

Health Reform Possible Even in Slowing Economy

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Senior Editor

ARLINGTON, VA. — Health care reform can be achieved even in difficult economic times, several speakers said at the annual meeting of the Association of Health Care Journalists.

"I think past history shows us that major social initiatives do happen exactly at a time of major economic crisis," said Dr. David U. Himmelstein of the department

of medicine at Harvard Medical School, Boston, and cofounder of Physicians for a National Health Program, a group that advocates for a single-payer health care system. "The New Deal is the outstanding example of that. We're facing a period where our country can't afford the health care system we have at present, and the pain is broadening far beyond the poor into the middle classes. ... That's the condition for political change."

Dr. Himmelstein added, however, that

the change probably will not come from Washington. "Political leadership has become the ultimate oxymoron. Demand from outside Washington can actually move this country as well. We had a charismatic president [John F. Kennedy] elected in 1960 who did not have very bold social programs that he proposed, yet he triggered a very broad outpouring of sentiment that succeeded in passing major social initiatives."

Karen Davis, Ph.D., president of the

Commonwealth Fund, a health policy research organization in New York, noted that during hard economic times, "people really get worried about health concerns, so the demand for their political leaders to do something about it grows whenever the economy tanks." However, states are less able to meet those increased demands "because sales tax revenues go down and unemployment compensation costs go up."

During the current downturn, federal lawmakers decided to give people tax rebates, but another way to stimulate the economy would have been to invest in the health sector, said Dr. Davis.

She criticized the Bush administration's decision to limit funding for the State Children's Health Insurance Program and other programs funded by the states and the federal government during this period. "It was the wrong response to the recession," she said. "We ought to have a counter-cyclical matching rate built into those programs, so that when the economy tanks, the federal government could pay more of

the costs," reducing the burden on states.

Julie Barnes, deputy director of the health policy program at the New America Foundation, a non-partisan Washington think tank, agreed. Although the recession is going to affect in-

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dividuals the most, "employers and businesses are in an excellent position to fix it," she said. "They're the ones we need to look at to determine how health benefits fit into health care costs."

Although it might be a scary idea, "what if we took employers out of the health care benefit business and pooled individuals instead?" she suggested. Employers would have more money because suddenly they wouldn't have to pay for employees' health benefits, and "the federal government gets back all that money that they're giving to employers right now. And wages can go up."

Tom Miller, resident fellow at the American Enterprise Institute, a public policy research organization in Washington, was less hopeful about the prospect of reform. "I'm an optimist—I think it's always dark before it gets really dark, but then it gets lighter," said Mr. Miller, who favors a free-market approach to health care. "In the short term, I wouldn't expect a lot of moving around. ... We're not going to have any mandate after 2 years of thrashing-around debate in Congress. We're going to get some marginal incentives that can provide a little additional assistance so some folks can get some more care."

He added, however, that Congress "is going to rewrite a good bit of the tax code in the next few years, and health care is going to get less in tax subsidies than it did before. As a result of that, we may rationalize the approach to tax financing of care." ■

Verdeso[™]
(desonide)
Foam, 0.05%

BRIEF SUMMARY OF PRESCRIBING INFORMATION

Rx Only

FOR TOPICAL USE ONLY
NOT FOR OPHTHALMIC, ORAL OR INTRAVAGINAL USE
INDICATIONS AND USAGE

Verdeso Foam is indicated for the treatment of mild to moderate atopic dermatitis in patients 3 months of age and older.

Patients should be instructed to use Verdeso Foam for the minimum amount of time necessary to achieve the desired results because of the potential for Verdeso Foam to suppress the hypothalamic-pituitary-adrenal (HPA) axis (see PRECAUTIONS). Treatment should not exceed 4 consecutive weeks.

CONTRAINDICATIONS

The use of Verdeso Foam is contraindicated in patients who are hypersensitive to desonide or to any ingredient in this preparation.

PRECAUTIONS

General: Systemic absorption of topical corticosteroids has produced reversible HPA axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glucosuria in some patients.

Conditions which augment systemic absorption include the application of topical corticosteroids over large body surface areas, prolonged use, or the addition of occlusive dressings. Therefore, patients applying a topical corticosteroid to a large body surface area or to areas under occlusion should be evaluated periodically for evidence of HPA axis suppression (see Laboratory Tests). If HPA axis suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application, or to substitute a less potent steroid.

