

# Citing Deficits, Senators Hesitate to Expand SCHIP

BY ALICIA AULT

Associate Editor, Practice Trends

WASHINGTON — As a Senate panel opened debate on reauthorization of the State Children's Health Insurance Program, legislators had doubts about expanding coverage to an estimated 9 million children who are eligible but who have not yet been enrolled.

SCHIP is due to expire on Sept. 30, but most states have been straining in the last

few years to pay for children already covered by the program, several witnesses said at a meeting of the Senate Finance Committee. Members of the committee also acknowledged that reality.

"Congress has simply not given [SCHIP] enough funds to meet the current demand for services," said committee chair Max Baucus (D-Mont.), who estimated that the program would need \$12 billion-\$15 billion over the next 5 years to maintain current coverage and \$45 billion to

bring all eligible children into SCHIP.

A last-minute deal signed into law at the end of 2006 allocated \$271 million to cover anticipated shortfalls for a dozen or so states, but at least 14 more states will run out of SCHIP funds for fiscal 2007 if Congress does not enact another bailout by mid-May, said Sen. Baucus.

In 2007, states will spend an estimated \$6.3 billion on SCHIP, but only \$5 billion has been allotted, said Cindy Mann, executive director of the Georgetown Univer-

sity Center for Children and Families, Washington. Without an influx of federal cash, 37 states will run out of funds this year, Ms. Mann testified to the Finance Committee.

As of fiscal 2005, SCHIP had 6 million enrollees, according to a Government Accountability Office (GAO) report released at the Finance Committee hearing. Enrollment grew fastest during the early years of the program and leveled off more recently.

Georgia Gov. Sonny Perdue testified that there has been no slowing of enrollment in his state, with an average 19% per month increase since June 2005. About 273,000 children are covered in Georgia, making it the fourth-largest SCHIP program in the country, he said. The Centers for Medicare and Medicaid Services had projected that only 130,000 children were eligible in Georgia, he said.

But, because of SCHIP rules, states that cover more children end up receiving a smaller allotment for the following year. "The successful implementation of SCHIP in any state automatically undermines maintaining funding to keep these kids enrolled in the program," Gov. Perdue testified, arguing for a change in the SCHIP funding formula.

Some senators questioned whether states' flexibility should be reined in, saying that some initiatives might be diluting the program's intent—to cover low-income children. Generally, federal law allows states to cover children in families with incomes up to 200% of the poverty level or 50 percentage

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points above the Medicaid eligibility standard as of 1997. According to the GAO report, seven states were covering families with incomes at 300% of the poverty level or higher. Thirty-nine states require some cost sharing by families, but 11 states charge no premiums or copayments.

Fifteen states cover adults—generally parents of Medicaid- or SCHIP-eligible children, pregnant women, or childless adults. The Health and Human Services department has granted waivers for those states, said Kathryn G. Allen, director of health care at the GAO.

Sen. Charles Grassley (R-Iowa), ranking minority member of the Finance Committee, said he was interested in giving states more flexibility but was not happy about extending coverage to adults.

"The issue is whether SCHIP funds used to cover adults has drained resources targeted by Congress for kids," said Sen. Grassley. "The 'C' stands for children. There is no 'A' in SCHIP."

Sen. Orrin Hatch (R-Utah) also questioned how states had been allowed to extend SCHIP benefits to adults. "We have to question whether these waivers have been properly approved," said Sen. Hatch. ■

\*Vusion™ Ointment is indicated for the adjunctive treatment of diaper dermatitis only when complicated by documented candidiasis (microscopic evidence of pseudohyphae and/or budding yeast) in immunocompetent pediatric patients 4 weeks and older. A positive fungal culture for *C. albicans* is not adequate evidence of candidal infection since colonization with *C. albicans* can result in a positive culture. The presence of candidal infection should be established by microscopic evaluation prior to initiating treatment.

Vusion™ Ointment should be used as part of a treatment regimen that includes measures directed at the underlying diaper dermatitis, including gentle cleansing of the diaper area and frequent diaper changes.



**Vusion™ Ointment should not be used as a substitute for frequent diaper changes. Vusion™ Ointment should not be used to prevent the occurrence of diaper dermatitis, since preventative use may result in the development of drug resistance.**

The safety of Vusion™ Ointment when used for longer than 7 days is not known.

Vusion™ Ointment should not be used in cases of known hypersensitivity to any of its components, in which case treatment should be discontinued.

**Vusion™**  
(0.25% miconazole nitrate/15% zinc oxide/  
81.35% white petrolatum) Ointment  
*Convenience in every tube.*

**VUSION™**  
(0.25% miconazole nitrate, 15% zinc oxide, and 81.35% white petrolatum)  
Ointment

#### BRIEF SUMMARY

**Rx only.**  
FOR TOPICAL USE ONLY.  
NOT FOR OPHTHALMIC, ORAL, OR INTRAVAGINAL USE.

#### INDICATIONS AND USAGE

VUSION Ointment is indicated for the adjunctive treatment of diaper dermatitis only when complicated by documented candidiasis (microscopic evidence of pseudohyphae and/or budding yeast), in immunocompetent pediatric patients 4 weeks and older. A positive fungal culture for *Candida albicans* is not adequate evidence of candidal infection since colonization with *C. albicans* can result in a positive culture. The presence of candidal infection should be established by microscopic evaluation prior to initiating treatment.

VUSION Ointment should be used as part of a treatment regimen that includes measures directed at the underlying diaper dermatitis, including gentle cleansing of the diaper area and frequent diaper changes.

