, dizziness, and hyperkinesias. Foreign labeling describes that dermal allergic reactions may occur with Flector® Patch treatment. Additionally, the treated area may become irritated or develop itching, erythema, edema, vesicles, or abnormal sensation.

DRUG ABUSE AND DEPENDENCE
Controlled Substance Class
Flector® Patch is not a controlled substance.
Physical and Psychological Dependence
Diclofenac, the active ingredient in Flector® Patch, is an NSAID that does not lead to physical or psychological dependence.

OVERDOSAGE
There is limited experience with overdose of Flector® Patch. In clinical studies, the maximum single dose administered was one Flector® Patch containing 180 mg of diclofenac epolamine. There were no serious adverse events. Should systemic side effects occur due to incorrect use or accidental overdose of this product, the general measures recommended for intoxication with non-steroidal anti-inflammatory drugs should be taken. Distributed by: King Pharmaceuticals, Inc., 501 Fifth St., Bristol, TN 37620, USA Telephone: 1-888-840-8884 www.FlectorPatch.com Manufactured for: IBSA Institut Biochimique SA, CH-6903 Lugano, Switzerland Manufactured by: Teikoku Seiyaku Co., Ltd., Sanbonmatsu, Kagawa 769-2695 Japan Version October 2009 FV161 1086 Ed. V10.09 M090143/090172