Recovery of HPA axis function is generally prompt upon discontinuation of topical corticosteroids. Infrequently, signs and symptoms of glucocorticosteroid insufficiency may occur requiring supplemental systemic corticosteroids. For information on systemic corticosteroid supplementation, see prescribing information for those products.

The effect of Verdeso Foam on HPA axis function was investigated in pediatric patients in one study. In this study, patients with atopic dermatitis covering at least 25% of their body applied Verdeso Foam twice daily for 4 weeks. Three out of 75 patients (4%) displayed adrenal suppression after 4 weeks of use based on the cosyntropin stimulation test. The laboratory suppression was transient; all subjects had returned to normal when tested 4 weeks post treatment.

Pediatric patients may be more susceptible to systemic toxicity from equivalent doses because of their larger skin surface area to body mass ratios (See PRECAUTIONS - Pediatric Use).

If irritation develops, Verdeso Foam should be discontinued and appropriate therapy instituted. Allergic contact dermatitis with corticosteroids is usually diagnosed by observing a failure to heal rather than noticing a clinical exacerbation, as with most products not containing corticosteroids. Such an observation should be corroborated with appropriate diagnostic patch testing. If concomitant skin infections are present or develop, the use of an appropriate antifungal, antibacterial or antiviral agent should be instituted. If a favorable response does not occur promptly, use of Verdeso Foam should be discontinued until the infection has been adequately controlled.

Information for Patients: Patients using topical corticosteroids should receive the following information and instructions:

1. This medication is to be used as directed by the physician. It is for external use only. Avoid contact with the eyes or other mucous membranes. The medication should not be dispensed directly onto the face. Dispense in hands and gently massage into affected areas of the face until the medication disappears. For areas other than the face, the medication may be dispensed directly on the affected area. Wash hands after use.
2. This medication should not be used for any disorder other than that for which it was prescribed.
3. The treated skin area should not be bandaged, otherwise covered, or wrapped so as to be occlusive unless directed by the physician.
4. Patients should report any signs of local or systemic adverse reactions to the physician.
5. Patients should inform their physicians that they are using Verdeso Foam if surgery is contemplated.
6. As with other corticosteroids, therapy should be discontinued when control is achieved. If no improvement is seen within 4 weeks, contact the physician.

Laboratory Tests: The cosyntropin (ACTH₁₋₂₄) stimulation test may be helpful in evaluating patients for HPA axis suppression.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Long-term animal studies have not been performed to evaluate the carcinogenic or photoco-carcinogenic potential of Verdeso Foam or the effect on fertility of desonide.

Desonide revealed no evidence of mutagenic potential based on the results of two in vitro genotoxicity tests (Ames assay, mouse lymphoma cell assay) and an in vivo genotoxicity test (mouse micronucleus assay).

Pregnancy: Teratogenic Effects: Pregnancy Category C: Corticosteroids have been shown to be teratogenic in laboratory animals when administered systemically at relatively low dosage levels. Some corticosteroids have been shown to be teratogenic after dermal application in laboratory animals.

There are no adequate and well-controlled studies of Verdeso Foam in pregnant women. Therefore, Verdeso Foam should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

No long-term reproductive studies in animals have been performed with Verdeso Foam. Dermal embryofetal development studies were conducted in rats and rabbits with a desonide cream, 0.05% formulation. Topical doses of 0.2, 0.6 and 2.0 g cream/kg/day of a desonide cream, 0.05% formulation or 2.0 g/kg of the cream base were administered topically to pregnant rats (gestational days 6-15) and pregnant rabbits (gestational days 6-18). Maternal body weight loss was noted at all dose levels of the desonide cream, 0.05% formulation in rats and rabbits. Teratogenic effects characteristic of corticosteroids were noted in both species. The desonide cream, 0.05% formulation was teratogenic in rats at topical doses of 0.6 and 2.0 g cream/kg/day and in rabbits at a topical dose of 2.0 g cream/kg/day. No teratogenic effects were noted for the desonide cream, 0.05% formulation at a topical dose of 0.2 g cream/kg/day in rats and at a topical dose of 0.6 g cream/kg/day in rabbits. These doses (0.2 g cream/kg/day in rats and 0.6 g cream/kg/day in rabbits) are similar to the maximum recommended human dose based on body surface area comparisons.