**VUSION Ointment should not be used as a substitute for frequent diaper changes. VUSION Ointment should not be used to prevent the occurrence of diaper dermatitis, since preventative use may result in the development of drug resistance.**

#### CONTRAINDICATIONS

VUSION Ointment is contraindicated in those patients with a history of sensitivity reactions to any of its components. It should be discontinued if hypersensitivity is noted.

#### PRECAUTIONS

**General:** If irritation occurs or if the disease worsens, use of the medication should be discontinued, and the health care provider should be contacted. For external use only. VUSION Ointment is for topical use only, and not for ophthalmic, oral or intravaginal use.

The safety and efficacy of VUSION Ointment has not been demonstrated in immunocompromised patients, or in infants less than 4 weeks of age (premature or term).

The safety and efficacy of VUSION Ointment have not been evaluated in incontinent adult patients. **VUSION Ointment should not be used to prevent the occurrence of diaper dermatitis, such as in an adult institutional setting, since preventative use may result in the development of drug resistance.**

**Information for Patients:** Patients using VUSION Ointment should receive the following information and instructions: (See Patient Package Insert)

- VUSION Ointment is to be used only for diaper dermatitis that is complicated by documented candidiasis (i.e. documented by microscopic testing).
- VUSION Ointment should not be used as a substitute for frequent diaper changes.
- VUSION Ointment should not be used to prevent diaper dermatitis.
- VUSION Ointment should not be used long term.
- VUSION Ointment is to be used only as directed by the health care provider.
- VUSION Ointment is for external use only. It is not to be used orally, intravaginally, or for the eyes.
- Gently cleanse the diaper area with lukewarm water or a very mild soap and pat the area dry with a soft towel before applying VUSION Ointment.
- Gently apply VUSION Ointment to the diaper area with the fingertips after each diaper change. Do not rub VUSION Ointment into the skin as this may cause additional irritation.
- Thoroughly wash hands after applying VUSION Ointment.
- Treatment should be continued for 7 days, even if there is improvement. Do not use VUSION Ointment for longer than 7 days. If symptoms have not improved by day 7, see your health care provider.
- VUSION Ointment should not be used on children for whom it is not prescribed.

**Drug Interactions:** Drug-drug interaction studies were not conducted. Although women who take a warfarin anticoagulant and use a miconazole intravaginal cream or suppository may be at risk for developing an increased prothrombin time, international normalized ratio (INR) and bleeding, the potential for this interaction to occur between warfarin and VUSION Ointment is unknown.

**Carcinogenesis, Mutagenesis, Impairment of fertility:** Studies to evaluate the carcinogenic potential of VUSION Ointment in animals have not been performed.

Miconazole nitrate was negative in a bacterial reverse mutation test, a chromosome aberration test in mice, and micronucleus assays in mice and rats.

Miconazole nitrate had no adverse effect on fertility in a study in rats at oral doses of up to 320 mg/kg/day, which is 89 times the maximum possible topical exposure of caregivers, assuming 100% absorption.

#### Pregnancy Category C:

There are no adequate and well-controlled studies of VUSION Ointment in pregnant women. Miconazole nitrate administration has been shown to result in prolonged gestation and decreased numbers of live young in rats and in increased number of resorptions and decreased number of live young in rabbits at oral doses of 100 mg/kg/day and 80 mg/kg/day, which are 28 and 45 times the maximum possible topical exposure of caregivers, respectively, assuming 100% absorption.

Pregnant women should exercise appropriate precautions when administering the product.

**Nursing Mothers:** Safety and efficacy of the product have not been established in nursing mothers. It is not known if the active components of VUSION Ointment may be present in milk. Nursing mothers should exercise appropriate precautions when administering the product.

**Pediatric Use:** Efficacy was not demonstrated in infants less than 4 weeks of age. Use in infants below the age of 4 weeks is not recommended. Safety and efficacy have not been established in very-low-birth-weight infants.

VUSION Ointment should not be used to prevent diaper dermatitis.

The safety of VUSION Ointment when used for longer than 7 days is not known.

**Geriatric Use:** Clinical studies of VUSION Ointment did not include any subjects aged 65 and over. Safety and effectiveness in a geriatric population have not been evaluated.

#### ADVERSE REACTIONS

A total of 835 infants and young children were evaluated in the clinical development program. Of 418 subjects in the VUSION Ointment group, 58 (14%) reported one or more adverse events. Of 417 subjects in the zinc oxide/white petrolatum control group, 85 (20%) reported one or more adverse events. Adverse events that occurred at a rate of  $\geq 1\%$  for subjects who were treated with VUSION were approximately the same in type and frequency as for subjects who were treated with zinc oxide/white petrolatum ointment.

The potential for dermal toxicity of VUSION Ointment formulation was investigated in healthy adult volunteers in four topical safety studies. These studies were conducted to assess the potential for contact phototoxicity, photoallergy, sensitization, and cumulative irritation potential. Phototesting was conducted with UV-A only. Results indicated that VUSION Ointment did not induce a contact dermal phototoxic response, contact dermal photoallergic response, or contact dermal sensitization in adult subjects. In addition, VUSION Ointment did not show any evidence of cumulative irritation potential in adult subjects.

#### OVERDOSAGE

VUSION Ointment is intended for topical use only. Young children are at risk for accidentally ingesting VUSION Ointment. A health care provider or poison control center should be contacted in the event of accidental ingestion.

Keep out of reach of children.

For additional information, please call toll free 1-866-440-5508.

#### Manufactured By:

DSM Pharmaceuticals, Inc.  
Greenville, NC 27834

#### For:

Barrier Therapeutics, Inc.  
600 College Road East  
Princeton, NJ 08540  
www.barriertherapeutics.com  
VU-008 February, 2006  
U.S. Patent No. 4,911,932

**Reference: 1.** Data on file, Barrier Therapeutics, Inc.

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