Nursing Mothers: Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. It is not known whether topical

administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk. Because many drugs are excreted in human milk, caution should be exercised when Verdeso Foam is administered to a nursing woman.

Pediatric Use: Because of a higher ratio of skin surface area to body mass, pediatric patients are at a greater risk than adults of HPA axis suppression and Cushing's syndrome when they are treated with topical corticosteroids. They are therefore also at greater risk of adrenal insufficiency during and/or after withdrawal of treatment. Adverse effects including striae have been reported with inappropriate use of topical corticosteroids in infants and children. HPA axis suppression, Cushing's syndrome, linear growth retardation, delayed weight gain, and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include low plasma cortisol levels and an absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema. Administration of topical corticosteroids to children should be limited to the least amount compatible with an effective therapeutic regimen. Chronic corticosteroid therapy may interfere with the growth and development of children.

The effect of Verdeso Foam on HPA axis function was investigated in pediatric patients, ages 6 months to 17 years, in one study. In this study, patients with atopic dermatitis covering at least 25% of their body applied Verdeso Foam twice daily for 4 weeks. Three out of 75 patients (4%) displayed adrenal suppression after 4 weeks of use based on the ACTH stimulation test. The suppression was transient; all subjects' cortisol levels had returned to normal when tested 4 weeks post treatment.

Safety of Verdeso Foam has not been evaluated in pediatric patients below the age of 3 months.

Geriatric Use: Clinical studies of Verdeso Foam did not include any subjects aged 65 or over to determine whether they respond differently from younger subjects. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

ADVERSE REACTIONS

In a controlled clinical study of 581 patients 3 months to 17 years of age, adverse events occurred at the application site in 6% of subjects treated with Verdeso Foam and 14% of subjects treated with vehicle foam. Other commonly reported adverse events for Verdeso Foam and vehicle foam are noted in Table 1 (Commonly Occurring Adverse Events).

Adverse Event	Verdeso Foam (N=387)	Vehicle Foam (N=194)
System Organ Class		
General disorders and administration site conditions		
Application site burning	11 (3%)	15 (8%)
Application site atrophy	5 (1%)	0 (0%)
Application site dermatitis	2 (1%)	1 (1%)
Application site reaction	3 (1%)	6 (3%)
Infections and infestations	79 (20%)	38 (20%)
Upper respiratory tract infection	37 (10%)	12 (6%)
Pharyngitis	2 (1%)	0 (0%)
Pharyngitis streptococcal	2 (1%)	1 (1%)
Viral infection	6 (2%)	0 (0%)
Nervous System Disorder	7 (2%)	1 (1%)
Headache	7 (2%)	1 (1%)
Psychiatric Disorder	3 (1%)	0 (0%)
Irritability	2 (1%)	0 (0%)
Respiratory, Thoracic and Mediastinal Disorders	27 (7%)	7 (4%)
Asthma	3 (1%)	0 (0%)
Cough	14 (4%)	3 (2%)
Skin and Subcutaneous Tissue Disorders	10 (3%)	6 (3%)
Dermatitis contact	3 (1%)	2 (1%)
Telangiectasia	3 (1%)	0 (0%)

Elevated blood pressure was observed in 6 (2%) subjects receiving Verdeso Foam and 1 (1%) subject receiving vehicle foam. Other local adverse events occurred at rates less than 1.0%. The majority of adverse reactions were transient and mild to moderate in severity, and they were not affected by age, race or gender. The following additional local adverse reactions have been reported with topical corticosteroids. They may occur more frequently with the use of occlusive dressings and higher potency corticosteroids. These reactions are listed in an approximate decreasing order of occurrence: folliculitis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, secondary infection, striae and miliaria.

OVERDOSAGE

Topically applied Verdeso Foam can be absorbed in sufficient amounts to produce systemic effects (see PRECAUTIONS).

WARNING

FLAMMABLE. AVOID FIRE, FLAME OR SMOKING DURING AND IMMEDIATELY FOLLOWING APPLICATION.

Contents under pressure. Do not puncture or incinerate. Do not expose to heat or store at temperatures above 120°F (49°C).

Avoid contact with eyes or other mucous membranes.

Keep out of reach of children.

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